FINAL PROGRAM

DIA 2016

JUNE 26–30 | PHILADELPHIA, PA

The Pennsylvania Convention Center

DIAglobal.org/DIA2016

A GATHERING OF GLOBAL PERSPECTIVES

Global Development
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- E-Clinical Technologies
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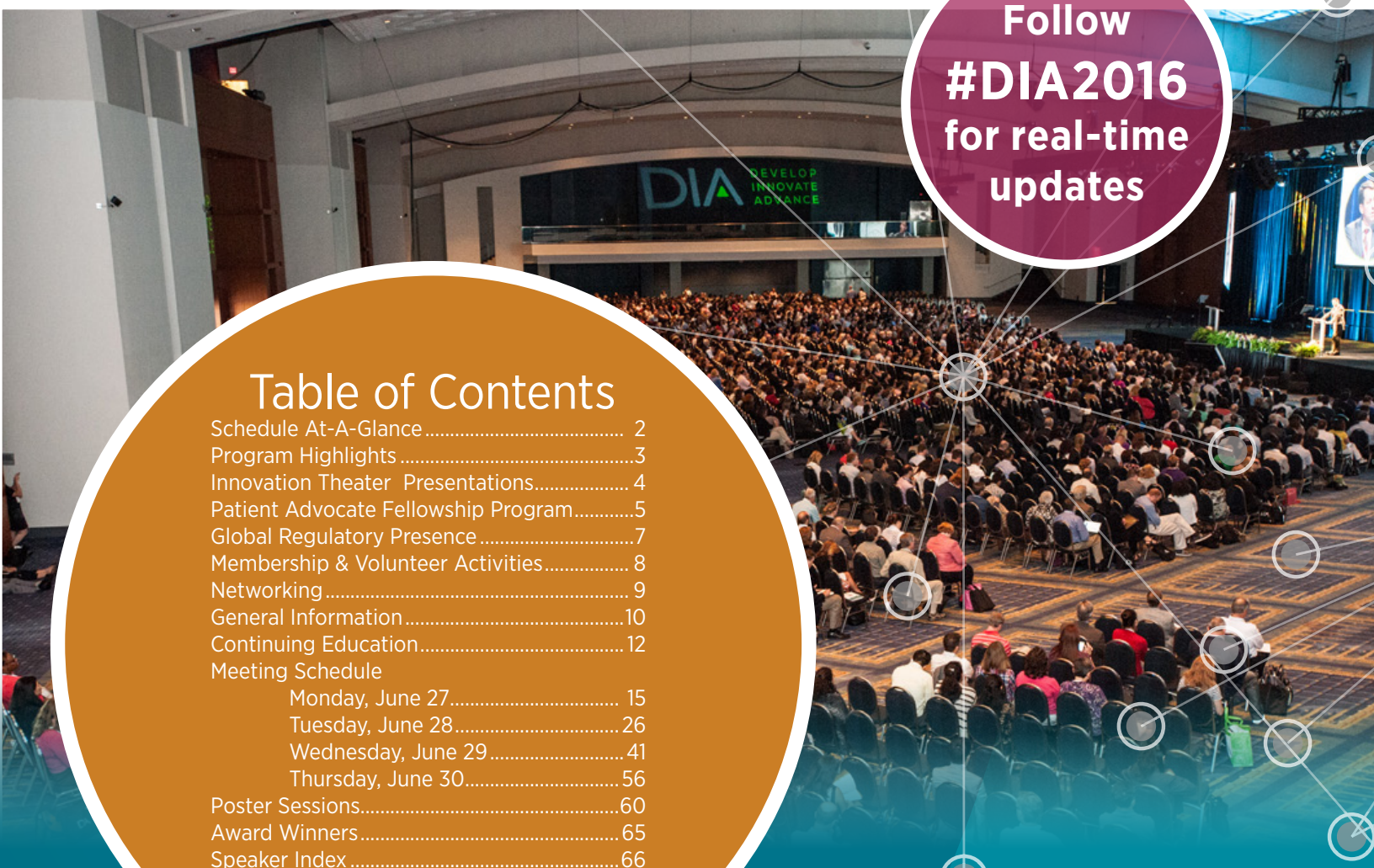
Final Program



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DIA 2016

Larry Brilliant, MD, MPH
Chairman of the
Skoll Global Threats Fund
DIA 2016 Keynote Speaker

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Senior Medical Officer
European Medicines Agency
DIA 2016 Program Co-Chair

Gigi Hirsch, MD
Executive Director
MIT Center for Biomedical Innovation
DIA 2016 Program Co-Chair

DIA 2016 Schedule At-A-Glance

JUNE 26–30 | PHILADELPHIA, PA *As of May 23, 2016. Schedule subject to change.*

SATURDAY, JUNE 25

Registration Hours:

9:00AM-5:00PM	Exhibitor Registration

SUNDAY, JUNE 26

Registration Hours:

8:00-9:00AM	Registration for Full Day and Morning Preconference Tutorials*
8:00AM-6:00PM	Exhibitor Registration
12:30-6:00PM	Registration for Afternoon Preconference Tutorials*, Conference Attendees, and Speakers

Schedule:

8:30AM-12:00PM	Half Day Morning Preconference Tutorials*
9:00AM-5:00PM	Full Day Preconference Tutorials*
11:45AM-12:00PM	Annual Meeting of Members (Liberty Ballroom A - Philadelphia Marriott Downtown)
1:00-4:30PM	Half Day Afternoon Preconference Tutorials*

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

MONDAY, JUNE 27

Registration Hours:

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

Schedule:

6:30-8:15AM	CISCRP Medical Heroes Appreciation 5K (Boathouse Row on Kelly Drive in Philadelphia)
7:00-8:30AM	Coffee and Light Refreshments (Grand Hall & Room 108 Concourse)
7:30-8:15AM	Annual Meeting Orientation and Networking (Room 104A)
8:30-9:45AM	Educational Opportunities Student Forum
9:30AM-6:00PM	Exhibit Hall Open Student Posters Open (Exhibit Hall A)
9:30-10:45AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B)
10:45-11:45AM	Engage and Exchange Session (Exhibit Hall A)
10:45AM-12:00PM	Educational Opportunities
11:45AM-2:30PM	Luncheon (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Engage and Exchange Sessions (Exhibit Hall A) Student Poster Session and Oral Presentations (Exhibit Hall A)
2:30-4:00PM	Plenary Session and Keynote Address (Ballroom AB)
4:00-6:00PM	Opening Reception (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Student Poster Session and Oral Presentations (Exhibit Hall A)

TUESDAY, JUNE 28

Registration Hours:

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

Schedule:

7:00-8:00AM	Coffee and Light Refreshments (Grand Hall & Room 108 Concourse)
8:00-9:30AM	DIAmond Sessions
9:00AM-5:00PM	Exhibit Hall Open Professional Posters Open
9:30-10:30AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Engage and Exchange Session (Exhibit Hall A) Professional Poster Session and Oral Presentations (Exhibit Hall A)
10:30-11:45AM	Educational Opportunities
10:45-11:45AM	Engage and Exchange Session (Exhibit Hall A)
11:30AM-2:00PM	Luncheon (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Engage and Exchange Session (Exhibit Hall A) Professional Poster Session and Oral Presentations (Exhibit Hall A)
12:00-1:00PM	DIA Community Meet & Eat (Exhibit Hall A)
12:00-1:45PM	Innovation Row Tour (Room 104A)
1:30-3:30PM	Exhibit Guest Passes
2:00-3:15PM	Educational Opportunities Engage and Exchange Session (Exhibit Hall A)
3:00-4:00PM	Refreshment Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B)
4:00-5:15PM	Educational Opportunities Engage and Exchange Session (Exhibit Hall A)

WEDNESDAY, JUNE 29

Registration Hours:

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

Schedule:

7:00-8:00AM	Coffee and Light Refreshments (Grand Hall & Room 108 Concourse)
8:00-9:30AM	DIAmond Sessions
9:00AM-4:00PM	Exhibit Hall Open Professional Posters Open (Exhibit Hall A)
9:30-10:30AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Engage and Exchange Session (Exhibit Hall A) Professional Poster Session and Oral Presentations (Exhibit Hall A)
10:30-11:45AM	Educational Opportunities
10:45-11:45AM	Engage and Exchange Session (Exhibit Hall A)
11:30AM-2:00PM	Luncheon (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B) Engage and Exchange Session (Exhibit Hall A) Professional Poster Session and Oral Presentations (Exhibit Hall A)
1:30-3:30PM	Exhibit Guest Passes
2:00-3:15PM	Educational Opportunities Engage and Exchange Session (Exhibit Hall A)
3:00-4:00PM	Refreshment Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall B)
3:15-4:00PM	Engage and Exchange Session (Exhibit Hall A)
4:00-5:15PM	Educational Opportunities

THURSDAY, JUNE 30

Registration Hours:

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

Schedule:

8:00-9:00AM	Coffee and Light Refreshments (Room 108 Concourse)
9:00-10:30AM	DIAmond Sessions
10:30-10:45AM	Coffee Break (Room 108 Concourse)
10:45AM-12:00PM	Educational Opportunities

Program Highlights

New Features for 2016

Engage and Exchange Sessions

Space is Limited

You spoke, we listened! Our new Engage and Exchange (E&E) Sessions in the Exhibit Hall allow you to engage with your fellow attendees in a new, collaborative learning environment for peer-to-peer networking and education. Exchange best practices and work with your fellow attendees to find solutions to common challenges that you can implement right away. These sessions are limited to 50 participants, and are available on a first come, first served basis. E&E Sessions will be scheduled throughout the meeting. Please check the DIA 2016 Global app and website for additional information.

DIAmond SESSIONS

Conversations on Today's Priorities

Hear from top thought leaders on global, interdisciplinary topics about the future of therapeutics, and how they affect you. Our DIAmond Sessions will bring together innovators from industry, academia, and government agencies to discuss key concepts, and have a conversation on today's priorities. See page 6 for more details.

Sunday Professional Development Opportunities

Looking for more educational opportunities? Join us Sunday afternoon for a short block of programming hosted by our Professional Development Track. Improve your presentation and networking skills at these interactive sessions, aimed to boost your personal professional development. See page 9 for more details.

Want to Know More?

See pages 6 through 9 for additional ways to LEARN and ENGAGE at DIA 2016!

Plenary Session and Keynote

Larry Brilliant, MD, MPH

Chairman of the Skoll Global Threats Fund

Keynote Speaker

Monday, June 27 | 2:30-4:00PM | Ballroom AB

Bad Bugs, Good People, and Big, Bold Ideas

The boldest and bravest innovators have saved humanity from the world's most nightmarish diseases. Who are these great minds? What motivated them? What are the innovations? What's next? Join Dr. Larry Brilliant - American physician, epidemiologist, technologist, author, and former director of Google's philanthropic arm - for inspiring stories of courageous, cutting-edge, and often crazy ideas that have defeated the ills of mankind.

Dr. Larry Brilliant is the Chairman of the Skoll Global Threats Fund (SGTF), whose mission is to confront global threats such as: Pandemics, Climate Change, Water, Nuclear Proliferation, and the Middle East Conflict. Brilliant is board certified in preventive medicine and public health, and co-founded The Seva Foundation, an international NGO whose programs and grantees have given back sight to over 3.5 million blind people in over 20 countries. Previously he worked as a United Nations medical officer, where he played a key role in the successful World Health Organization (WHO) smallpox eradication program in South Asia.

Innovation Theater Schedule

Exhibit Hall B

Participating Exhibiting Companies will showcase their expertise and solutions in this year's schedule.

Monday, June 27

DBMS Consulting | 10:00AM
Accelerating Clinical Trial Innovation: Technology Case Studies for Improving Data Collection, Monitoring, and Medical Coding Processes

Tata Consultancy | 12:15PM
Data Transparency Initiative: An Innovative Solution

PAREXEL | 1:00PM
Balancing Rapid Approval with Demonstration of Value

Quintiles Transnational | 1:45PM
Evidence Optimization: Fueling Smarter Clinical Development and Value Generation

BBK Worldwide | 4:30PM
Reimagining the Patient Experience Through mHealth Technologies

ConvergeHEALTH by Deloitte | 5:15PM
Leveraging Sentinel Data, Methods, and Tools to Support Postmarket Product Safety and Surveillance — Innovation in Medical Evidence Development and Surveillance (IMEDS) Program

Tuesday, June 28

Covance Inc. | 9:45AM
Leveraging Patient Data and Historical Investigator Performance Data to Realize Faster Patient Recruitment

Quintiles Transnational | 12:00PM
Transforming Patient Recruitment Through Site and Patient Engagement

PRA Health Services | 12:40PM
Transforming EMR to EDC

Veeva Systems | 1:20PM
The Great RIM Throwdown! How Are You Managing Regulatory Events?

Veeva Systems | 3:25PM
2016 Paperless TMF Survey: Trends and Insights

Wednesday, June 29

SAS Institute Inc. JMP Division | 9:45AM
Efficient Safety Assessment in Clinical Trials Using the Computer-Generated Adverse Event Narratives of JMP Clinical

SAS Institute Inc. | 12:00PM
Empowering Action – Fueling Safety and Operational Efficiency

Salesforce | 12:40PM
Connect to Your Patients, Providers, and Partners in a Whole New Way with the Salesforce Platform

SAP America | 1:20PM
Too Much R&D Data to Develop New Drugs and Medical Devices?

DBMS Consulting | 3:25PM
Safety Data Delay is a Risk-Enhanced Signal Detection with Customized MedDRA and Drug Grouping Queries

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CenterWatch

Patient Advocate Fellowship Program

Patients and patient advocates are influencing all stages of the therapeutic life cycle in increasingly substantive ways; industry and regulators are expanding processes that incorporate patient insights earlier and earlier in the drug development process. Through the support of the Patient Advocate Fellowship Program, DIA provides the perfect forum for patient advocates to network and collaborate with industry, policy makers, academia, and health professionals on innovations to bring safe and effective therapies to market faster.

Meet the Patient Fellows at Booth **#1631**

Join the Conversation.
Follow **#DIA2016Patients**
for real-time updates.

Here are just some of the patient organizations represented:

ASSOCIATION FOR CREATINE DEFICIENCIES
EDUCATION ADVOCACY RESEARCH

BEYOND CELIAC
awareness • advocacy • action

Canadian Digestive Health Foundation

Choroideremia RESEARCH FOUNDATION

FD FIBROUS DYSPLASIA FOUNDATION

FIGHT COLORECTAL CANCER

Global Genes®
Allies in Rare Disease

GLOBAL HEALTHY LIVING FOUNDATION

iConquerMS™

Jeff FOUNDATION

MS National Multiple Sclerosis Society

NTMir Nontuberculous Mycobacteria
NTM Info & Research, Inc.

MOVING FORWARD TOGETHER TO CURE LUPUS

Alliance for Lupus Research

Lupus Research Institute

S.L.E. LUPUS FOUNDATION

Bridge the Gap SYNGAP Education & Research Foundation

Meeting Highlights

Learn

DIAmond SESSIONS

Conversations on Today's Priorities

Tuesday, June 28 | 8:00–9:30AM

Changing Cultures to Advance Patient Engagement–*Room 103ABC*
A diverse panel will discuss reframing the challenges of cultural change to achieve the best outcomes for patients in the health care process.

Next Generation Collaborations: Transforming the Industry–*Ballroom A*
This forum will bring together a diverse panel representing some of the industry's most influential and powerful organizations for a candid and innovative conversation about what is needed to shake up the current ecosystem and truly transform patient health.

International Regulatory Convergence, Collaboration, and Cooperation–*Room 114*
(8:00–9:45AM)
Join senior leadership from international regulatory authorities to hear the latest on multi- and bilateral initiatives that avoid duplication and increase mutual reliance, their strategic governance, and their impact on industry.

Wednesday, June 29 | 8:00–9:30AM

Europe and the US: Making Outcomes-Based Health Care Possible—*Room 114*
This session will discuss the benefits and challenges of outcomes-based health care, as well as the remaining barriers to implementation.

The Future of Big Data—*Room 103ABC*
This dynamic forward-focused session will bring together industry, technology innovators, academia, and government agencies to paint a colorful picture of how they will drive advances in health care founded on big data platforms.

Value-Based Health Care Decision Making: The Quest for Smarter Spending—*Ballroom A*
Hear perspectives from multiple stakeholders to better understand the challenges and implications brought by this new focus towards value, and uncover ideas of collaboration to realize smarter health care spending.

Thursday, June 30 | 9:00–10:30AM

Protocol Development Is a Team Sport—*Room 103ABC*
Unique viewpoints will be presented to serve as the basis for a moderated discussion that analyzes the current process for protocol development, while suggesting approaches to more fully incorporate the patient voice into protocol design and implementation.

EMA/FDA Question Time—*Room 114*
Leadership from the EMA and FDA will explore topics covered by the EMA/FDA confidentiality arrangements and discuss how both Agencies contribute to the global development and supervision of medicines.

The content noted on this page was made available to DIA as of May 24, 2016.

Global Regulatory Session Highlights

Tuesday, June 28

CBER Town Hall: State of the Center and Plans for the Future *—Room 203AB*
(2:00–3:15PM)
This forum will provide an overview of CBER's current work on ongoing initiatives and will summarize its priorities moving forward.

Update from Health Canada*—Room 202AB*
(2:00–3:00PM)
The forum will focus on biotherapeutic products (monoclonal antibodies, hormones and enzymes, and cytokines) and will have both clinical, and chemistry and manufacturing representation, and allow attendees to speak directly to regulators from Health Canada.

PMDA Town Hall*—Room 202AB*
(4:00–5:15PM)
The progress of the Pharmaceuticals and Medical Devices Agency (PMDA) International Strategic Plan 2015, which was announced after the success of shortening the review period for medicines products, will be presented and will include audience Q&A.

Wednesday, June 29

FDA-Health Canada Regulatory Cooperation Council Town Hall*—Room 201C*
(10:30–11:30AM)
FDA and Health Canada will highlight their work under the Regulatory Cooperation Council (RCC) phase 2 and request stakeholder input on their current initiatives.

Thursday, June 30

CDER Town Hall*—Room 114*
(10:45AM–12:00PM)
This forum is a round table discussion with FDA leadership, and will include updates on regulatory issues.

Meeting Highlights
Engage

Member Engagement Area
Grand Hall

Are you looking to make the most of your DIA membership? Stop by the DIA Member Engagement Area located in the Grand Hall, next to speaker registration. Learn how to take advantage of volunteer opportunities to raise your visibility and enjoy a tour of our brand new Community platform. Becoming a DIA member is the first step to joining a global network where you can play an important role advancing health care product development through global collaboration, communication, and education.

DIA Communities—The More You Put In, the More You Get Out

This exclusive DIA member benefit helps members stay connected even after the meeting ends! Continue the networking and information sharing as part of DIA's member Communities. DIA Communities provide a way for members across the globe to interact with their peers or to form cross-disciplinary teams. It is here that members share information, raise concerns, mentor one another, and find answers together—accomplishing more as a group than any one person could accomplish alone.

- Keep up to date on hot topics and Community-generated content
- Share best practices, knowledge resources, articles, and more
- Get involved, resolve issues, and evolve health care

Join at DIAglobal.org/Communities

DIA Community Networking Area
Exhibit Hall Entrance A

A dedicated area is available for you to meet with your fellow Community members throughout the week or to learn more about DIA's Communities. Each table will include a sign related to a specific Community Interest Area. Look for the designated area in Exhibit Hall A, near the Posters Area, where you can relax and enjoy an informal opportunity to network.

DIA Community Meet & Eat
Tuesday, June 28 | 12:00–1:00PM

Join Community members and interested attendees at the Community Meet & Eat, held in the Community Networking Area, to learn more about community and volunteer opportunities.

DIA and You: Driving Ideas to Action

Learn more about the benefits you get as a DIA Member

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Sunday Professional Development Sessions
Room 202AB

Powerful Presentations
2:45–4:00PM

Networking: It's Personal–Understanding Yourself and Others to Maximize Personal Interaction
4:15–5:30PM
This session will be followed by an informal gathering at the Field House to practice your newly acquired networking skills.

Annual Meeting Orientation and Networking
Monday, June 27 | 7:30–8:15AM
Room 104A
Attending DIA 2016 for the first time? We encourage you to attend the Annual Meeting Orientation and Networking Session to learn how to make the most of your time at the meeting, and meet fellow first timers.

DIA 2016: Student Forum
Monday, June 27 | 8:30–9:45AM
Room 108A
Explore career opportunities in industry and in government agencies, and see how DIA student chapters have helped students start their careers, while participating in chapter events and opportunities.

Student Poster Session and Oral Presentations
Monday, June 27 | 12:15–2:15PM; 4:15–5:30PM
Exhibit Hall A
Students from around the world will showcase their research in this year's Poster Session.

Opening Reception
Monday, June 27 | 4:00–6:00PM
Network with 7000+ attendees and 450+ exhibitors at the Opening Reception in the Exhibit Hall.

Student Poster Awards Ceremony
Monday, June 27 | 5:30PM
DIA Booth #1425
Join us as we present the awards to the Student Poster Presentation winners.

Innovation Row Tour
Tuesday, June 28 | 12:00–1:45PM
Room 104A
Hear key leaders in the clinical and product development space showcase their health care products, services, and technologies in development and recently on the market to a panel of professors, business development professionals, and potential investors.

Professional Poster Sessions and Oral Presentations
Session 1
Tuesday, June 28 | 9:40–10:20AM; 12:00–1:45PM
Exhibit Hall A

Session 2
Wednesday, June 29 | 9:40–10:20AM; 12:00–1:45PM
Exhibit Hall A
Learn about cutting edge research from a diverse group of life science professionals on various topics.

Refreshment Breaks
Meet up with your colleagues to plan your day. Coffee and light refreshments will be available in the Grand Hall & Room 108 Concourse:

Monday, June 27 | 7:00–8:30AM
Tuesday, June 28 | 7:00–8:00AM
Wednesday, June 29 | 7:00–8:00AM
Thursday, June 30 | 8:00–9:00AM (Room 108 Concourse)

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

Monday, June 27 | 9:30–10:45AM
Tuesday, June 28 | 9:30–10:30AM; 3:00–4:00PM
Wednesday, June 29 | 9:30–10:30AM; 3:00–4:00PM
Thursday, June 30 | 10:30–10:45AM (Room 108 Concourse)

Luncheon in the Exhibit Hall
Discuss what you've learned and meet with exhibitors at our daily luncheon in the Exhibit Hall:

Monday, June 27 | 11:45AM–2:30PM
Tuesday, June 28 | 11:30AM–2:00PM
Wednesday, June 29 | 11:30AM–2:00PM

General Information

Accessing Presentations
To access presentations, visit DIAglobal.org/DIA2016 for more information.

Baggage Check
There will be an area adjacent to room 107, near the 12th and Arch Street entrance, where you can check your belongings ($3 per item) Monday–Thursday. The Baggage Check will be available:

Monday-Wednesday, June 27-29 | 7:00AM–6:30PM
Thursday, June 30 | 8:00AM–12:30PM

Business Center
The Pennsylvania Convention Center FedEx Office, located outside Exhibit Hall B, offers an array of business services and products, tailored to meet your needs. For more information call 215.925.1218 or Fax 215.925.3738.

DIA Career Center
DIA's interactive Career Center is your premier resource for online employment connections! 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 over 60 top health care associations and professional organizations. Job seekers receive FREE and confidential resume posting, automated weekly email notification of new job listings, and the ability to save jobs for later review.

For additional information, visit the DIA Booth (#1425) or the DIA Community Networking Area, located in the Exhibit Hall.

Free DIA WiFi
DIA will be providing complimentary WiFi service throughout the Pennsylvania Convention Center. To utilize this service, simply connect to "DIA Free WiFi" and enter the key "DIA2016". Once connected you will be redirected to the DIA website. Don't forget to download the DIA Global app by searching "DIA Global" in your app store.

Dress Code
Dress code is business casual. Neckties, business suits, or other business attire are acceptable, but not necessary. The Convention Center may be chilly so bring a sweater or jacket; comfortable shoes are a must!

First Aid Center
First Aid is available for routine health problems and emergency care. The First Aid Center is located in the the back of Exhibit Hall B, near the lunch voucher exchange area. In case of emergency dial 4911 from any convention center phone or 215.418.4911 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 Attendee Registration, located in Grand Hall, until the end of the event. Items remaining at the close of the meeting will be turned over to the Pennsylvania Convention Center. At that point, you can call 215.418.4911.

Lunch Voucher Program
A voucher program is being used for DIA's luncheon service. Your vouchers are included with your badge. Please keep your vouchers in a safe place, as replacements will not be issued.

Vouchers are not redeemable for cash. Only one voucher can be used per transaction and they are not transferable. Therefore, you will need to pick up your own lunch. Vouchers can be used in the Exhibit Hall only, and are valid Monday, 11:45AM–2:30PM, and Tuesday–Wednesday, 11:30AM–2:00PM.

In order to expedite this service each day, please reference the voucher flyer included in your registration bag for a list of menu items and additional instructions for your voucher exchange.

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Meeting Name Badge

There will be a $25 fee for badge reprints. If you require a badge reprint, please visit the Cashier at Attendee Registration. Identification will be required. Additionally, the QR code on your conference badge contains your contact information. Allowing exhibitors to scan the QR code will provide them with your contact information.

Private Social Functions Policy

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

Saturday, June 25 | All times
Sunday, June 26 | All times
Monday, June 27 | Before 8:00AM and after 6:00PM
Tuesday, June 28 | Before 8:00AM and after 5:00PM
Wednesday, June 29 | Before 8:00AM and after 5:00PM
Thursday, June 30 | 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 alternate selection in the event that a room is filled to capacity. Those with press passes are only able to attend sessions when room is available.

Getting Around Philadelphia

By Taxi

Walking around Philadelphia is easy, however, if you are in a hurry, or the weather changes, taxicabs are plentiful and relatively inexpensive. Fare from the airport to Center City is $28 to $35, and fare from Philadelphia's 30th Street Station to the Convention Center typically costs $10 to $15. Taxis will arrive and depart from 12th and Arch Streets (entrance near room 107).

By Public Transit

SEPTA Rail Lines service the entire Philadelphia Region. Jefferson Station (formerly Market East Station) is connected to the Convention Center.

The Septa Airport Regional Rail Line is the most convenient way to travel to and from the airport and downtown, and you can do so in just 25 minutes. Trains depart every half hour from 5:00AM until midnight. Trains stop at Terminals A-F, Amtrak's 30th Street Station, Suburban Station (16th and JFK Boulevard), and Jefferson Station. The onboard (cash only) fare to Center City is $8 on weekdays and $7 on evenings and weekends.

From Amtrak's 30th Street Station, take the SEPTA Regional Rail to the Jefferson Station (connected to the Convention Center). The regional rail train departs every few minutes. With your Amtrak ticket, the ride to Center City is free.

Other SEPTA Regional Rail Lines can shuttle you throughout the region. Please visit SEPTA.org or call 1.215.580.7800 for more information.

Show Your Badge Discounts

Show your DIA badge to many vendors, shops, and restaurateur around the city to receive special exclusive discounts for DIA 2016 attendees. Visit discoverphl.com/deals for a list of participating locations.

Concierge Services

Philadelphia restaurant and city information desks will be available throughout the meeting. Desks are located at the 12th and Arch Street entrance (near room 107), and between the Exhibit Hall A and B entrance.

DIA Courtesy Shuttle to/from Convention Center

Complimentary shuttle service will be provided between the Convention Center and DIA hotels that are not within walking distance of the Convention Center, Monday–Thursday. The shuttle will be available in the morning and at the conclusion of DIA events each day. Shuttles will arrive and depart from 12th and Arch Streets (entrance near room 107). Please note that you must be staying at a DIA hotel to utilize the complimentary shuttle. A shuttle pass and shuttle schedule will be provided to all participants when checking into their hotel, and use of the shuttle pass will be strictly enforced.

CONTINUING EDUCATION

DIA 2016 brings together key thought leaders and innovators from industry, academia, regulatory and government agencies, health, and patient and philanthropic organizations from around the globe—and across all disciplines involved in the discovery, development, and life cycle management of health care products. The DIA Annual Meeting 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 2016, participants should be able to:

- Compare the current regional regulatory and public policy environment pertaining to pharmaceuticals and related products
- Discuss the regulatory and economic factors that impact the global biopharmaceutical industry
- Recognize the challenges facing regulatory agencies and industry in research study design and statistical methodology
- Identify relevant data, document, and systems standards and integration approaches; explain their impact on quality and end-to-end efficiency in data collection, management, submission, and approval processes for medical products
- Describe the current and future scope of innovative technology, including wearables and other mobile devices, in the generation and collection of electronic source data in clinical research and post-market assessment to improve patient outcomes
- Discuss the role of big data and analytics, their applications throughout the product life cycle, and their ethical, legal, and security implications for patient data
- Identify legal, advertising, and marketing issues related to providing product information
- Apply principles of risk assessment and management to development and post-market phases of new health care products
- Summarize issues in safety reporting and data analysis regarding adverse events
- Distinguish regional approaches to integration of evidence-based medicine and comparative effectiveness research into health care decision making
- Describe current issues in designing and implementing clinical trials, including patient recruitment, site selection, and management of multi-regional clinical trials
- Identify current opportunities and challenges in the area of personalized medicine for disease treatment
- Examine ways to provide appropriate support to the clinical trial process that will ultimately impact patient care

Specific learning objectives for each offering are found on the DIA 2016 website under the program description details and will be shown in all meeting rooms.

Select program offerings (including sessions, forums, workshops, symposia) may be approved for *AMA PRA Category 1 Credits™*, pharmacy or nursing contact hours, or Project Management Institute 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 2016 website with the statement CME, Pharmacy, Nursing, or PMI PDUs. IACET continuing CEUs are offered for all program offerings. CE credits are **NOT AVAILABLE** for Track 20: Innovation Theater, Track 21: Poster Presentations, Track 22: Engage and Exchange, or Track 23: Opening Plenary.

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS

Accreditation Council for Continuing Medical Education (ACCME)

PIM Postgraduate Institute for Medicine

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Postgraduate Institute for Medicine (PIM) and the Drug Information Association (DIA). PIM is accredited by the ACCME to provide continuing medical education for physicians.

The Postgraduate Institute for Medicine designates this live activity for a maximum of 18.75 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Accreditation Council for Pharmacy Education (ACPE)

ACPE

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants can earn up to 16 contact hours or 1.6 continuing education units (CEUs) for participating in the Annual Meeting program offerings.

ACPE Credit Requests MUST BE SUBMITTED BY FRIDAY, AUGUST 12, 2016

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

All approved ACPE UANs and activity types are on the DIA 2016 Annual Meeting website at www.DIAglobal.org/DIA2016CE and on each designated offering description.

American Nurses Credentialing Center (ANCC)

This educational activity for 18.75 contact hours is provided by PIM.

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

Select program offerings (including sessions, forums, workshops, and symposia) 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 2016 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 Track 20: Innovation Theater, Track 21: Poster Presentations, Track 22: Engage and Exchange, or Track 23: Opening Plenary.

The content noted on this page was made available to DIA as of May 24, 2016.

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 9.75 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 2016 Annual Meeting website at www.DIAglobal.org/DIA2016CE and on each designated offering description.

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

International Association for Continuing Education and Training (IACET)

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

As an IACET accredited provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.8 CEUs for this program.

CONTINUING LEGAL EDUCATION

For attorneys who would like to receive continuing legal education credits for attending DIA 2016, please complete your state's application for credit and submit accordingly. If you require additional information, please contact DIA at CE@DIAglobal.org.

CE CREDIT ALLOCATION

Annual Meeting Program Offerings, Sunday–Thursday, June 26–30

Credit amounts range from .5 hours to 1.75 hours depending upon the length of time for each offering. This program offers up to 18.75 *AMA PRA Category 1 Credits™*; 1.8 IACET CEUs (.2 IACET CEUs are offered for a 1.75 or 1.5 hour program offering and .1 IACET CEU is offered for a 1.25, 1, or .5 hour offering); Nursing 18.75 contact hours; Pharmacy 16 contact hours or 1.6 CEUs; and 9.75 PMI PDUs

DIA CERTIFICATE PROGRAMS

Individuals enrolled in DIA Certificate Programs may receive elective units as 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 2016 Preconference Tutorials. See specific units that are available for each offering on the DIA 2016 website. For more information on DIA's Certificate Program, visit DIAglobal.org/certificateprograms.

Participants who would like to receive continuing education credit for DIA 2016 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, 30 minutes for the 1.25 and 1 hour offerings, and within 15 minutes for the 30 minute 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 5

To access My Transcript:

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

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

EVALUATION

Access to DIA 2016 Annual Meeting online evaluations are found at DIAglobal.org/DIA2016evals. All participant scanned data will be uploaded into the evaluation portal, so only the offerings you attended will appear in your records. Attendees will sign into the evaluation portal utilizing their email address and Badge ID.

The evaluation portal opens on Sunday, June 26 and closes on Wednesday, July 29.

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 2017 Annual Meeting. Eligible attendees must complete all program offering evaluations from each offering time frame as well as the overall evaluation. The winner of the drawing will be contacted by DIA the week of August 1, 2016.

DISCLAIMER

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

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

Disclosure of Conflicts of Interest

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

DIA 2016 TRACKS AND INTEREST AREAS

Track #	Track Title	Interest Area
Track 01	Clinical Operations	Academic Health Centers/Investigative Sites (AHC/IS), Clinical Research (CR), Clinical Supplies (CS), Manufacturing (MF), Research and Development (RD)
Track 02	Project/Portfolio Management and Strategic Planning	Financing (FI), Project Management (PM), Strategic Planning (SP)
Track 03	Innovative Partnering Models and Outsourcing Strategies	Outsourcing (OS)
Track 04	Preclinical and Translational Development/Early Phase Clinical Development	Biotechnology (BT), Nonclinical (NC), Pharmacology (PC)
Track 05	Regulation of Product Advertising and Marketing in an Ever-Changing World	Advertising and Promotion (AP), Marketing (MA)
Track 06	Medical Communication/Medical Writing and Medical Science Liaisons	Medical Communications (MC), Medical Science Liaisons (MSL), Medical Writing (MW)
Track 07	Technology/Data/Records and Submissions	Information Technology (IT), eClinical (EC), Clinical Data Management (CDM), Document Management (DM),Study EndPoints/Clinical Outcomes Assessment (SE), Submissions (SUBS),Validation (VA)
Track 08	Regulatory Affairs	Regulatory Affairs (RA)
Track 09	Medical Devices/In Vitro Diagnostics and Combination Products	Combination Products (CmbP), Medical Devices and Diagnostics (MDD)
Track 10	Public Policy/Health Care Compliance/Law	Public Policy, Health Care Compliance/Law (PPLC)
Track 11	Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice	Good Clinical Practice (GCP), Quality Assurance, Quality Control (QA/QC)
Track 12	Pharmaceutical Quality	Chemistry, Manufacturing and Controls/Good Manufacturing Practices (CMC/GMP)
Track 13	Comparative Effectiveness Research/Global Health Outcomes and Economics	Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine (CEHTAEbM), Pricing and Reimbursement (PR)
Track 14	Clinical Safety and Pharmacovigilance	Clinical Safety and Pharmacovigilance (CP)
Track 15	Statistical Science and Quantitative Thinking	Statistical Science (ST)
Track 16	Professional Development	Professional Education, Training, and Development (PETD)
Track 17	Rare/Orphan Diseases	Rare/Orphan Diseases (ROD), Patient Engagement (PT)
Track 18	Global Regulatory	ALL
Track 19	DIAmond	ALL
Track 20	Innovation Theaters	ALL
Track 21	Poster Presentations	ALL
Track 22	Engage and Exchange	ALL

CONTENT LEVEL GUIDE

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

● **Basic Level Content:**
Appropriate for individuals new to the topic/subject area.

■ **Primarily Intermediate Level Content:**
Appropriate for individuals who already have a basic understanding of the topic/subject area.

◆ **Primarily Advanced Level Content:**
Appropriate for individuals with an in-depth knowledge of the topic/subject area.

DIFFERENT FORMATS FOR DIFFERENT LEARNERS

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

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

SYMPOSIUM
A blend of three 20-minute presentations.

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

The content noted on this page was made available to DIA as of May 24, 2016.

The following agenda details were made available to DIA on May 24. 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 25

Registration Hours:

9:00AM–5:00PM Exhibitor Registration

SUNDAY, JUNE 26

Registration Hours:

8:00–9:00AM Registration for Full Day and Morning Preconference Tutorials*

8:00AM–6:00PM Exhibitor Registration

12:30–6:00PM Registration for Afternoon Preconference Tutorials*, Conference Attendees, and Speakers

Schedule:

8:30AM–12:00PM Half Day Morning Preconference Tutorials*

9:00AM–5:00PM Full Day Preconference Tutorials*

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

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

11:45AM–12:00PM

Annual Meeting of Members
Liberty Ballroom A - Philadelphia Marriott Downtown

#001 Track 16 – Professional Development

Related Interest Area(s): PETD

2:45–4:00PM | Level: ● | Format: WORKSHOP
Room 202AB | *CME and Nursing*

Powerful Presentations

CHAIRPERSON

Lynn King, MHA
Senior Director, Clinical Operations, TKL Research, Inc.

SPEAKER(S)

Message Primacy: Using Imagery and Storytelling to Create Memorable Presentations
Robin Whitsell
President, Whitsell Innovations, Inc.

#002 Track 16 – Professional Development

Related Interest Area(s): PETD

4:15–5:30PM | Level: ● | Format: WORKSHOP
Room 202AB | *CME and Nursing*

Networking: It's Personal - Understanding Yourself and Others to Maximize Personal Interaction

CHAIRPERSON

Christopher Matheus, MBA
Director, Business Development, YPrime Inc.

Facilitator
Bob Muzerall
Vice President, Sales and Sales Training, AMPLEXOR Life Sciences, LLC

MONDAY, JUNE 27

Registration Hours:

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

7:00–8:30AM

Coffee and Light Refreshments
Grand Hall and Room 108 Concourse

7:30–8:15AM

Annual Meeting Orientation and Networking
Room 104A

#101 Track 01A – Clinical Operations

Related Interest Area(s): CR, EC, GCP, PT

8:30–9:45AM | Level: ● | Format: SYMPOSIUM
Room 113C | *CME and Nursing*

Opportunities for Improving Informed Consent of Clinical Research Volunteers

CHAIRPERSON

Jennifer Lentz
Global Informed Consent Consultant, Global Clinical Operations, Eli Lilly and Company

SPEAKER(S)

Transforming Informed Consent: Initiatives of the Clinical Trials Transformation Initiative and TransCelerate BioPharma, Inc.
Jennifer Lentz
Global Informed Consent Consultant, Global Clinical Operations, Eli Lilly and Company

Engaging Investigators and Site Staff in Adoption and Implementation of e-Consent: A World View
Susan Brink, DrPH
Executive Vice President, e-Consent Products and Services, Enforme Interactive

Applicable Lessons Learned from the CTTI Antibacterial Drug Development Program
Pamela Tenaerts, DrMed, MBA
Executive Director, Clinical Trials Transformation Initiative (CTTI)

#102 Track 01B – Clinical Operations

Related Interest Area(s): CR, EC, RA, IT, VA

8:30–9:45AM | Level: ● | Format: FORUM

Room 113A | *CME and Nursing*

Digital Health Debate

CHAIRPERSON

Nariman Nasser
Digital Strategist, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

SPEAKER(S)

Move from Pilot to Platform: Four Strategies to Enable Digital Health Approaches to Scale in Research Programs
John Reites
Senior Director, Head of Digital Health Acceleration, Quintiles Inc.

mHealth in Clinical Research and Development: Is It All Hype?
Brett Villagrand
Consultant

Site Perspective
Joshua R. Korzenik, MD
Director, Crohn's and Colitis Center, Brigham and Women's Hospital

#103 Track 01C – Clinical Operations

Related Interest Area(s): CR, PT, GCP, FI

8:30–9:45AM | Level: ■ | Format: SESSION

Room 113B | *CME and Nursing*

Decision Tools to Drive Efficient Recruitment and Retention: Making Recruitment a Science

CHAIRPERSON

James Kremidas
Executive Director, Association of Clinical Research Professionals (ACRP)

SPEAKER(S)

Matchmaking: Systematizing Best Fit Tactics for Study Needs
Lewis Millen
Operational Intelligence Leader, Roche, United Kingdom

The Art and Science of Site Level Recruitment Planning: Tools, Tactics, and Tips?
Beth D. Harper, MBA
President, Clinical Performance Partners, Inc.

#104 Track 02A – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): RA, RD, SP, BT, ROD

8:30–9:45AM | Level: ◆ | Format: FORUM

Room 105AB | *CME, Pharmacy, Nursing, and PMI PDUs*

Impact of Biologics, Vaccines, Oncology, and Breakthrough Therapy Designation on Traditional Global Drug Development Strategy

CHAIRPERSON

Eva M. Finney, PhD, PMP
Director, Global Project & Alliance Management, Merck & Co., Inc.

Panelists
Susan Uptain, PhD
Head of Regulatory Affairs Operations, Baxalta

David Robinson, PhD
Principal Consultant, Robinson Vaccines and Biologics LLC

#105 Track 02B – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): RA, SP, RD

8:30–9:45AM | Level: ■ | Format: FORUM

Room 107AB | *CME, Nursing, and PMI PDUs*

Maximize the Value of Your Product by Beginning with the End in Mind

CHAIRPERSON

Jayanthi Reddy, MBA, MS, PMP
Director and Cardiovascular Pipeline Leader, Global Project Management, Merck & Co., Inc.

Panelists
Bill Hanlon, PhD
Global Regulatory Affairs, Covance Inc.

Carrie Furin
Pharmaceutical Project Manager, Eli Lilly and Company

#106 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): PT, CR

8:30–9:30AM | Level: ■ | Format: FORUM

Room 112AB | *CME and Nursing*

Fostering a Partnership to Advance Innovation: Niche Service Leads to Breakthrough in Patient Recruitment and Retention Challenges

CHAIRPERSON

Gail Adinamis
Chief Executive Officer, GlobalCare Clinical Trials

SPEAKER(S)

Breaking Through Corporate Silos to Promote Innovation
Denisa McKnight, MSc
Global Category Manager - Patient Engagement and Media, GPPS, Roche Products Limited, United Kingdom

#107 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): CR, CP

8:30–9:45AM | Level: ■ | Format: FORUM

Room 202AB | *CME, Pharmacy and Nursing*

Fatal Drug Trials in Phase 1: Understanding Risk, Subject Safety, Timelines, and Cost

CHAIRPERSON

William B. Smith, MD
President, New Orleans Center for Clinical Research

Panelists
Howard Greenberg, MD
Medical Safety Officer, Janssen Pharmaceuticals, Inc.

Thijs Van Iersel, MD
Senior Director of Science, Early Development Services, PRA Health Sciences, Netherlands

Mary L. Westrick, PhD
Adjunct Professor, University of Wisconsin

#108 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

Related Interest Area(s): AP, PPLC, RA, MDD

8:30–9:45AM | Level: ■ | Format: FORUM
Room 203AB | *CME, Pharmacy, and Nursing*

Drug/In Vitro Diagnostic Device Advertising and Promotion: Unapproved Combination Product or Awareness?

CHAIRPERSON
Kimberly Belsky, MS
Executive Director, OneSource Regulatory

Panelists
Alan G. Minsk, JD
Partner, Head of Food and Drug Team, Arnall Golden Gregory LLP

Minnie Baylor-Henry, JD, RPh
President, B Henry & Associates

#109 Track 07 – Technology/Data/Records and Submissions

Related Interest Area(s): EC, CDM, RA, IT

8:30–9:45AM | Level: ■ | Format: SESSION
Room 201C | *CME and Nursing*

EHR in Clinical Research: Heralding a New Era

CHAIRPERSON
Trisha D. Simpson
Director, Global Biometry Standards, UCB Biosciences, Inc.

SPEAKER(S)

EHR to EDC Data Transfer: Experiences and Lessons
Ian Sparks
Senior Director, Research Science, Medidata Solutions Worldwide, United Kingdom

The eSource Stakeholders Group and Next Steps
Michael A. Ibara, PharmD
Head of Digital Healthcare, CDISC

EHR-EDC Integration Case Study: The Good, the Bad and the Beautiful
Sue S. Dubman, MA
Director, IT and Informatics, University of California San Francisco (UCSF)

#110 Track 08A – Regulatory Affairs

Related Interest Area(s): BT, RA

8:30–9:45AM | Level: ■ | Format: FORUM
Room 201B | *CME, Pharmacy, and Nursing*

Updates and Pending Issues in the US Biosimilar Environment

CHAIRPERSON
Andrew S. Robertson, JD, PhD
Director, Global Regulatory Policy, Merck & Co., Inc.

Panelists
Karen M. Hauda, JD, MSc
Senior Director, Regulatory Policy, Novo Nordisk Inc.

Mark McCamish, MD, PhD
Global Head Biopharm and Oncology Injectables Development, Sandoz International GmbH, Germany

Sundar Ramanan, PhD
Director, Global Biosimilars R&D Policy, Amgen Inc.

#111 Track 08B – Regulatory Affairs

Related Interest Area(s): RA

8:30–9:45AM | Level: ■ | Format: SESSION
Room 204B | *CME, Pharmacy, and Nursing*

Global Regulatory Harmonization in Asia: Is a New Trend Occurring?

CHAIRPERSON
Akio Uemura, PhD
Senior Director, Head of Development, Japan, Allergan Japan K.K., Japan

SPEAKER(S)

Impacts of ICH E17 Guideline in Asian Drug Development
Yoshiaki Uyama, PhD
Director, Office of Medical Informatics and Epidemiology, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Regulatory Changes in China and Its Impact for Regional/Global Trial Planning
Dan Zhang, MD, MBA, MPH
Chairman and Chief Executive Officer, Fountain Medical Development Ltd. (FMD), China

Update on Clinical and Regulatory Environment for Drug Development in Korea
Min Soo Park, MD, PhD
Chair of KCGI; Professor, Pediatrics and Clinical Pharmacology, Korea Clinical Trials Global Initiative; Yonsei University College of Medicine, Republic of Korea

#112 Track 08C – Regulatory Affairs

Related Interest Area(s): CR, IT

8:30–9:45AM | Level: ■ | Format: SESSION
Room 204C | *CME and Nursing*

The Upcoming European Clinical Trials Regulation

CHAIRPERSON
Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

SPEAKER(S)

Clinical Trials in Europe: What Will Change?
Elke Stahl, PhD
Nonclinical Assessor, Clinical Trial Unit, BfArM, Germany

The EU Portal and Database: A Pillar of the Clinical Trial Regulation
Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

Getting Ready for the Changes: A Sponsor Perspective
Nick Sykes, MS
Senior Director, Worldwide Regulatory Strategy, Pfizer Ltd., United Kingdom

Transparency in Clinical Trials: A European Update
Marie-Agnes Heine, MA
Head of Communication Department, Stakeholders and Communication Division, European Medicines Agency, European Union

#113 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RD, CR

8:30–9:45AM | Level: ◆ | Format: SESSION
Room 108B | *CME, Pharmacy, and Nursing*

Clinical Developments in Immuno-Oncology, Part 1 of 2: Science, Current Methodologies, and Achievements

CHAIRPERSON

Holger G. Adelmann, DrMed, PhD
Senior Vice President and Managing Director, DIA EMEA, Switzerland

SPEAKER(S)

Overview of Immuno-Oncology
Ashok K. Gupta, MD, PhD
Vice President, Head of Clinical Immuno-Oncology, MedImmune

Molecular Predictors of Response to Immuno-Oncology Therapeutics
Koustubh Ranade, PhD
Associate Director, MedImmune

Opportunities and Challenges for the Use of Biomarkers in Anti-PD1/PD-L1 Immunotherapy
Ti Cai, PhD
Director, Global Clinical Biomarkers and Companion Diagnostics, EMD Serono

#114 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR, PT

8:30–9:45AM | Level: ■ | Format: SESSION
Room 204A | *CME, Pharmacy, and Nursing*

Bringing the Trial to the Patient: Making the Patient Voice Central from Trial Design Onward

CHAIRPERSON

Jonca C. Bull, MD
Assistant Commissioner for Minority Health, Office of the Commissioner, FDA

SPEAKER(S)

Patient Perspective
Jane Perlmutter, PhD, MBA
Founder and President, Gemini Group

Patient Centric Trial Design: It's More Than Just the Trial
Joseph Kim, MA, MBA
Senior Advisor, Clinical Innovation, Eli Lilly and Company

FDA Perspective
Elektra Johanna Papadopoulos, MD, MPH
Acting Associate Director, Clinical Outcome Assessments Staff, Office of New Drugs, CDER, FDA

#115 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QA/QC, PT

8:30–9:45AM | Level: ■ | Format: SESSION
Room 111AB | *CME, Pharmacy, and Nursing*

Clinically Relevant Specifications: Translating Voice of the Patient Into Quality Attributes of the Product

CHAIRPERSON

Richard T. Lostritto, PhD, MS
Acting Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

SPEAKER(S)

Specification Setting and Biowaiver Approaches for Drug Products Presenting Strength Dependent Dissolution Profiles
Sandra Suarez Sharp, PhD
Biopharmaceutics Lead (Acting), DB Branch II, ODNP, Office of Pharmaceutical Quality, CDER, FDA

Industry Perspective
Ganapthy Mohan, PhD
Head of Global CMC, Merck & Co., Inc.

FDA Perspective
Laurie Graham
Acting Director, DIPAP, OPPQ, Office of Pharmaceutical Quality, CDER, FDA

#116 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

8:30–9:45AM | Level: ■ | Format: SESSION
Room 103C | *CME and Nursing*

Has the EU Good Pharmacovigilance Practices Delivered on Its Intended Promise and Commitment?

CHAIRPERSON

Valerie E. Simmons, MD, FFPM
EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd, United Kingdom

SPEAKER(S)

Introduction, General Overview of Implementation of the EU GVP Guidelines: Did They Actually Deliver?
Valerie E. Simmons, MD, FFPM
EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd, United Kingdom

IMI PROTECT: Challenges, Successes, and the Effect on PhV in Europe
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Real World & Late Phase Research, Quintiles Inc., United Kingdom

Important Risks Resulting from EU PV Legislation and Guidance: Best Practice to Allow Optimized Patient Safety?
Leonardo Ebeling, MD, PhD
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

#117 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

8:30–9:30AM | Level: ■ | Format: SESSION
Room 109AB | *CME and Nursing*

IDMP: A Compliance Project or a New Way of Conducting Business?

CHAIRPERSON

Rune Bergendorff, MSc
Managing Consultant, NNIT A/S, Denmark

SPEAKER(S)

ISO IDMP Impact Assessment on the Risk Management Plan
Debbie Persaud, MSc
Regulatory Affairs SME, NNIT Inc.

Quality Control Perspective
Bernie Coney, MA
Head of R&D Global Regulatory Affairs and QA IT, Shire

#118 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, SE

8:30–9:45AM | Level: ■ | Format: FORUM
Room 201A | *CME and Nursing*

The Interpretation of PRO Scores and Responder Analyses in the Presence of Missing Data

CHAIRPERSON

Scott Komo
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Panelists
Yeh-Fong Chen, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Lisa A. Kammerman, PhD, MS
Senior Statistical Science Director, AstraZeneca

#119 Track 16A – Professional Development

Related Interest Area(s): PETD, PT, CR

8:30–9:45AM | Level: ● | Format: WORKSHOP
Room 102AB | *CME, Pharmacy, and Nursing*

Narrative Medicine: Innovative Techniques for Including the Voice of the Patient in Clinical Trials

CHAIRPERSON

Jesus Rivera, MSc
Senior Learning Manager, Bristol-Myers Squibb Company

Facilitator
Lauralee Leonard
Senior Medical Writer, Bristol-Myers Squibb Company

#120 Track 16B – Professional Development

Related Interest Area(s): PETD

8:30–9:45AM | Level: ● | Format: SESSION
Room 108A | *No CE available*

DIA 2016: Student Forum

CHAIRPERSON

Danny Benau, PhD
Director, Biomedical Writing Programs, University of the Sciences

SPEAKER(S)

Government Positions: Opportunities, Considerations, and Processes for Federal Employment
Tammy Massie
Mathematical Statistician, Office of Equal Opportunity and Customer Outreach, National Institutes of Health (NIH)

DIA Student Chapter Membership as Part of a Career Springboard
Philip Masaitis
Student, Philadelphia College of Pharmacy, University of the Sciences

Opportunities in the Drug Safety Arena
Sameer Thapar, PharmD
Director, Global PV, Oracle; Assistant Professor, Drug Safety and PV, Rutgers, The State University of New Jersey

#121 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD, CR

8:30–9:45AM | Level: ■ | Format: SYMPOSIUM
Room 103A | *CME, Pharmacy, and Nursing*

Rare Disease Clinical Trials: Coping with Unique Challenges

CHAIRPERSON

Maureen Smith
Patient Advocate / Secretary, Canadian Organization For Rare Disorders (CORD), Canada

SPEAKER(S)

Rare Disease: Understanding Operational Challenges
Linda Martin, MBA
President and Founder, KMR Group Inc.

Orphan Indications and Clinical Trials: Coping with Unique Challenges and Why Rare Diseases Warrant Special Treatment
Stephan de la Motte, MD
Chief Medical Advisor, Synteract HCR, Inc., Germany

Solving Enrollment Challenges for Rare Disease Global Clinical Trials in Latin America
Sara G. Tylosky, MBA
President, Farmacon

9:30–10:45AM

Coffee Break in Exhibit Hall

9:30AM–6:00PM

Student Poster Session in Exhibit Hall A

#122 Track 20 – Innovation Theaters

Related Interest Area(s): CR, DM, IT

10:00–10:30AM | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

DBMS Innovation Theater: Accelerating Clinical Trial Innovation: Technology Case Studies for Improving Data Collection, Monitoring, and Medical Coding Processes

#123 Track 01A – Clinical Operations

Related Interest Area(s): CR, RD, SP, RA, FI

10:45AM–12:00PM | Level: ■ | Format: SYMPOSIUM

Room 113B | *CME and Nursing*

Global Clinical Trials: Innovative Approaches to Clinical Trials in Japan, India, and Latin America

CHAIRPERSON

Larry A. Blankstein, PhD
Consultant, Clinical Development, Blankstein Consulting Group

SPEAKER(S)

Issues and Solutions When Conducting Complex Caucasian Clinical Studies in Japan
Andrew Melli
Senior Manager, SOUSEIKAI Global Clinical Research Center, Japan

Clinical Trials in India: An Update on Current Status
Charu Gautam, MD
Director, Global Clinical Operations, Cliantha Research Ltd, India

Clinical Research in Latin America: Boosting Innovation Through Policy Measures
Maria João Queiroz, MD
Chief Executive Officer, Eurotrials, Portugal

#124 Track 01B – Clinical Operations

Related Interest Area(s): CR, GCP, QC, CDM, RA

10:45AM–12:00PM | Level: ■ | Format: SYMPOSIUM

Room 113C | *CME, Pharmacy, and Nursing*

Risk-Based Monitoring in Clinical Trials

CHAIRPERSON

Ellen Kelso
Executive Director, Chesapeake IRB

SPEAKER(S)

How to Successfully Plan and Implement a Risk-Based Monitoring Strategy
Francois Torche, MBA
Chief Executive Officer, CluePoints, Belgium

Risk-Based Monitoring: What Does It Mean for Clinical Study Sites?
Jill Collins, MEd, MS
Executive Director, Clinical Innovation, INC Research

The Impact of Risk-Based Monitoring on Site Performance: Reducing Risks While Improving Patient Safety and Study Quality
Robin Douglas, MA
Site Solutions Director, Site and Patient Networks, Quintiles

#125 Track 01C – Clinical Operations

Related Interest Area(s): ROD, PT, CR

10:45AM–12:00PM | Level: ● | Format: SESSION

Room 113A | *CME, Pharmacy, and Nursing*

Patient Recruitment in Rare Diseases: Ideas and Framework for Out-of-the-Box Exploration

CHAIRPERSON

Badri Rengarajan, MD
Medical Affairs Head, ASPIRE Unit, Actelion

SPEAKER(S)

Patient Concierge: Maximizing Patient Engagement in Rare Disease Studies
Donny Chen, MBA
Director, Medical Affairs Research Operations, PPD

Direct-to-Patient Digital Recruitment: A Targeted Approach to Recruitment Enrollment and Retention Problems
Bethany Bray, MBA, MSc
Chief Executive Officer, Co-Founder, AutoCruitment

Bringing Clinical Trials to Patients: Leveraging Convergent Data Sources to Accelerate Recruitment
Scott Douglas Schliebner, MPH
Vice President, Scientific Affairs, Rare Diseases - Federal Programs, PRA Health Sciences

#126 Track 02 – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): ST, CR, RD

10:45AM–12:00PM | Level: ● | Format: WORKSHOP

Room 102AB | *CME, Pharmacy, and Nursing*

Hope Is Not a Strategy: Quantifying Knowledge for Better Decision Making in Clinical Development

CHAIRPERSON

Colleen Russell, MS
Associate Director, Biostatistics, PAREXEL International

Facilitators
Sharon Cornell Murray, PhD
Associate Director, Biostatistics, PAREXEL International

David A. Burt
Director, Biostatistics, Trevena Inc.

#127 Track 03A – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS

10:45AM–12:00PM | Level: ■ | Format: FORUM

Room 112AB | *CME and Nursing*

Innovative Partnerships: gOVERN - A Research and Early Development's Outsourcing Vision to Enable Resourcing INovation

CHAIRPERSON

Hilary Nelson
Senior Clinical Program Leader, Genentech, A Member of the Roche Group

Panelists
Margaret Taylor
Associate Director, Oncology Program Group Leader, Clinical Operations, Genentech, A Member of the Roche Group

Jami Norris
Vice President, Clinical Development Strategic Partnerships, Quintiles

Kerryn Cress, MS
Senior Director, PPD

#128 Track 03B – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, RD

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 111AB | *CME and Nursing*

Alliance Management Forum

CHAIRPERSON
Solomon Babani, MBA
Vice President, BioPharma Solutions, Covance Inc.

SPEAKER(S)

Applying Alliance Management Principles to Help CROs Build Successful Relationships with Small and Emerging BioPharma Companies
Solomon Babani, MBA
Vice President, BioPharma Solutions, Covance Inc.

New and Emerging Skillsets Needed to Manage Strategic Partnerships
Andrew Townshend
Senior Vice President, Alliance Development, INC Research

Panelist
Deirdre F. BeVard
Vice President, Development Operations, Nektar Therapeutics

#129 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MC, MA, SP

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 203AB | *CME, Pharmacy, Nursing, and PMI PDUs*

Delivering Value Through Medical Information Metrics

CHAIRPERSON
Sara Doshi, PharmD
Director, Medical Information Strategy and Capabilities, GMI, Eli Lilly and Company

SPEAKER(S)

Delivering Value Through Medical Information Metrics
Dipti Tankala, PharmD, RPh
Associate Medical Information Manager, Astellas Pharma Canada Inc., Canada

Effective and Efficient Use of Customer Interactions Data to Anticipate Customer Needs Through Text Analytic Metrics
Edward J. Brauer, PharmD
US ML/RML Strategy and Capabilities Fellow, Lilly USA, LLC

Tools for Data Insights in Medical Information
Zachary Furqueron, MBA
Director/Team Leader, Analytics and Reporting Group, External Medical Communications, Pfizer Inc

#130 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): EC, CR, CEHTAEbM

10:45AM–12:00PM | Level: ● | Format: SESSION
Room 201C | *CME, Pharmacy, and Nursing*

Take Two Aspirin and Text Me in the Morning: Technology Suited for 20,000 Virtual Patients on the PCORI Aspirin Trial

CHAIRPERSON
Anthony Costello
Chief Executive Officer, Mytrus, Inc.

SPEAKER(S)

ADAPTABLE: A 20,000 Patient Study Leveraging Health Systems, EHR, and Patients to Transform Clinical Research
Adrian Hernandez
Co-PI, PCORnet Coordinating Center, Professor of Medicine, Duke Clinical Research Institute (DCRI)

Update From REACHnet
Elizabeth Nauman, PhD, MPH
Research Director, Research Action for Health Network (REACHnet), Louisiana Public Health Institute (LPHI)

#131 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): DM, IT, RA

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 204B | *CME and Nursing*

IDMP Update

CHAIRPERSON
Vada A. Perkins, BSN, MSc
Deputy Associate Director for Review Management (Acting), CBER, FDA

SPEAKER(S)

ISO IDMP: Benefits Beyond Compliance
Niels Gronning, MSc
Principal Consultant, NNIT A/S, Denmark

Interoperability and Standardization Within the Life Sciences: Justification, Mechanisms, and Opportunities
Tom Macfarlane, RAC
Director, EU Regulatory Affairs Lead, Accenture, United Kingdom

#132 Track 07C – Technology/Data/Records and Submissions

Related Interest Area(s): SE, EC

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 204C | *CME, Pharmacy, and Nursing*

Electronic Implementation of New PRO Measures to Assess Treatment Benefit in Irritable Bowel Syndrome Trials: Lessons Learned

CHAIRPERSON
Stephen Joel Coons, PhD
Executive Director, PRO Consortium, Critical Path Institute

SPEAKER(S)

Pharmaceutical Industry Perspective
David S. Reasner, PhD
President and Founder, Albemarle Scientific Consulting LLC

ePRO Technology Provider Perspective
Cindy Howry, MS
Vice President, Product Strategy and Innovation; Vice Director, ePRO Consortium, YPrime

ePRO Technology Provider Perspective
Adam Butler
Senior Vice President, Strategic Development and Corporate Marketing, Bracket

FDA Perspective
Sarrit Kovacs
Clinical Outcomes Assessments Reviewer, COA Staff, Office of New Drugs, CDER, FDA

#133 Track 08 – Regulatory Affairs

Related Interest Area(s): RA, RD, CR

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 201B | *CME, Pharmacy, and Nursing*

Take Advantage of Global Expedited Pathways: Breakthrough, Sakigake, PRIME!

CHAIRPERSON
Khyati Roberts, RPh
Senior Director, Regulatory Policy and Intelligence, AbbVie Inc.

SPEAKER(S)

The New Japanese "Sakigake" Strategy for Accelerated Development and Approval: Status, Procedure, and Prospects for Industry
Alberto Grignolo, PhD
Corporate Vice President, PAREXEL International

Strategies for Using the New European PRIME Pathway
Sharon N. Olmstead
Global Head, Development and Regulatory Policy, Novartis Pharmaceuticals Corporation

#134 Track 09A – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 103A | *CME, Pharmacy, and Nursing*

How Can We Utilize Mobile Health for Better Quality of Life and Medical Economy?

CHAIRPERSON
Madoka Murakami
Unit Chief, Division of Regulatory Cooperation, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

SPEAKER(S)

Academic Perspective
Hiroshi Hosoi, MD, PhD
President, Nara Medical University, Japan

Industry Perspective
Nersi Nazari, PhD
Chairman and Chief Executive Officer, Vital Connect Inc.

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

#135 Track 09B – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RD, CR

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 108B | *CME, Pharmacy, and Nursing*

Clinical Developments in Immuno-Oncology, Part 2 of 2: Clinical Implementation of Biomarkers

CHAIRPERSON
Holger G. Adelmann, DrMed, PhD
Senior Vice President and Managing Director, DIA EMEA, Switzerland

Panelists
Juergen Scheuenpflug
Global Head, Clinical Biomarkers and Companion Diagnostics, Merck & Co., Inc., Germany

Arnold B. Gelb, MD, MS
Senior Director, Clinical Biomarkers and Companion Diagnostics, EMD Serono Research & Development Institute, Inc.

Brandon Higgs, PhD
Principal Scientist, MedImmune

Marc Theoret, MD
Medical Officer, Office of Oncology Drug Products, CDER, FDA

#136 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): CR

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 202AB | *CME and Nursing*

Clinical Data Disclosure and Transparency: ClinicalTrials.gov Final Rule, EU Requirements, and Other Key Updates

CHAIRPERSON
Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

Panelists
Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, NCBI, National Library of Medicine, NIH

Marla Jo Brickman, PhD
Senior Director/Team Leader, Clinical Trial Disclosure Group, Pfizer Inc

#137 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): GCP, CR, IT

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 204A | *CME and Nursing*

Using Technology to Make Trials Accessible to More Clinical Trial Participants

CHAIRPERSON

Linda M. Coleman, Esq., JD
Director, Human Research Protection Program, Yale University

SPEAKER(S)

Mobile Clinical Trial Technologies: Use Cases and GCP Compliance Considerations
Philip J. Coran, Esq., JD, MBA
Senior Director of Quality and Regulatory Affairs, Medidata Solutions Worldwide

Mobile Technology in Research: A Compliance and Ethics Review Perspective
Linda M. Coleman, Esq., JD
Director, Human Research Protection Program, Yale University

Mobile Health Applications and eConsent: A Sponsor's Perspective
Kevin Hudziak, MS
Consultant, Innovation Lead, Eli Lilly and Company

#138 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QA/QC, RA

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 109AB | *CME, Pharmacy, and Nursing*

Risk Communication and Management: The Art of Communicating Risk - Challenges and Best Practices

CHAIRPERSON

Kristin Murray, MS
Director, Global CMC Regulatory Affairs, Shire Pharmaceuticals

SPEAKER(S)

Benefit-Risk Considerations and Strategies for Investigation and Control of Impurities
David White
Principle Scientist, AstraZeneca, United Kingdom

Risky Communication: Best Practices for Communicating Product Quality Risks and Uncertainty
Wendy Wilson-Lee, PhD
Chemist, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

Applications of Risk Management Tools to Quality by Design and Control Strategy Creation in Rare Disease
Joseph Kauten
Biologics CMC Control Strategy Leader, Shire Pharmaceuticals

#139 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM, PT

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 105AB | *CME, Pharmacy, and Nursing*

Measuring the Impact and Influence of Patient Input on Regulatory and Health Technology Assessment Decision Making: What Are the Key Considerations?

CHAIRPERSON

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

SPEAKER(S)

FDA Perspective
Theresa M. Mullin, PhD
Director, Office of Strategic Programs, CDER, FDA

Empowering Patients as Organizational Change Agents
Durhane Wong-Rieger, PhD, MA
President and Chief Executive Officer, Canadian Organization For Rare Disorders (CORD), Canada

HTA Perspective
Victoria Thomas, MSc
Head of Public Involvement, Public Involvement Programme, National Institute For Health and Care Excellence (NICE), United Kingdom

#140 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP, RA

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 108A | *CME, Pharmacy, and Nursing*

Understanding, Developing, and Implementing an Anticipated Events Review Process: Adoption of the FDA IND Rule on Safety Reporting Requirements

CHAIRPERSON

Robert (Mac) Gordon, MS
Biostatistician, Janssen Pharmaceutical Companies of Johnson & Johnson

SPEAKER(S)

Using Case Studies to Facilitate Implementation of the FDA Rule for IND Safety Reporting
Marsha Millikan
Advisor, Expedited Reporting Global Patient Safety, Eli Lilly and Company

FDA Perspective
Jonathan P. Jarow, PhD
Director (Acting), Office of Medical Policy, CDER, FDA

One Company's Approach to Developing and Implementing an Anticipated Events Review Process
Robert (Mac) Gordon, MS
Biostatistician, Janssen Pharmaceutical Companies of Johnson & Johnson

#141 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST

10:45AM–12:00PM | Level: ■ | Format: SESSION

Room 201A | *CME and Nursing*

Transforming Health Care Data for Clinical Research: Strategy and Experiences from the PCORnet Common Data Model

CHAIRPERSON

Shelley Rusincovitch

Project Leader in Applied Informatics and Architecture, Duke Translational Research Institute

SPEAKER(S)

Leveraging a Common Data Model for a Pragmatic Clinical Trial in a Distributed Research Network: The PCORnet ADAPTABLE Study
Lesley H. Curtis, PhD
Professor of Medicine; Director, Center for Pragmatic Health Services Research, Duke Clinical Research Institute (DCRI)

A Common Data Model and Diversity of Stakeholder Beliefs: How Do You Know What You Actually Know, Collectively?
Aaron Sorensen, MA
Senior Bibliometrics Consultant, Digital Science

Applying the PCORnet Common Data Model to the EHR Ancillary Study of the HARMONY Trial: Strategy and Design Considerations
Carol E. Koro, PhD
Senior Director, Worldwide Epidemiology, GlaxoSmithKline

#142 Track 16 – Professional Development

Related Interest Area(s): PETD

10:45–11:45AM | Level: ● | Format: SESSION

Room 107AB | *No CE available*

Why We All Need Mentors (and How to Be a Good Mentor to Others)

CHAIRPERSON

David B. Stein

Independent eClinical Consultant, D. Bartley Consulting

SPEAKER(S)

CRA Retention: Insider's Perspectives on Interventions to Anchor a Tenured, Talented Workforce
Nadia Bracken
Clinical Trials Manager, Gilead Sciences, Inc.

#143 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD

10:45AM–12:00PM | Level: ■ | Format: SYMPOSIUM

Room 103C | *CME and Nursing*

Priority Review Vouchers: Past Experiences, Legislative Reform, and Tips for Sponsors

CHAIRPERSON

Andrew S. Robertson, JD, PhD

Director, Global Regulatory Policy, Merck & Co., Inc.

SPEAKER(S)

Priority Review Vouchers: A New Paradigm for Funding Research?
Patricia Rose Anderson, RAC
Vice President, Regulatory Services, MAPI, Canada

The Priority Review Voucher: The Value, the Pipeline, and the Opportunities for R&D
Andrew S. Robertson, JD, PhD
Director, Global Regulatory Policy, Merck & Co., Inc.

Priority Review Vouchers: Legislation and History - What You Need to Know
Alexander Varond, JD
Associate, Hyman, Phelps & McNamara, PC

#144 Track 22 – Engage and Exchange

Related Interest Area(s): GCP

10:45–11:45AM | Level: ■ | Format: WORKSHOP

Exhibit Hall A | *No CE available*

Root Cause Analysis: Getting to 'Why' When Something Goes Wrong in Your Trial

CHAIRPERSON

Keith John Barber

Executive Director, INC Research, United Kingdom

Facilitator
Helen Howitt
Director, Process Quality Management, INC Research, United Kingdom

11:45AM-2:30PM

Luncheon in Exhibit Hall

#145 Track 21: Poster Presentations

12:15-2:15PM

Exhibit Hall A | *No CE Available*

Student Poster Session and Oral Presentations 1A

#146 Track 20 – Innovation Theaters

Related Interest Area(s): IT, DM

12:15–12:45PM | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

Tata Consultancy Services Innovation Theater: Data Transparency Initiative: An Innovative Solution

#147 Track 22 – Engage and Exchange

Related Interest Area(s): CEHTAEbM, ST

12:15–1:15PM | Level: ■ | Format: WORKSHOP
Exhibit Hall A | *No CE available*

Interpreting Meaningful Change on PRO Instruments: Methods in Action

CHAIRPERSON
Cheryl D. Coon, PhD
Principal, Outcometrix

Facilitator
Scott Komo
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

#148 Track 20 – Innovation Theaters

Related Interest Area(s): RA

1:00–1:30PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

PAREXEL Innovation Theater: Balancing Rapid Approval with Demonstration of Value

#149 Track 22 – Engage and Exchange

Related Interest Area(s): PPLC, RA

1:30–2:15PM | Level: ■ | Format: WORKSHOP
Exhibit Hall A | *No CE available*

EMA's Publication Policy 0070: Best Practices for Implementation

CHAIRPERSON
Robert Paarlberg, MS
Principal, Paarlberg & Associates LLC

Facilitator
Helle-Mai Gawrylewski, MA
Senior Director, Medical Writing and Alliance Management, Janssen Research & Development, LLC

#150 Track 20 – Innovation Theaters

Related Interest Area(s): CR, CEHTAEbM

1:45–2:15PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

Quintiles Innovation Theater: Evidence Optimization: Fueling Smarter Clinical Development and Value Generation

#151 Track 23 – Opening Plenary

2:30–4:00PM | Level: ■ | Format: SESSION
Ballroom AB | *No CE available*

Plenary Session and Keynote Address

Opening Remarks
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Gigi Hirsch, MD
Executive Director, Massachusetts Institute of Technology (MIT) Center For Biomedical Innovation

Welcome Remarks
Barbara Lopez Kunz
Global Chief Executive, DIA

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

Tatsuo Kurokawa, PhD
Professor, Div. of Drug Development and Regulatory Sciences, Faculty of Pharmacy, Keio University

Keynote Address: Bad Bugs, Good People, and Big, Bold Ideas
Larry Brilliant, MD, MPH
Chairman, Skoll Global Threats Fund

4:00-6:00PM

Opening Reception in Exhibit Hall

#152 Track 21: Poster Presentations

4:15–5:30PM
Exhibit Hall A | *No CE Available*

Student Poster Session and Oral Presentations 1B

#153 Track 20 – Innovation Theaters

Related Interest Area(s): CR, PT

4:30–5:00PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

BBK Innovation Theater: Reimagining the Patient Experience Through mHealth Technologies

#154 Track 20 – Innovation Theaters

Related Interest Area(s): CP

5:15–5:45PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

Deloitte Innovation Theater: Leveraging Sentinel Data, Methods, and Tools to Support Postmarket Product Safety and Surveillance – Innovation in Medical Evidence Development and Surveillance Program

5:30PM

Student Poster Awards Ceremony
DIA Booth #1425

TUESDAY, JUNE 28

Registration Hours:

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

7:00–8:00AM

Coffee and Light Refreshments
Grand Hall and Room 108 Concourse

#201 Track 19A

DIAmond SESSIONS

Related Interest Area(s): RA

8:00–9:45AM | Level: ■ | Format: FORUM
Room 114 | *CME and Nursing*

International Regulatory Convergence, Collaboration, and Cooperation

CHAIRPERSON
Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

Panelists

Guido Rasi, MD
Executive Director, European Medicines Agency, European Union

Robert M. Califf, MD
Commissioner, FDA

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

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

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

Ian Hudson, MD, FFPM, FRCP
ICMRA Project Lead; Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

John Skerritt, PhD
ICMRA Project Lead; Deputy Secretary for Health products Regulation, Department of Health, Australia

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

#202 Track 19B

DIAmond SESSIONS

Related Interest Area(s): CR

8:00–9:30AM | Level: ■ | Format: FORUM
Room 103ABC | *CME, Pharmacy, and Nursing*

Changing Cultures to Advance Patient Engagement

CHAIRPERSON
Kimberly McCleary
Director of Strategic Initiatives, FasterCures, A Center of the Milken Institute

Panelists

Lode Dewulf, MD, FFPM
Vice President and Chief Patient Affairs Officer, UCB, Belgium

Andrea Stern Ferris
President and Chairman, LUNGevity Foundation

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

Durhane Wong-Rieger, PhD, MA
President and Chief Executive Officer, Canadian Organization For Rare Disorders (CORD), Canada

#203 Track 19C

DIAmond SESSIONS

Related Interest Area(s): RD

8:00–9:30AM | Level: ■ | Format: FORUM
Ballroom A | *CME, Pharmacy, and Nursing*

Next Generation Collaborations: Transforming the Industry

CHAIRPERSON
Dalvir Gill, PhD
Chief Executive Officer, Transcelerate Biopharma Inc.

Panelists

Jonathan P. Jarow, PhD
Director (Acting), Office of Medical Policy, CDER, FDA

C. David Nicholson, PhD
Executive Vice President, Brand R&D, Allergan Inc.

Margaret A. Anderson, MA
Executive Director, FasterCures, A Center of the Milken Institute

9:30–10:30AM

Coffee Break in Exhibit Hall

#204 Track 21: Poster Presentations

9:40–10:20AM
Exhibit Hall A | *No CE Available*

Professional Poster Session and Oral Presentations 1A

#205 Track 22 – Engage and Exchange

Related Interest Area(s): PETD

9:40–10:25AM | Level: ● | Format: WORKSHOP
Exhibit Hall A | *No CE available*

It's Not You; It's Me: Dealing with Team Challenges, Critique, and Criticism

CHAIRPERSON
Robin Whitsell
President, Whitsell Innovations, Inc.

#206 Track 20 – Innovation Theaters

Related Interest Area(s): IT, CR

9:45–10:15AM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

Covance Innovation Theater: Leveraging Patient Data and Historical Investigator Performance Data to Realize Faster Patient Recruitment

#207 Track 01A – Clinical Operations

Related Interest Area(s): CR, EC, RA, GCP, PPLC

10:30–11:30AM | Level: ● | Format: SESSION
Room 108A | *CME, Pharmacy, and Nursing*

Advancing the Appropriate Use of Mobile Clinical Trials: The Clinical Trials Transformation Initiative

CHAIRPERSON
Kristen Miller
Health Scientist Policy Analyst, Office of Medical Policy, CDER, FDA

SPEAKER(S)

Clinical Trials in the 21st Century: If They Could Put a Man on the Moon...
Robert A. DiCicco, PharmD
Vice President, Clinical Pharmacology Sciences and Operations, GlaxoSmithKline

Patient Perspective
Cynthia Geoghegan
Patient Representative, Patients and Partners LLC

#208 Track 01B – Clinical Operations

Related Interest Area(s): CR, PT

10:30–11:45AM | Level: ■ | Format: FORUM
Room 108B | *CME and Nursing*

Measuring Return on Engagement: An Interim Report on the DIA-Tufts CSDD Metrics Study

CHAIRPERSONS
Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts University
Elizabeth Lincoln, MA
Global Director of Engagement, DIA

Panelists
Kathleen A. Foley, PhD
Manager Outcomes Research, Merck & Company
John Manganaro, PharmD, MS
Deputy Director, Regulatory Policy and Intelligence, Bayer HealthCare Pharmaceuticals
Jeffrey W. Sherman, MD, FACP
Chief Medical Officer and Executive Vice President, Research Development and Regulatory, Horizon Pharma, Inc.

#209 Track 02A – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): PM, PETD

10:30–11:45AM | Level: ■ | Format: WORKSHOP
Room 102AB | *CME, Nursing, and PMI PDUs*

The Promotable Project Manager: Leadership Behaviors Critical to Success in the Life Sciences

CHAIRPERSON
Richard J. Heaslip, PhD
Founder, Programmatic Sciences LLC

#210 Track 02B – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): PM, RD, PETD

10:30–11:45AM | Level: ● | Format: SESSION
Room 105AB | *CME, Nursing, and PMI PDUs*

Effective Strategies to Leverage PMO Best Practices for Program and Portfolio Management

CHAIRPERSON
Karen M. Marks
Vice President, Global Program Management Office, Baxter International, Inc.

SPEAKER(S)

What Value Can a Project Management Office Bring to Your Organization?
Kristin Fitzgerald, MBA, PMP
Director, Global Project Management, Project Management Office, Merck & Co., Inc.

Driving Innovation by Expanding the Role of Integrated Project Portfolio: Challenges and Best Practices
Dinesh Singh, MBA
Client Partner, Life Sciences, Cognizant Technology Solutions Corporation, United Kingdom

#211 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RD

10:30–11:45AM | Level: ■ | Format: FORUM
Room 111AB | *CME and Nursing*

Collaboration with a Purpose

CHAIRPERSON
Christine Pierre, RN
President, Society for Clinical Research Sites

Panelists
Rehbar H. Tayyabkhan, MBA, MSc
Executive Director, Global Clinical Operations, Bristol-Myers Squibb Company

Douglas J. Peddicord, PhD
Executive Director, Association of Clinical Research Organizations (ACRO)

#212 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): PC, ST, ROD

10:30–11:45AM | Level: ■ | Format: SYMPOSIUM
Room 113A | *CME, Pharmacy, and Nursing*

Special Populations in Clinical Pharmacology Studies

CHAIRPERSON
William B. Smith, MD
President, New Orleans Center for Clinical Research

SPEAKER(S)

Special Populations in Clinical Pharmacology Studies: Evolving Challenges
William B. Smith, MD
President, New Orleans Center for Clinical Research

Investigational Product and Drug-Drug Interactions in Specialty Populations with Comorbidities: Options in Addressing Safety, Data, Timelines, and Costs
Harry W. Alcorn, Jr., PharmD
Chief Scientific Officer, DaVita Clinical Research

Fast to Patient: Shifting from Healthy Volunteer to Patient Population
Richard Scheyer, MD
Vice President, Medical Affairs, Medpace

QTcF in Special Populations
Robert Kleinman, MD
Chief Medical Officer and Vice President, Global Cardiology, ERT

#213 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

Related Interest Area(s): AP, RA, MA, PPLC

10:30–11:30AM | Level: ● | Format: FORUM
Room 107AB | *CME, Pharmacy, and Nursing*

FDA Enforcement Update: Advertising and Promotion

CHAIRPERSON
Philomena McArthur, JD
Senior Director, Regulatory Advertising and Promotion and Healthcare Compliance, Johnson & Johnson International

SPEAKER(S)

CDER Perspective
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, OMP, CDER, FDA

CBER Perspective
Lisa L. Stockbridge, PhD
Branch Chief, Advertising and Promotional Labeling Branch, OCBQ, CBER, FDA

#214 Track 06A – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MC, MW

10:30–11:45AM | Level: ■ | Format: SESSION
Room 203AB | *CME and Nursing*

Product Management Strategies: Maximizing Content Re-Use to Meet Diverse Customer Information Needs

CHAIRPERSON
Frank Hubbard, PhD
President, Global Regulatory Writing Solutions, Inc.

SPEAKER(S)

An Overview of Content Re-use and Product Information Management Strategies: What's In It for Me?
Frank Hubbard, PhD
President, Global Regulatory Writing Solutions, Inc.

Content Management and Re-Use: Efficient Streamlining of Product Information Content and Life Cycle
Susan Bairnsfather, MSc
Chief Executive Officer, Regulatory Writer, Regulatory Affairs Professional and Statistical Analyst, EPharmaTech LLC

Developing a Strategy for Content Transformation
Cecil Lee, RPh
Knowledge Management Consultant, Global Medical Information, Eli Lilly and Company

#215 Track 06B – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MSL, MC

10:30–11:30AM | Level: ■ | Format: SESSION
Room 202AB | *CME, Pharmacy, and Nursing*

Exploring the Use of Virtual Technologies Within Medical Affairs Organizations

CHAIRPERSON
J. Lynn Bass, PharmD, RPh
Director, Medical Affairs, Jazz Pharmaceuticals

SPEAKER(S)

Experience of Leveraging External Virtual Teams to Expand the Capabilities of a Newly Formed Medical Affairs Organization
Rachel Couchenour, PharmD, MBA
Senior Director, Medical Affairs, Oxigene, Inc.

Meeting Thought Leader Needs with Technology
Craig J. Klinger, RPh
Consultant, Field Medical Liaison Strategy and Capabilities - Trainer, Lilly USA, LLC

#216 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, RA, IT, ST

10:30–11:45AM | Level: ■ | Format: SESSION
Room 204C | *CME and Nursing*

Implementing a Successful Metadata Repository: The Journey of a Thousand Milestones Begins with a Single Step

CHAIRPERSON
David Handelsman
Senior Director, Industry Strategy, d-Wise

SPEAKER(S)

Semantic Metadata Repository at the Core of E2E eClinical Solutions
Isabelle M. de Zegher, MD, MSc
Vice President, PAREXEL Informatics, Belgium

Implementing a Metadata Repository Based on Value and Not Technology
David Handelsman
Senior Director, Industry Strategy, d-Wise

Metadata Repositories: From the Outside In
Wayne R. Kubick, MBA
Chief Technology Officer, HL7

#217 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): SUBS, CDM, IT, RA

10:30–11:45AM | Level: ■ | Format: FORUM
Room 201C | *CME and Nursing*

Electronic Submissions Gateway: Next Generation

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

SPEAKER(S)

FDA eCTD v4.0 Two-Way Communication
Mark A. Gray
Senior Project Manager, BSS, CBER, FDA

Panelists
Virginia Hussong
Director, Division of Data Management Services & Solutions, OBI, Office of Strategic Programs, CDER, FDA

La Misha Fields
IT Program Manager, Electronic Submissions Gateway, Office of Information Management Technology, Office of the Commissioner, FDA

#218 Track 08A – Regulatory Affairs

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

10:30–11:30AM | Level: ■ | Format: FORUM
Room 201B | *CME, Pharmacy, and Nursing*

Lessons Learned from Eight Years of Drug Development Tool/Novel Methodology Qualification

CHAIRPERSON
Martha Ann Brumfield, PhD
President and Chief Executive Officer, Critical Path Institute

SPEAKER(S)

EMA Perspective
Sabine Haubenreisser, PhD, MSc
Liaison to the US FDA, European Medicines Agency, European Union

FDA Perspective
ShaAvhree Y. Buckman-Garner, MD, PhD
Director, Office of Translational Sciences, CDER, FDA

#219 Track 08B – Regulatory Affairs

Related Interest Area(s): BT, CEHTAEbM, RA, RD

10:30–11:45AM | Level: ◆ | Format: SESSION
Room 204B | *CME, Pharmacy, and Nursing*

Regulatory Science Considerations Applying to Novel Combinations of Biologics and Bifunctional Biologics Development

CHAIRPERSON
Owen Fields, PhD
Vice President, Inflammatory and Immunology, WW Safety and Regulatory, Pfizer Inc

SPEAKER(S)

Unique Challenges in the Regulation of Bispecific Antibodies
Raj G. Nair, MD, PhD
Medical Officer, DPARP, Office of New Drugs, CDER, FDA

Unique Preclinical and Clinical Aspects of Bifunctional Development
Rakesh Dixit, PhD
Vice President, R&D, Global Head, Biologics Safety Assessment, MedImmune

Q and A Panel
Badrul Chowdhury, MD, PhD
Director, Division of Pulmonary, Allergy, and Rheumatology Products, Office of New Drugs, CDER, FDA

#220 Track 08C – Regulatory Affairs

Related Interest Area(s): RA

10:30–11:30AM | Level: ■ | Format: SESSION
Room 109AB | *CME and Nursing*

Regulatory Changes in China and the Impact to Global Drug Development Planning

CHAIRPERSON
Dan Zhang, MD, MBA, MPH
Chairman and Chief Executive Officer, Fountain Medical Development Ltd. (FMD), China

SPEAKER(S)

Innovative Biopharmaceutical Drug Development in China: Trends and Transformations
Helena Zhang, MD, MBA
Senior Director and Chief Medical Officer, Quintiles, China

Regulatory Changes in China
Feng Yi
Former Assistant to the Director-General, CFDA; Senior Vice President, Medical and Regulatory Affairs, Fountain (Beijing) Medical Technology Development Co., Ltd., China

#221 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RA

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

Room 103A | *CME, Pharmacy, and Nursing*

Envision the Future: How Big Data and Artificial Intelligence Change Our Regulatory Environment

CHAIRPERSON

Joseph C. Scheeren, PharmD
Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care AG, Switzerland

SPEAKER(S)

Current Status of Big Data Use in the Health Care Sector: View from the Market
Luke D. Dunlap, MSc
Senior Principal, Real World Evidence Solutions, IMS Health

Big Data Being Part of FDA eHealth Policy: Viewpoint of the Regulator
Robert M. Califf, MD
Commissioner, FDA

Challenges of Big Data in the Regulatory Environment from the Legal Point of View
Denise Esposito
Partner, Covington & Burling LLP

#222 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR, PT

10:30–11:30AM | Level: ■ | Format: FORUM

Room 204A | *CME, Pharmacy, and Nursing*

Valuing the Clinical Trial Patient

CHAIRPERSON

Jane Perlmutter, PhD, MBA
Founder and President, Gemini Group

SPEAKER(S)

Bioethical Considerations with the Return of Individual Research Results and Incidental Findings to Clinical Trial Research Participants
Sandra Prucka, MS
Consultant Scientist, Tailored Therapeutics-Oncology, Eli Lilly and Company

Panelist
Deborah Howe
Associate Director, TA Lead, Specialty and Vendor Alliance Lead, Bristol-Myers Squibb Company

#223 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

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

Room 112AB | *CME, Pharmacy, and Nursing*

Global Harmonization: Current ICH Quality Initiatives

CHAIRPERSON

Moheb M. Nasr, PhD, MS
Vice President, CMC Regulatory Strategy, GlaxoSmithKline

SPEAKER(S)

A Holistic Approach for Global Management of Manufacturing Changes
Romuald Braun, MSc
Managing Director, uanotau GmbH, Switzerland

ICH Q11 IWG Update
Timothy J.N. Watson, PhD
Research Fellow, GCMC Advisory Office, Pfizer Inc

What Is Needed to Make ICH Q12 a True Transformational Guideline?
Roger Nosal, MA, MS
Vice President and Head, Global CMC, Pfizer Inc

#224 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): SE, CR

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

Room 201A | *CME, Pharmacy, and Nursing*

Identifying Patient-Centered Outcomes for Use in Observational Research: Why and How

CHAIRPERSON

Michelle Leavy, MPH
Director, Scientific Relations, Better Outcomes

Panelist
Elise Berliner, PhD
Director, Technology Assessment Program, Agency For Healthcare Research and Quality (AHRQ)

#225 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

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

Room 113B | *CME, Pharmacy, and Nursing*

One Size Does Not Fit All: Best Practices for Right-Sized Signal Management Systems

CHAIRPERSON

Deirdre McCarthy, MS
Senior Benefit Risk Management Director, Quintiles

SPEAKER(S)

What Is the Utility of GIS Technology in the Postmarket Setting?
Henry "Skip" Francis, MD
Director for Data Mining and Informatics Evaluation and Research, Office of Translational Sciences, CDER, FDA

Practical Tools for Signal Management: How Do You Overcome Challenges and Meet the Regulatory Needs of Pharmacovigilance?
Shelley Gandhi, MS
Strategic Advisor, Pharmacovigilance & Drug Safety, NDA Group, United Kingdom

Global Signal Detection with Regional Relevance: Development and Field Testing of Surveillance Strategies for the Emerging Indian Market
Ola Caster, PhD
Senior Researcher, Uppsala Monitoring Centre, Sweden

#226 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

10:30–11:45AM | Level: ■ | Format: FORUM
Room 113C
CME and Nursing

The Global Conundrum: Herding Cats - Identifying Risk Across Pharmacovigilance Networks and Seeking Simplicity in Multi-Country Pharmacovigilance Activities

CHAIRPERSON

Hershell William Thompson, MBA, MSc
Managing Consultant, Navitas Life Sciences, Inc.

SPEAKER(S)

Managing a PV Affiliates Network: The Challenges and Considerations in Maintaining Oversight and In-Country Connections
Lesia Tontisakis, BSN
Director, Pharmacovigilance, Global Patient Safety and Epidemiology, Allergan

A Global Conundrum: Seeking Simplicity in Multi-Country Pharmacovigilance Activities
Marco Anelli
Head of Pharmacovigilance and Medical Affairs Advisory Services, Productlife Group, Italy

#227 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD, RA

10:30–11:30AM | Level: ■ | Format: SESSION
Room 103C
CME, Pharmacy, and Nursing

Unique Global Regulatory Considerations and Drug Development Incentives in Rare Disease and Orphan Drug Development

CHAIRPERSON

Maureen Smith
Patient Advocate / Secretary, Canadian Organization For Rare Disorders (CORD), Canada

SPEAKER(S)

Maximizing the Advantages of US and EU Orphan Drug Designation Incentives
Irene Pan, MSc
Senior Research Scientist, UBC: An Express Scripts Company, Canada

Global Regulatory Considerations in Rare Disease and Orphan Drug Development: When Patients Are Waiting and Everyday Counts
Lauren Peterson Tornetta, MBA, MS
Director, Global Regulatory Affairs, Pfizer Inc

#228 Track 22 – Engage and Exchange

Related Interest Area(s): CR

10:45–11:45AM | Level: ■ | Format: WORKSHOP
Exhibit Hall A
No CE available

Increase Value of Clinical Trials Through Impactful Branding

CHAIRPERSON

Neil Weisman
Executive Vice President and General Manager, Continuum Clinical

Facilitators
Robert Klein
Chief Strategy Officer, Continuum Clinical

Marie Eckerd
Global Feasibility and Recruitment Partner, AstraZeneca Pharmaceuticals LP

11:30AM–2:00PM

Luncheon in Exhibit Hall

#229 Track 21: Poster Presentations

12:00–1:45PM
Exhibit Hall A
No CE Available

Professional Poster Session and Oral Presentations 1B

#230 Track 20 – Innovation Theaters

Related Interest Area(s): CR, PT

12:00–12:30PM | Level: ■ | Format: SESSION
Exhibit Hall B
No CE available

Quintiles Innovation Theater: Transforming Patient Recruitment Through Site and Patient Engagement

#231 Track 22 – Engage and Exchange

Related Interest Area(s): MW, SUBS

12:00–1:00PM | Level: ● | Format: WORKSHOP
Exhibit Hall A
No CE available

Introduction to Structured Content

CHAIRPERSON

Ann Rockley, MLIS
Chief Executive Officer, The Rockley Group Inc., Canada

12:00–1:00PM

DIA Community Meet & Eat
Exhibit Hall A

12:00–1:45PM

Innovation Row Tour
Room 104A

#232 Track 20 – Innovation Theaters

Related Interest Area(s): IT

12:40–1:10PM | Level: ■ | Format: SESSION
Exhibit Hall B
No CE available

PRA Innovation Theater: Transforming EMR to EDC

#233 Track 20 – Innovation Theaters

Related Interest Area(s): RA

1:20–1:50pm | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

Veeva Innovation Theater: The Great RIM Throwdown! How Are You Managing Regulatory Events?

#234 Track 01A – Clinical Operations

Related Interest Area(s): CR

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

Room 109AB | *CME and Nursing*

TransCelerate's Risk-Based Monitoring: Sharing What We Are Learning

CHAIRPERSON

Brett Wilson
Head, Monitoring Excellence, Bristol-Myers Squibb Company, Canada

SPEAKER(S)

TransCelerate RBM Successful Practices and Lessons Learned
Joanne Benedict, MSc
Senior Advisor, Genentech, A Member of the Roche Group

TransCelerate's Approach to Understanding and Managing Site and Other Stakeholder Expectations, Wants, and Needs
Kate Owen
Vice President, Clinical Trial Management, Novo Nordisk Inc.

Site Representative
Allison Camacho
Research Manager, Dallas Diabetes and Endocrine Center

Searching for a Technology Solution to Support Risk-Based Monitoring
Mary Cusack, MBA, MS
Associate Director, eClinical Operations, Global Data Strategies and Solutions, Bristol-Myers Squibb Company

#235 Track 01B – Clinical Operations

Related Interest Area(s): CS, CR, RD

2:00–3:00pm | Level: ● | Format: SESSION

Room 113A | *CME and Nursing*

Global Clinical Supply Logistics Study

CHAIRPERSON

Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts University

SPEAKER(S)

Distribution Networks and Strategies
Eric A. Valentine, MBA
Global Director, Clinical Distribution Services, Catalent Pharma Solutions

Cycle Time Metrics and Impact on Study Conduct
Cheryl D. Mahon, PharmD
Director, Clinical Pharmacy, Astellas Pharma US, Inc.

#236 Track 02 – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): PT, PPLC, RA, AP, ROD

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

Room 108B | *CME, Pharmacy, and Nursing*

Expanded Access: Ethical, Regulatory, and Policy Challenges and Considerations

CHAIRPERSON

Kim M. Quaintance-Lunn
Head, US Regulatory Policy, Bayer HealthCare Pharmaceuticals

SPEAKER(S)

Is There a Better Way? An Industry Perspective
Sandra A. Morris, PhD, PMP
Vice President, Strategy Realization, Johnson & Johnson

The Ethics of Compassionate Use
Alison Bateman-House, PhD, MA, MPH
Rudin Postdoctoral Fellow, Division of Medical Ethics, New York University Langone Medical Center

#237 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): RA, PM, SP, FI, PETD

2:00–3:00pm | Level: ■ | Format: SESSION

Room 112AB | *CME, Nursing, and PMI PDUs*

Acquisitions and Mergers: When Companies' Regulatory Operations Systems and Processes Converge

CHAIRPERSON

Sarah Powell, RAC
President, Powell Regulatory Services

SPEAKER(S)

Challenges and Business Impact Associated with Mergers and Acquisitions
Meredith K. Sewell
Director, Global Regulatory Publishing, Allergan

Building a Regulatory Information Management Capability for the Next Decade: People, Process, and Technology - Case Study
Dominique E. Lagrave, PharmD, MSc
Director GRAAS Operations, Global Regulatory Writing, Amgen Inc.

#238 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

Related Interest Area(s): AP, RA, MA, PPLC

2:00–3:15pm | Level: ● | Format: SESSION

Room 107AB | *CME, Pharmacy, and Nursing*

Prescription Drug Marketing Regulatory Primer

CHAIRPERSON

Lucy Rose, MBA
President, Lucy Rose and Associates, LLC

SPEAKER(S)

FDA Perspective
Thomas W. Abrams, MBA, RPh
Director, Office of Prescription Drug Promotion, Office of Medical Policy, CDER, FDA

#239 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): IT, EC, SE, VA

2:00–3:15pm | Level: ■ | Format: SYMPOSIUM
Room 201C | *CME and Nursing*

Cloud Compliance: Clinical Software Challenges and Vendor Auditor Views

CHAIRPERSON

Teri Stokes, PhD, MS, MT
Director, Quality Assurance Compliance, Cytel Inc.

SPEAKER(S)

Software as a Service (SaaS) and Cloud Provider Qualification: An Auditor's Perspective
Calvin H. Kim, MS
Senior GxP IT Auditor, Bayer HealthCare Pharmaceuticals

Maintaining the Validation Status of Software as a Service (SaaS) in a Regulated Environment
Anu Virkar, MA, MS, PMP
Vice President, Quality and Compliance, Merge eClinical

Are You Cloud Compliant? Practical Considerations for Managing Clinical Data in the Cloud
Srinivas Karri, MSc
Director, Clinical Warehousing Cloud Strategy, Oracle Corporation, United Kingdom

#240 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CR, CDM

2:00–3:15pm | Level: ● | Format: SESSION
Room 204B | *CME and Nursing*

CFAST at Year Three: Innovative Approaches to Adding Breadth, Depth, and Value to Therapeutic Area Standards

CHAIRPERSON

Rhonda Facile, MS
Vice President, Standards and Development, CDISC

SPEAKER(S)

CFAST Program Participation and the FDA Specification Project
Ron D. Fitzmartin, PhD, MBA
Senior Advisor, Office of Strategic Programs, CDER, FDA

ADaM and Therapeutic Area User Guides: Current Thinking
Susan J. Kenny, PhD
President, Maximum Likelihood, Inc.

Biomedical Concepts and End-to-End Metadata Development
Diane E. Wold, PhD
Director, Concept Modeling, CDISC

#241 Track 08 – Regulatory Affairs

Related Interest Area(s): RA, RD, PPLC

2:00–3:15pm | Level: ■ | Format: FORUM
Room 201B | *CME, Pharmacy, and Nursing*

Disease Interception: Shifting the Paradigm from Treatment to Prevention of Disease

CHAIRPERSON

Karin Van Baelen, PharmD
Head, Global Regulatory Affairs, Janssen Pharmaceutical Companies of Johnson & Johnson, Belgium

SPEAKER(S)

FDA Perspective
Ellis Unger, MD
Director, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

EU Perspective
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Payer Perspective
Sean R. Tunis, MD, MSc
Founder and Chief Executive Officer, Center For Medical Technology Policy (CMPT)

#242 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): RA

2:00–3:15pm | Level: ■ | Format: SESSION
Room 108A | *CME, Pharmacy, and Nursing*

Regulatory Challenges in the Development of Combination Products Involving Digital Technology

CHAIRPERSON

Todd Paporello, PharmD, MBA
Vice President and Head of North American Regulatory Affairs, Bayer HealthCare Pharmaceuticals

SPEAKER(S)

Determining the Regulatory Classification of Software Used in Tandem with Pharmaceuticals
Bradley Merrill Thompson, JD, MBA
General Counsel, Combination Products Coalition, Epstein, Becker and Green P.C.

Tool to Product: An Interactive Case Study in the Evolution of a Pharma App from Clinic to Commercial
Anthony D. Watson, MBA, MS
Associate Vice President, Regulatory Affairs - Devices, Sanofi US

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

#243 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PT

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

Room 204C | *CME, Pharmacy, and Nursing*

Patient Involvement Today and Tomorrow: What's in It for Patients?

CHAIRPERSON

Marc M. Boutin, JD
Chief Executive Officer, National Health Council (NHC)

Panelists

Lode Dewulf, MD, FFPM
Vice President and Chief Patient Affairs Officer, UCB, Belgium

Theresa M. Mullin, PhD
Director, Office of Strategic Programs, CDER, FDA

Anton Hoos, MD, PhD, MBA
Head of Medical Affairs, Amgen GmbH, Switzerland

Bettina Ryll
Founder, Melanoma Patient Network Europe, Sweden

Isabelle Moulon, MD
Head of Patients and Healthcare Professionals Department, European Medicines Agency, European Union

#244 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): GCP

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

Room 204A | *CME and Nursing*

Transforming Clinical Development Through Enterprise Quality Management

CHAIRPERSON

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

SPEAKER(S)

Executive Leadership Position on Quality
John Hubbard, PhD
President and Chief Executive Officer, BioClinica

Establishing a Quality Management System During Accelerated Growth of a Lean Operation
Coleen Glessner, MBA
Vice President, R&D Quality and Compliance, Alexion

Research and Development QA Comprehensive Quality Strategy: An Approach to Ensuring Quality and Managing Quality Risks Across the Drug Life Cycle
Kevin Grebner
Director, Clinical Quality Assurance, AbbVie Inc.

#245 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QA/QC

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

Room 111AB | *CME and Nursing*

Risk-Based Inspections

CHAIRPERSON

Mahesh R. Ramanadham, PharmD, MBA
Division Director (Acting), Division of Inspectional Assessment, OPF, Office of Pharmaceutical Quality, CDER, FDA

SPEAKER(S)

Quality Agreements: Defining the Business of Pharmaceutical Quality
Karen Bossert, PhD, RPh
Vice President, Scientific Affairs, Lyophilization Technology, Inc.

Integrated Quality Assessment of the Manufacturing Process and Facilities
Robert Iser, MS
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER, FDA

#246 Track 13A – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM

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

Room 103A | *CME, Pharmacy, and Nursing*

Valuing the Signal and the Noise in Health Care Horizon Scanning

CHAIRPERSON

Christian Cuevas, PhD
Senior Clinical Analyst, Health Technology Assessment Group, ECRI Institute

SPEAKER(S)

Horizon Scanning Systems: An Example from England
Derek J. Ward, MD, MPH
Co-Director, NIHR Horizon Scanning Research & Intelligence Centre, United Kingdom

Panelists

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

Christian Cuevas, PhD
Senior Clinical Analyst, Health Technology Assessment Group, ECRI Institute

#247 Track 13B – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): SE

2:00–3:15pm | Level: ● | Format: SESSION

Room 105AB | *CME, Pharmacy, and Nursing*

Fit for Purpose and Modern Validity Theory in PROs

CHAIRPERSON

R.J. Wirth, PhD
President and Managing Partner, Vector Psychometric Group, LLC

SPEAKER(S)

Current Thinking in Validity Theory
Jonathan D. Rubright, PhD, MSc
Psychometrician, National Board of Medical Examiners

Validity: US Regulatory Considerations
Ashley F. Slagle, PhD, MS
Scientific and Regulatory Consultant, Aspen Consulting, LLC

How Does Fit for Purpose Fit in Validity Theory?
Michael Edwards, PhD, MA
Managing Partner, Vector Psychometric Group, LLC

#248 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

2:00–3:15pm | Level: ● | Format: FORUM
Room 113C | *CME, Pharmacy, and Nursing*

Mind the Gaps: The Science of Designing, Implementing, and Evaluating Benefit-Risk Communication for Medicinal Products

CHAIRPERSON

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

SPEAKER(S)

Communicating Risk Information to Patients: Gaps in Current Approaches and How Health Literacy and Information Orientation Measures Can Improve Effectiveness
Kristina Birnbrauer, PhD
Senior Project Manager, UBC: An Express Scripts Company

Gaps and Best Practices in Designing Risk Minimization Communication Campaigns
Elaine H. Morrato, DrPH, MPH
Associate Dean for Public Health Practice, Colorado School of Public Health

#249 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

2:00–3:15pm | Level: ■ | Format: SESSION
Room 113B | *CME and Nursing*

Current Topics for Pharmacovigilance in Japan

CHAIRPERSON

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

SPEAKER(S)

Observational Studies in Japan and Asia
Stewart Geary, MD
Senior Vice President, Chief Medical Officer, Eisai Co., Ltd., Japan

Relief Services in Occurrence of Serious Adverse Drug Reactions
Naohiro Otaki, PhD, MS
Technical Officer, Application Review Division I, Office of Relief Funds, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Root Cause Analysis of and Solutions for Under Reporting Safety Information of ICSRs in Clinical Research and Sales Activities
Teiki Iwaoka, PhD, MS
Executive Consultant, Director of Drug Safety Outsourcing Planning, CAC Croit Corporation, Japan

#250 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, CR

2:00–3:15pm | Level: ■ | Format: FORUM
Room 201A | *CME, Pharmacy, and Nursing*

Open-Label, Long-Term Extension Studies: Study Designs and Ethics

CHAIRPERSON

Lisa A. Kammerman, PhD, MS
Senior Statistical Science Director, AstraZeneca

SPEAKER(S)

Delayed-Start Study Design and Analyses for Demonstrating Disease Modification
Scott Andersen, MS
Principal Research Scientist, Eli Lilly and Company

Bioethics of Open-Label Extension Studies
Robert M. Nelson, MD, PhD
Deputy Director and Senior Pediatric Ethicist, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

When, if Ever, Open-Label Extension Studies Are Needed and Appropriate (and What Are the Alternatives)?
Jesse Aaron Berlin, DrSc, MSc
Vice President and Global Head of Epidemiology, Johnson & Johnson

#251 Track 16 – Professional Development

Related Interest Area(s): PETD

2:00–3:15pm | Level: ◆ | Format: WORKSHOP
Room 102AB | *CME and Nursing*

Embracing Virtual Training Solutions in 2016: Focus on Performance!

CHAIRPERSON

Liz Wool, BSN
Global Head of Training, Barnett International

Facilitator
Jim Bohlen
Vice President, Business Development, Blue Sky Broadcast

#252 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD, RA

2:00–3:00pm | Level: ● | Format: SESSION
Room 103C | *CME, Pharmacy, and Nursing*

Capturing Real-World Data in Rare Diseases

CHAIRPERSON

Badri Rengarajan, MD
Medical Affairs Head, ASPIRE Unit, Actelion

SPEAKER(S)

Unique Paradigms to Rare Diseases Research
Donny Chen, MBA
Director, Medical Affairs Research Operations, PPD

Real-World Evidence and Rare Diseases
Derenda Nichols
Senior Director, Clinical Trial Management, Medpace

#253 Track 18A – Global Regulatory

Related Interest Area(s): RA

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

Room 202AB | *CME, Pharmacy, and Nursing*

Update from Health Canada

CHAIRPERSON

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

Panelist
Jeffrey Skene
Division Chief, Monoclonal Antibodies, Health Canada

#254 Track 18B – Global Regulatory

Related Interest Area(s): RA

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

Room 203AB | *CME, Pharmacy, and Nursing*

CBER Town Hall: State of the Center and Plans for the Future

CHAIRPERSON

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

Panelists
Zuben Sauna, PhD
Research Biologist, Office of Blood Research and Review, CBER, FDA

Victor Lu, PhD
Biologist, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

Sara Gagneten, PhD
Associate Division Director, Policy, Office of Vaccines Research and Review, CBER, FDA

Richard Forshee, PhD
Associate Director for Research, Office of Biostatistics and Epidemiology, CBER, FDA

#255 Track 22 – Engage and Exchange

Related Interest Area(s): MW, MC

2:00–3:00PM | Level: ● | Format: WORKSHOP

Exhibit Hall A | *No CE available*

Lost in Translation: The Importance of Data Presentation

CHAIRPERSON

Barry Drees, PhD
Senior Partner, Trilogy Writing & Consulting GmbH, Germany

3:00–4:00PM

Refreshment Break in Exhibit Hall

#256 Track 20 – Innovation Theaters

Related Interest Area(s): SUBS

3:25–3:55PM | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

Veeva Innovation Theater: 2016 Paperless TMF Survey: Trends and Insights

#257 Track 01 – Clinical Operations

Related Interest Area(s): CR, EC, IT, VA

4:00–5:15PM | Level: ■ | Format: SESSION

Room 113A | *CME, Pharmacy, and Nursing*

Mobile Apps for Clinical Trials: DIY or AMAZON Strategy? When to Build, When to Buy

CHAIRPERSON

Jane E. Myles, MS
Head, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

SPEAKER(S)

Implementing Mobile Technology from the Site Perspective
James Kremidas
Executive Director, Association of Clinical Research Professionals (ACRP)

Build, Inspire, or Spin Off: Case Studies on Tech Develoment in Clinical Research
Joseph Kim, MA, MBA
Senior Advisor, Clinical Innovation, Eli Lilly and Company

International Case Studies and Regulatory Experience
Jeffrey Lee, MBA
Chief Executive Officer, mProve Health

#259 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, RA, SP

4:00–5:15PM | Level: ■ | Format: SESSION

Room 112AB | *CME and Nursing*

Innovative Regulatory Solutions: Utilizing Flexible Outsourcing Strategies

CHAIRPERSON

Andrew Verderame, MBA, RAC
President, Pharmalex US, LLC

SPEAKER(S)

Regulatory Outsourcing: Consultant Perspective
Andrew Verderame, MBA, RAC
President, Pharmalex US, LLC

Regulatory Outsourcing: Industry Perspective
Dietmar Boecker, PhD
Vice President, Head Regulatory Affairs - Established Products and International Development, Bayer Pharma AG, Germany

Outsourcing Life Cycle Management: A Model of Efficiency
Alistair Davidson
Senior Director, Delivery Solutions, Regulatory Affairs, PPD, United Kingdom

#260 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): CP, PC, CR, RD

4:00–5:15pm | Level: ■ | Format: SYMPOSIUM
Room 113C | *CME, Pharmacy, and Nursing*

A Risk-Benefit Approach to Planning Early Clinical Development

CHAIRPERSON

Howard Greenberg, MD
Medical Safety Officer, Janssen Pharmaceuticals, Inc.

SPEAKER(S)

Structured Risk Assessment and Risk Mitigation in First-in-Human Studies
Thijs Van Iersel, MD
Senior Director of Science, Early Development Services, PRA Health Sciences, Netherlands

Dose Finding for Cell and Gene Therapies: Is Safety the Main Driver?
Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

Site Training as a Critical Key to Safety
Donna W. Dorozinsky, MSN, RN
President, Just In Time GCP

#261 Track 05 – Regulation of Product Advertising and Marketing in an Ever-Changing World

Related Interest Area(s): AP, RA, MA, PPLC

4:00–5:15pm | Level: ■ | Format: SESSION
Room 107AB | *CME, Pharmacy, and Nursing*

Marketing After Amarin and Pacira

CHAIRPERSON

John Kamp, JD, PhD
Executive Director, Coalition For Healthcare Communication

SPEAKER(S)

Life After Amarin and Pacira: Understanding Off-Label Promotion in 2016
Alexander Varond, JD
Associate, Hyman, Phelps & McNamara, PC

Panelists
Jeffrey K. Francer, JD, MPA
Vice President and Senior Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)

Kellie B. Combs, JD
Counsel, Ropes & Gray LLP

#262 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MC, PT

4:00–5:00pm | Level: ■ | Format: SESSION
Room 201A | *CME, Pharmacy, and Nursing*

Solving Challenges and Employing Best Practices in Medical Information Contact Centers

CHAIRPERSON

Chris O'Shaughnessy
Vice President, Sales, C3i Healthcare Connections

SPEAKER(S)

Industry Point of View
Dominick L. Albano, PharmD, MBA
Vice President, Global Medical Information, Pfizer Inc

Industry Point of View
Elke M. Blaetz, MS, RPh
Regional Medical Information Lead, North America, Shire PLC

#263 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): PT, CR

4:00–5:15pm | Level: ■ | Format: SESSION
Room 201B | *CME, Pharmacy, and Nursing*

Patient Centricity in Clinical Trials

CHAIRPERSON

Doug Bain
Co-Chief Executive Officer / Chief Technology Officer, eClinicalHealth Ltd., United Kingdom

SPEAKER(S)

Applying Process Management to Support Site and Patient Engagement in Clinical Trials
Doug Bain
Co-Chief Executive Officer / Chief Technology Officer, eClinicalHealth Ltd, United Kingdom

Enhancing Patient-Centered Research: Combining Technology with Other Direct-to-Patient Contact Strategies
Chris Watson, PhD
Director of Product Strategy, Exco InTouch, United Kingdom

Patient-Centricity and Real-Time Data Monitoring
Bruno Gagnon, MPharm
Executive Consultant, Clinical Operations, Myokardia, Inc.

#264 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): SUBS, CDM, IT, RA, EC

4:00–5:15pm | Level: ■ | Format: SESSION
Room 204B | *CME, Pharmacy, and Nursing*

FDA Update on Data Standards

CHAIRPERSON

Mary Ann Slack
Deputy Director, Office of Strategic Programs, CDER, FDA

SPEAKER(S)

OCP Update
Eileen E. Navarro Almario, MD, MS, FACP
Lead Medical Officer, Office of Computational Sciences, Office of Translational Sciences, CDER, FDA

CDER Perspective
Colleen Ratliffe, MS, PMP
Project Management Officer, Office of Strategic Programs, CDER, FDA

FDA Update
Stephen E. Wilson, DrPH
Director, Division of Biometrics III, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

#265 Track 07C – Technology/Data/Records and Submissions

Related Interest Area(s): SE, EC, CR, CDM

4:00–5:15PM | Level: ■ | Format: SESSION
Room 203AB | *CME, Pharmacy, and Nursing*

Enabling Innovative New Endpoint Measurement Using Mobile Technology

CHAIRPERSON
Bill Byrom, PhD
Senior Director, Product Innovation, ICON plc, United Kingdom

SPEAKER(S)

Leveraging Smartphone Sensors and Apple Research Kit to Measure Health Outcomes
Bill Byrom, PhD
Senior Director, Product Innovation, ICON plc, United Kingdom

Mobile Face Analysis for Mental and Developmental Health Screening
Guillermo Sapiro, DrSc
School Professor, Electrical and Computer Engineering, Duke University

Bringing Active Tests and Passive Monitoring for Parkinson's Disease Into an Interventional Clinical Trial: Towards Measuring Health Outcomes Using Smartphones
Christian Gossens, PhD
Global Head, Early Development Workflows, F. Hoffmann-La Roche Ltd, Switzerland

#266 Track 08 – Regulatory Affairs

Related Interest Area(s): PT, RA, ROD

4:00–5:15PM | Level: ■ | Format: FORUM
Room 108A | *CME, Pharmacy, and Nursing*

Perspectives on Expanded Access to Investigational New Drugs

CHAIRPERSON
Kevin Bugin, MS, RAC
Chief, Project Management Staff, Office of New Drugs, CDER, FDA

SPEAKER(S)

Introduction and FDA Regulator Perspective
Jonathan P. Jarow, PhD
Director (Acting), Office of Medical Policy, CDER, FDA

Industry Perspective on Expanded Access
Kenneth I. Moch, MBA
Managing Partner, Salutramed Group, LLC

Patient Advocacy and Expanded Access
Robert Erwin
President, Marti Nelson Cancer Foundation

Global Environment for Expanded Access or Compassionate Use Programs
Katalin Abraham
Director and Lead for Oncology and Biologics, Regulatory Affairs International, Merck & Co., Inc.

#267 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): CmbP, PPLC, RA

4:00–5:15PM | Level: ■ | Format: FORUM
Room 105AB | *CME and Nursing*

FDA Institutes/Centers of Excellence: A Step Toward Patient Focused Drug Development?

CHAIRPERSON
Ellen V. Sigal
Founder and Chairperson, Friends of Cancer Research

Panelists
Steven K. Galson, MD, MPH
Senior Vice President, Global Regulatory Affairs and Safety, Amgen Inc.

Eric H. Rubin, MD
Medical Oncologist and Vice President, Global Clinical Oncology, Merck Research Laboratories

#268 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): BT

4:00–5:15PM | Level: ■ | Format: SESSION
Room 201C | *CME and Nursing*

Emerging Biopharma Therapeutic Modalities: Scientific and Policy Implications

CHAIRPERSON
Adam Hacker, PhD
Vice President, Head of Vaccines and Microbiome, Global Regulatory Affairs, Janssen-Cilag Ltd., United Kingdom

SPEAKER(S)

Microbiome: What Is It and Why Do We Need to Prepare for It?
Adam Hacker, PhD
Vice President, Head of Vaccines and Microbiome, Global Regulatory Affairs, Janssen-Cilag Ltd., United Kingdom

Regenerative Medicine
Anne-Virginie L. Eggiman, MS
Vice President, Regulatory Science, bluebird bio, Inc.

Responding to Global Health Emergencies: A Regulatory Perspective
Luciana Borio, MD
Acting Chief Scientist, Office of the Chief Scientist, Office of the Commissioner, FDA

#269 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): QC

4:00–5:00pm | Level: ■ | Format: FORUM
Room 204A | *CME and Nursing*

Making Quality Stick: Building a Complete Quality Culture

CHAIRPERSON
Coleen Glessner, MBA
Vice President, R&D Quality and Compliance, Alexion

Panelists
William Andrew Erhardt, DrMed
Vice President, Global Product Development, Pfizer Inc

Elizabeth Luczak, MBA
Vice President, Regulatory Compliance Quality Assurance, Covance Inc.

#270 Track 12 – Pharmaceutical Quality

Related Interest Area(s): SP

4:00–5:15pm | Level: ■ | Format: SESSION
Room 111AB | *CME and Nursing*

Implementing Knowledge Management: Industry Perspectives

CHAIRPERSON
Paige Kane
Director, MMD KM CoE, Merck & Co., Inc.

SPEAKER(S)

Think Big but Start Small: The Evolution of Knowledge Management at a Large Pharmaceutical Company
Jodi Schuttig, MBA
Director, Knowledge Management, Merck & Co., Inc.

CMC Data Readiness and Future Proofing for IDMP
Kim S. Northam
Manager, Regulatory Affairs, Accenture Accelerated R&D Services, United Kingdom

Why Wonder When You Can Know?
James Roberts, PhD
Head, Platform Analysis, GlaxoSmithKline

#271 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): SE, CR

4:00–5:15pm | Level: ■ | Format: FORUM
Room 103A | *CME, Pharmacy, and Nursing*

The Things Kids Say: Clinical Outcome Assessments in Pediatric Clinical Trials

CHAIRPERSON
Gina Calarco, BSN, MPH, RN
Associate Director, Pediatric Center of Excellence, Quintiles

SPEAKER(S)

Overview of Regulatory Perspective of Developing and Utilizing COA/PRO in Pediatric Clinical Trials
Andrew E. Mulberg, MD
Deputy Division Director, Gastroenterology and Inborn Errors Products, Office of New Drugs, CDER, FDA

Case Studies for the Development of COA/PRO Tools for Use in Pediatric Clinical Trials
Diane Turner-Bowker, PhD
Director, Patient-Centered Outcomes, Adelphi Values

#272 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): OS, CP

4:00–5:15pm | Level: ■ | Format: SESSION
Room 113B | *CME, Pharmacy, and Nursing*

How Can We Build Reliability and Quality When Outsourcing Pharmacovigilance?

CHAIRPERSON
Brian David Edwards, MD, MRCP
Vice President, ACRES; Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., United Kingdom

SPEAKER(S)

Pharmacovigilance Sourcing, Emerging Business Models
Kelly Traverso
Specialist Leader, Deloitte

Pragmatic Approach to Pharmacovigilance Outsourcing
Lillian M. Kirk, DrSc
Director, Global Pharmacovigilance Case Management, Alexion

#273 Track 15A – Statistical Science and Quantitative Thinking

Related Interest Area(s): CP, RA

4:00–5:15pm | Level: ■ | Format: SESSION
Room 109AB | *CME, Pharmacy, and Nursing*

Improving Adverse Drug Reaction Information in Product Labels

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

SPEAKER(S)

Rational Presentation of Adverse Reactions in Drug Labeling
Ellis Unger, MD
Director, Office of Drug Evaluation I, Office of New Drugs, CDER, FDA

A New Paradigm in Patient Safety: The Importance of End-to-End Labeling and Tracking in Ensuring Pharmacovigilance Compliance
Denis Fung, PhD, MBA
Principal Consultant, Navitas Life Sciences Limited, United Kingdom

Augmenting Product Labels with Real-World Evidence: Lessons from OHDSI
Patrick Ryan, PhD, MS
Head, Epidemiology Analytics, Janssen Pharmaceuticals, Inc.

#274 Track 15B – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST

4:00–5:15PM | Level: ■ | Format: SESSION
Room 108B | *CME, Pharmacy, and Nursing*

Statistical Issues in the Evaluation of Biosimilars

CHAIRPERSON
Gregory Levin, PhD
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

SPEAKER(S)

A Novel Statistical Model of the Relationship Between Exposure to a Biopharmaceutical and Immunogenic Reactions
Marek Ancukiewicz, PhD
Senior Biostatistician, PAREXEL International

Statistical Methodology to Assess Biosimilarity Based on Totality of the Evidence
Zhiying "Jean" Pan, PhD
Senior Manager, Biostatistics, Amgen Inc.

#275 Track 16 – Professional Development

Related Interest Area(s): PETD, SP

4:00–5:15PM | Level: ◆ | Format: WORKSHOP
Room 102AB | *CME and Nursing*

Creating a Competency-Based Onboarding and Learning Program on a Budget

CHAIRPERSON
Patterson Shafer
Specialist Leader, Deloitte Consulting LLP

SPEAKER(S)

Create an Onboarding Curriculum That Fits Your Budget
Liz Wool, BSN
Global Head of Training, Barnett International

#276 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): SE, CR, PT

4:00–5:15PM | Level: ■ | Format: SESSION
Room 103C | *CME, Pharmacy, and Nursing*

Using Input from Patient Communities to Develop PRO Instruments

CHAIRPERSON
Badri Rengarajan, MD
Medical Affairs Head, ASPIRE Unit, Actelion

SPEAKER(S)

Engaging Online Communities to Understand Patient Experiences
Chad Gwaltney, PhD
Principal Consultant, Gwaltney Consulting

Developing a Disease-Specific PRO Tool from a Patient-Centric Research Network
Badri Rengarajan, MD
Medical Affairs Head, ASPIRE Unit, Actelion

Regulatory Perspective
Elektra Johanna Papadopoulos, MD, MPH
Acting Associate Director, Clinical Outcome Assessments Staff, Office of New Drugs, CDER, FDA

#277 Track 18 – Global Regulatory

Related Interest Area(s): RA, SP

4:00–5:15PM | Level: ■ | Format: FORUM
Room 202AB | *CME and Nursing*

PMDA Town Hall

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

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

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

Nobumasa Nakashima, PhD
International Planning Director for Pharmaceuticals, Ministry of Health, Labour and Welfare (MHLW), Japan

#278 Track 22 – Engage and Exchange

Related Interest Area(s): CR

4:00–5:00PM | Level: ■ | Format: WORKSHOP
Exhibit Hall A | *No CE available*

Real Life Application of Risk-Based Monitoring

CHAIRPERSON
Brett Wilson
Head, Monitoring Excellence, Bristol-Myers Squibb Company, Canada

Facilitators
Lisa Horne-Lucero, BSN
Consultant, RBM Operations, Clinical Risk Management, Eli Lilly and Company

Kate Owen
Vice President, Clinical Trial Management, Novo Nordisk Inc.

WEDNESDAY, JUNE 29

Registration Hours:

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

7:00–8:00AM

Coffee and Light Refreshments
Grand Hall and Room 108 Concourse

#301 Track 19A

DIAmond SESSIONS

Related Interest Area(s): PPLC, IT

8:00–9:30AM | Level: ■ | Format: FORUM
Room 103ABC | *CME and Nursing*

The Future of Big Data

CHAIRPERSON
Nancy Bradish Myers, JD
President, Catalyst Healthcare Consulting, Ltd.

Panelists
Michael J. Doherty
Head, Strategic Innovation, Pharmaceutical Development; Executive Advisor, Foundation Medicine Inc., Hoffmann-La Roche Ltd.

Sally A. Howard, JD
Head of Regulatory Affairs and Policy, Human Longevity, Inc.

Kara N. Dennis, MA, MBA
Managing Director, Mobile Health, Medidata Solutions Worldwide

#302 Track 19B

DIAmond SESSIONS

Related Interest Area(s): CEHTAEbM, RA

8:00–9:30AM | Level: ■ | Format: FORUM
Room 114 | *CME, Pharmacy, and Nursing*

Europe and the US: Making Outcomes-Based Health Care Possible

CHAIRPERSON
Duane Schulthess, MBA
Managing Director, VitalTransformation, Belgium

SPEAKER(S)

European Approaches to Outcomes-Based Health Care
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

New Outcomes Models
Gigi Hirsch, MD
Executive Director, Massachusetts Institute of Technology (MIT) Center For Biomedical Innovation

Big Data for Better Outcomes: Innovative Medicines Initiative – IMI Taking the Lead
Richard Bergstrom, MS
Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

Panelist
Representative Invited
Pharmaceutical Research and Manufacturers of America (PhRMA)

#303 Track 19C

DIAmond SESSIONS

Related Interest Area(s): CEHTAEbM, RD

8:00–9:30AM | Level: ■ | Format: FORUM
Ballroom A | *CME and Nursing*

Value-Based Health Care Decision Making: The Quest for Smarter Spending

CHAIRPERSON
Jennifer Snow
Director, Health Policy, Xcenda

Panelists
Sally Okun, RN
Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe

Sarah Garner, PhD, MPharm
Associate Director – Science Policy and Research, National Institute for Health and Care Excellence (NICE), United Kingdom

Richard J. Willke, PhD
Chief Science Officer, International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

Newell McElwee, PharmD, MPH
Executive Director, US Outcomes Research, Merck & Co., Inc.

9:30–10:30AM

Coffee Break in Exhibit Hall

#304 Track 21: Poster Presentations

9:40–10:20AM
Exhibit Hall A *No CE Available*

Professional Poster Session and Oral Presentations 2A

#305 Track 22 – Engage and Exchange

Related Interest Area(s): CP, CDM

9:40–10:25AM Level: ■ Format: WORKSHOP
Exhibit Hall A *No CE available*

MedDRA: Use in the Review of New Drug Applications at the FDA

CHAIRPERSON
David Richardson
Medical Officer, MedDRA MSSO

Facilitator
Christopher Damian Breder, MD, PhD
Medical Officer, Office of New Drugs, CDER, FDA

#306 Track 20 – Innovation Theaters

Related Interest Area(s): CP

9:45–10:15AM Level: ■ Format: SESSION
Exhibit Hall B *No CE available*

SAS/JMP Innovation Theater: Efficient Safety Assessment in Clinical Trials Using the Computer-Generated Adverse Event Narratives of JMP Clinical

#307 Track 01A – Clinical Operations

Related Interest Area(s): CR, AHC/IS, GCP

10:30–11:45AM Level: ■ Format: SYMPOSIUM
Room 108A *CME and Nursing*

Mythbusting Site Productivity: Referral Practices and Untapped Site Options

CHAIRPERSON
Jane E. Myles, MS
Head, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

SPEAKER(S)

Integrating Overlooked Health Care Networks into Clinical Trial Site Selection
Sowmya Banda
Graduate Intern, Clinical Trial Planning and Operations, Bristol-Myers Squibb Company

Study of Health Care Provider Perceptions and Patient Referral Practices
Mary Jo Lamberti, PhD, MA
Senior Research Fellow, Tufts University

Site Perspective
David Leduc
Senior Director of Strategic Alliances, Addario Lung Cancer Medical Institute

#308 Track 01B – Clinical Operations

Related Interest Area(s): CR, PT

10:30–11:45AM Level: ■ Format: WORKSHOP
Room 102AB *CME, Pharmacy, and Nursing*

Patient Recruitment Workshop: Survey Results and Practical Application

CHAIRPERSON
Robin Marcus, BSN, RN
Senior Vice President, Business Development and Strategic Initiatives, GlobalCare Clinical Trials

Facilitator
Stella Stergiopoulos
Senior Project Manager, Tufts Center for the Study of Drug Development

#309 Track 02A – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): RD, SP, RA

10:30–11:45AM Level: ■ Format: FORUM
Room 105AB *CME, Nursing, and PMI PDUs*

Global Stakeholder Management: Across the Ocean Between East and West

CHAIRPERSON
Atsushi Tsukamoto, PhD, MSc, PMP
Senior Director, R&D Strategy and Coordination Group, Planning and Management Department, Daiichi Sankyo Co., Ltd., Japan

Panelists
Robert A. Hilke, MA
Chief Executive Officer, Hilke Communications Corporation, Japan

Gareth Julian Monteath, PhD, MBA, MS
Executive Director, Link Global Solution Inc., Japan

#310 Track 02B – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): CM, PM, RD

10:30–11:45AM Level: ◆ Format: SESSION
Room 108B *CME, Nursing, and PMI PDUs*

Bridging CMC and Project Management to Achieve High Quality Product Submissions and Launch

CHAIRPERSON
Russell Maus, PhD
Director, Merck & Co., Inc.

SPEAKER(S)

CMC Case Study 2: Combination Device/Biologic Product
Maria Paola Schick, PMP
CMC Integration Project Manager, Amgen Inc.

Case Study 3: Bioequivalency of Inhaled Products
Bela Elkin, PhD
Laboratory Manager, PPD

#311 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, QC, RD, SP

10:30–11:45AM Level: ■ Format: SESSION
Room 111AB *CME and Nursing*

Outsourcing: Assessing CRO Performance and Challenges

CHAIRPERSON
Scott R. Martin, JD
Principal, KMR Group Inc.

Creating an External Alliances Structure
Robert Middel
Head of External Alliances, Portfolio Delivery Operations, Janssen Biologics B.V., Netherlands

How Real World Research Challenges Outsourcing Strategies
Michael George Minor
Senior Vice President, Global Head Operations and Strategic Planning, ICON Peri-Approval and Observational Research

Controlling Study Level Budgets with CROs
Michael Williamson, MSc
Associate Director Outsourcing and Contracts Management, UCB Biosciences, Inc.

#312 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): NC, BT, RA, RD, CMC/GMP, SUBS

10:30–11:30AM Level: ■ Format: SESSION
Room 113C *CME and Nursing*

Human Tissue Models: A Look into the Future of Safety Pharmacology Studies

CHAIRPERSON
Michelle Cathian Beharry, MS
Non-Clinical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

SPEAKER(S)

Overcoming Barriers to Human Tissue Use for Safety Assessment
Anthony Holmes, PhD
Head, Technology Development, NC3Rs, United Kingdom

The Use of Human Tissue Technologies in Support of Clinical Trials and Marketing Authorization Regulatory Submissions
Michelle Cathian Beharry, MS
Non-Clinical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

#313 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): DM, RA, RD, CR

10:30–11:45AM Level: ◆ Format: FORUM
Room 204B *CME and Nursing*

The Future of Clinical Research Data: 2020 and Beyond

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

Panelists
David A. Evans, MS
Managing Director, Accelerated Research & Development Services, Accenture

Armando Oliva, MD
President and Chief Medical Officer, Semantica LLC

Kenneth A. Getz, MBA
Chairman, CISCRP; Director of Sponsored Research, Tufts Center for the Study of Drug Development

#314 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): CR, QA/QC, RA, CDM, IT

10:30–11:30AM Level: ■ Format: FORUM
Room 203AB *CME, Pharmacy, and Nursing*

Transforming Clinical Protocols into a Digital Platform: Driving Quality and Efficiency End-to-End

CHAIRPERSON
Robert A. DiCicco, PharmD
Vice President, Clinical Pharmacology Sciences and Operations, GlaxoSmithKline

Panelists
Eileen E. Navarro Almario, MD, MS, FACP
Lead Medical Officer, Office of Computational Sciences, Office of Translational Sciences, CDER, FDA

Rebecca D. Kush, PhD
President and Chief Executive Officer, CDISC

Christine Pierre, RN
President, Society for Clinical Research Sites

#315 Track 08A – Regulatory Affairs

Related Interest Area(s): CR, RD, SP, RA, PPLC

10:30–11:45AM Level: ■ Format: FORUM
Room 201B *CME, Pharmacy, and Nursing*

Enhancing Pediatric Product Development in a Global Regulatory Environment: Extrapolation and Modeling and Simulation, Oh My!

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

SPEAKER(S)

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

FDA Perspective
Mary Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of Special Medical Programs, FDA

Health Canada Perspective
Ariel E. Arias, MD, PhD
Senior Advisor, Centre for Biologics Evaluation, BGTD, Health Canada

#316 Track 08B – Regulatory Affairs

Related Interest Area(s): CP, PT, CR, RA, PT

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

Room 204C | *CME, Pharmacy, and Nursing*

What's Your Preference? The Emerging Importance of Patient Preference Elicitation

CHAIRPERSON

Rebecca A. Noel, DrPH, MPH
Global Benefit-Risk Lead, Global Patient Safety, Eli Lilly and Company

SPEAKER(S)

Regulatory Perspective
Isabelle Moulon, MD
Head of Patients and Healthcare Professionals Department, European Medicines Agency, European Union

Patient Perspective
Andrea Stern Ferris
President and Chairman, LUNGevity Foundation

Industry Perspective
Bennett Levitan, MD, PhD
Senior Director, Benefit-Risk Assessment, Department of Epidemiology, Janssen Research & Development

#317 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD, RA

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

Room 103C | *CME, Pharmacy, and Nursing*

Global Medical Device Development: Regulatory Concordance or Discordance?

CHAIRPERSON

Mary Ann Smith, MS, RPh
DRA Policy Head of Medical Device and Combination Products, Novartis Pharmaceuticals Corporation

SPEAKER(S)

Industry Perspective
Anthony D. Watson, MBA, MS
Associate Vice President, Regulatory Affairs-Devices, Sanofi US

US Regulatory Perspective
Representative Invited
Regulatory Review Officer, CDRH, FDA

#318 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): CR, PPLC

10:30–11:30AM | Level: ◆ | Format: SESSION

Room 202AB | *CME and Nursing*

Changes to Common Rule Likely Affecting FDA-Governed Research

CHAIRPERSON

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

SPEAKER(S)

Industry Perspective
David Vulcano, MBA, RAC
Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

Industry Perspective
Douglas J. Peddicord, PhD
Executive Director, Association of Clinical Research Organizations (ACRO)

#319 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR, CDM

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

Room 204A | *CME and Nursing*

Unlocking the Mysteries of Knowledge Management and Potential Applications for Clinical Development

CHAIRPERSON

Kathy Salzano
Director, Quality and Continuous Improvement, Merck & Co., Inc.

SPEAKER(S)

Overview of TransCelerate Conceptual Knowledge Management Framework
Christa A. Maurer
Regional Quality Lead, Intercon, Bristol-Myers Squibb Company

Unlocking the Mystery of Knowledge Management: Applying Concepts to a Trial Master File
David William Fryrear, MSc
Senior Director, Clinical and Pharmacovigilance Quality Assurance, AbbVie Inc.

Application of Knowledge Management in Regulatory Intelligence
Carolyn Louise Hynes, PhD
Senior Director, Global Regulatory Intelligence, GlaxoSmithKline, United Kingdom

#320 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): SP

10:30–11:00AM | Level: ■ | Format: SESSION

Room 201A | *CME and Nursing*

Design Thinking to Redesign the Clinical Trial Business Model and Improve Efficiency and Quality of Clinical Trials

CHAIRPERSON

Patricia Leuchten
Chief Executive Officer and President, The Avoca Group

#321 Track 12 – Pharmaceutical Quality

Related Interest Area(s): CMC, RA

10:30–11:45AM | Level: ■ | Format: FORUM
Room 113B | *CME, Pharmacy, and Nursing*

Office of Pharmaceutical Quality Update

CHAIRPERSON

Robert Iser, MS
Acting Director, Office of Process and Facilities, Office of Pharmaceutical Quality, CDER , FDA

Panelists

Michael Kopcha, PhD, RPh
Director, Office of Pharmaceutical Quality, CDER, FDA

Lawrence X. Yu, PhD
Deputy Director, Office of Pharmaceutical Quality, CDER, FDA

#322 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM

10:30–11:30AM | Level: ■ | Format: SESSION
Room 107AB | *CME, Pharmacy, and Nursing*

Real-World Evidence in Drug Development: Creating the Right Environment for Enhanced Pre-Launch Evidence

CHAIRPERSON

Pieter Stolk, PharmD, PhD
Project Manager, University Medical Centre Utrecht, Netherlands

SPEAKER(S)

The Environment for Enhanced Pre-Launch Evidence: An EU Perspective
Chris Chinn, MSc
Head of Real World Data Strategy and Partnerships, Sanofi, United Kingdom

The Environment for Enhanced Pre-Launch Evidence: A US Perspective
Gregory Daniel, PhD, MPH
Deputy Director, Duke-Margolis Center for Health Policy, Duke University

#323 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

10:30–11:45AM | Level: ● | Format: SESSION
Room 113A | *CME, Pharmacy, and Nursing*

Social Listening for Pharmacovigilance: Practical Considerations and Challenges for Implementation

CHAIRPERSON

Laurie S. Anderson, PharmD
Safety Evaluation and Risk Management Scientist, GlaxoSmithKline

SPEAKER(S)

Current Gaps and Challenges in Pharmacovigilance with Response to Social Media
Lalitha P. Aiyer, MD, MBA, MS
President and Senior Medical Advisor, Medical and Pharma Advisors Group

A Real-World Look at Mining Social Media for Adverse Events: Impact of Regulatory Definitions and Methods
Michael A. Ibara, PharmD
Head of Digital Healthcare, CDISC

Real-World Use of Social Listening for Pharmacovigilance Currently in the Pharmaceutical Industry
Lorrie Schifano, PharmD
Director, Global Clinical Safety and Pharmacovigilance SERM, Development US, GlaxoSmithKline

#324 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, CR

10:30–11:45AM | Level: ● | Format: SESSION
Room 109AB | *CME, Pharmacy, and Nursing*

Implementing Adaptive Designs Involves Greater Teamwork

CHAIRPERSON

Eva R. Miller, PhD, MS
Independent Biostatistical Consultant

SPEAKER(S)

The Biostatistician's Role in Adaptive Design Team: Power Calculations Using GSDesign
Kenneth Liu, PhD
Senior Principal Scientist, Merck & Co. Inc.

The Drug Supplies Manager's Role in Planning and Implementing Flexible Drug Supply Management in Adaptively Designed Trials
Micheline D. Marshall, MBA
Head Randomization and Trial Supply Management, Janssen Pharmaceutical Companies of Johnson & Johnson

Pivotal Roles of the Statistician, Physician, and Project Manager in Simple and Complex Adaptive Trial Designs
Richard McNally, MA, MBA, MS, MSc, PMP
Statistical Fellow, Covance Inc.

#325 Track 16 – Professional Development

Related Interest Area(s): PETD

10:30–11:45AM | Level: ● | Format: FORUM
Room 112AB | *No CE available*

Reinventing You: How to Change Your Career Fearlessly!

CHAIRPERSON

Kimberly Belsky, MS
Executive Director, OneSource Regulatory

SPEAKER(S)

You've Worked a Long Time for a Sponsor, Now What?
Betsy Fallen, RN
Consultant, BA Fallen Consulting LLC

Moving Within Pharma: Medical Affairs to Pharmacovigilance
Stephen Knowles, MD, MRCP
Senior Director, Global Patient Safety, Medical and Benefit Risk Management, Eli Lilly and Company

Through the Revolving Door: From Government to Private Practice
Heidi F. Gertner
Partner, Hogan Lovells US LLP

#326 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD

10:30–11:45AM | Level: ● | Format: FORUM
Room 103A | *CME, Pharmacy, and Nursing*

FDA Rare Disease Town Hall

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

Panelists
Jonathan C. Goldsmith, MD, FACP
Associate Director for Rare Diseases, Office of New Drugs, CDER, FDA

Andrew E. Mulberg, MD
Deputy Division Director, Gastroenterology and Inborn Errors Products, Office of New Drugs, CDER, FDA

Debra Yvonne Lewis, MBA
Deputy Director, Office of Orphan Products Development, Office of the Commissioner, FDA

#327 Track 18 – Global Regulatory

Related Interest Area(s): RA

10:30–11:30AM | Level: ■ | Format: SESSION
Room 201C | *CME and Nursing*

FDA–Health Canada Regulatory Cooperation Council Town Hall

CHAIRPERSON
Sema D. Hashemi, MSc
Director, Office of Regional and Country Affairs, Office of the Commissioner, FDA

Panelists
Mary Lou Valdez, MS
Associate Commissioner for International Programs, Office of the Commissioner, FDA

Ed Morgan
Director General, Policy, Planning and International Affairs Directorate, Health Canada

#328 Track 22 – Engage and Exchange

Related Interest Area(s): PPLC

10:45–11:45AM | Level: ● | Format: WORKSHOP
Exhibit Hall A | *No CE available*

The Ethics of "Big Data" Biomedical Science

CHAIRPERSON
Wendy Louise Lipworth, MD, PhD
Senior Research Fellow, Centre for Values, Ethics and the Law in Medicine, University of Sydney, Australia

11:30AM–2:00PM

Luncheon in Exhibit Hall

#329 Track 21: Poster Presentations

12:00–1:45PM
Exhibit Hall A | *No CE Available*

Professional Poster Session and Oral Presentations 2B

#330 Track 20 – Innovation Theaters

Related Interest Area(s): CR

12:00–12:30PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

SAS Innovation Theater: Empowering Action – Fueling Safety and Operational Efficiency

#331 Track 22 – Engage and Exchange

Related Interest Area(s): GCP

12:00–1:00PM | Level: ■ | Format: WORKSHOP
Exhibit Hall A | *No CE available*

Applying Design Thinking to Clinical Development: Human-Centered Approaches to Improve Quality and Efficiency

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

Facilitators
Andrew Marshall, MA
Principal, Primed Consulting, LLC

JoAnn Muir
Global Head Franchise Quality Assurance, Novartis Pharmaceuticals Corporation

#332A Track 20 – Innovation Theaters

Related Interest Area(s): PT

12:40-1:10PM | Level: ■ | Format: SESSION
Exhibit Hall B | *No CE available*

Salesforce Innovation Theater: Connect to Your Patients, Providers, and Partners in a Whole New Way with the Salesforce Platform

#332B Track 20 – Innovation Theaters

Related Interest Area(s): RD

1:20–1:50PM | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

SAP Innovation Theater: Too Much R&D Data to Develop New Drugs and Medical Devices?

#333 Track 01A – Clinical Operations

Related Interest Area(s): PT, ROD, SP

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

Room 113A | *CME, Pharmacy, and Nursing*

Hearing the Patient Voice in Pharma and What Patients Want You to Know

CHAIRPERSON

Ed Miseta, MBA
Executive Editor, Life Science Leader

Panelists

Roslyn F. Schneider
Global Patient Affairs Lead, Pfizer Inc

Beverly L. Harrison
Senior Director, Patient Support, Janssen R&D, LLC

Eric J. Peacock, MBA
Co-Founder and Chief Executive Officer, MyHealthTeams

#334 Track 01B – Clinical Operations

Related Interest Area(s): CR

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

Room 113B | *CME and Nursing*

Risky Business: Latest Trends, Strategies, and Tools for Predicting Success and Monitoring Risk During Clinical Trial Operations

CHAIRPERSON

Angelique Hopkins, MPH
Associate Director Clinical Trial Analytics, Bristol-Myers Squibb Company

SPEAKER(S)

RBM Industry Trends: How the Landscape Has Changed Between 2013–15
Linda B. Sullivan, MBA
Co-Founder and President, Metrics Champion Consortium LLC

Metrics, Not Magic: Predicting Risk of Site Failure
Lucas Glass, MS
Manager, Data Scientist, Clinical Trial Optimization Solutions, IMS Health

#335 Track 01C – Clinical Operations

Related Interest Area(s): ROD, CR

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

Room 113C | *CME, Pharmacy, and Nursing*

Multi-Ethnic, Special Populations, and Patient Diversity in Clinical Trials

CHAIRPERSON

Lisa Palladino Kim, MS
Faculty, Rutgers, The State University of New Jersey

SPEAKER(S)

Pediatric Studies: Experiences, Best Practices, and Trends
Conrad Hawkins
Associate Consultant, KMR Group

Conduct of Clinical Trials in Special Populations and Developing Regions: Challenges and Opportunities
Stephen G. Reams, MA
Advisor, Clinical Project Management, Eli Lilly and Company

Medicines Development for Geriatric Patients: Unmet Needs?
Dinah Duarte, PharmD, MSc
Head, Scientific Evaluation Unit, Directorate of Medicinal Products, INFARMED, Portugal

#336 Track 02 – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): PR, SP, CEHTAEbM, FI

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

Room 105AB | *CME, Pharmacy, Nursing, and PMI PDUs*

Effect of International Reference Pricing on Planning for Global New Product Launches

CHAIRPERSON

Matthew Steven Curin, PharmD
Associate Director, Project Management, Astellas Pharma US, Inc.

SPEAKER(S)

What Every Project Manager Should Know About HTA and Pricing
Claire Corry, MS
Director, Global Project and Alliance Management, Merck & Co., Inc.

Mapping the Global Launch Sequence in a Partnership
Nathan J. Murray
Global PRA Advisor, Autoimmune, Eli Lilly and Company

Practical Application of Global Launch Best Practices: A Case Study
Matthew Steven Curin, PharmD
Associate Director, Project Management, Astellas Pharma US, Inc.

#337 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, PM, RD, RA, QC, GCP

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

Room 112AB | *CME and Nursing*

Overcoming Deficiencies in the Oversight of Outsourced Clinical Programs: Collaboration and Utilization of Industry Leading Guidelines and Tools

CHAIRPERSON

Mike Collins, PhD, MS
Head of R&D Global Vendor Management, Alexion

Panelists

Grace M. Crawford, MS
Vice President, Clinical Quality and Compliance, MedImmune

Joseph A. Fortunato
Senior Vice President, Corporate Quality Assurance and Compliance, InVentiv Health Clinical

Steven B. Whittaker
Executive Director, Quality Consortium, The Avoca Group

#338 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): CP, PC, ST, RD, CR

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

Room 201A | *CME, Pharmacy, and Nursing*

Evolving Methods in Pain Trials: Evaluating Abuse Deterrence, Drug Interactions, and Appropriate Patient Selection

CHAIRPERSON

Beatrice Setnik, PhD
Vice President, Clinical Pharmacology, Early Phase, INC Research

SPEAKER(S)

Abuse Deterrent Opioids: Benchtop and Clinical Approaches to Testing Real World Drug Abuse
Beatrice Setnik, PhD
Vice President, Clinical Pharmacology, Early Phase, INC Research

A Quantitative Approach to Understanding the Dynamic Interplay Between Pain and Concomitant Medications, and Genetics
Galina Bernstein, PhD
Research Scientist, PK, Scientific Affairs, INC Research, Canada

Proposal to Use of Biomarker Methods to Enable Stratification of Patient Populations in Clinical Trials for Neuropathic Pain
Andrew Whiles, LLM, MBA
Director, Regulatory Affairs, Pfizer Ltd., United Kingdom

#339 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): CP, RA

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

Room 203AB | *CME, Pharmacy, and Nursing*

Evolution of Patient Safety Reporting: PSURs to RMPs, Challenges, and How to Face Them

CHAIRPERSON

Sven Schirp
Head of Global Pharmacovigilance Writing, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

SPEAKER(S)

Periodic Reporting in Drug Safety: From Safety Updates to Continuous Benefit-Risk Evaluations
Leonardo Ebeling, MD, PhD
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

The EU-Risk Management Plan from a Medical Writer's Perspective
Sven Schirp
Head of Global Pharmacovigilance Writing, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Writing the Lay Summary (Section VI) of Risk Management Plans: Why and How?
Lisa Chamberlain James, PhD
Senior Partner, Trilogy Writing & Consulting Ltd., United Kingdom

#340 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): CR, EC, CDM, RA

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

Room 204C | *CME and Nursing*

eSource: Using Source Data Capture from Electronic Health Records to Improve Clinical Research

CHAIRPERSON

Michael A. Ibara, PharmD
Head of Digital Healthcare, CDISC

SPEAKER(S)

Academic Perspective
Amy Harris Nordo, BSN, MS, RN
Product Manager, Maestro Care for Research and Retrieve Form Data Capture (RFD), Duke University

Current FDA eSource Demonstration Projects and Overall Effort
Mitra Rocca, MSc
Associate Director, Medical Informatics, Office of Translational Science, CDER, FDA

EHR Pilot Study: Lessons Learned Thus Far
Trisha D. Simpson
Director, GLobal Biometry Standards, UCB Biosciences, Inc.

#341 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): DM, CDM, RA, CR

2:00–3:00PM | Level: ■ | Format: SESSION
Room 204B | *CME and Nursing*

eTMF: Selection, Implementation, and What's Next?

CHAIRPERSON

Karen Jane Roy, MPharm
Senior Vice President, Client Solutions, Phlexglobal, United Kingdom

SPEAKER(S)

eTMF: Challenges and Possible Solutions
Laxman Kumar Jakkala, Sr., PhD
Director, Global Quality Assurance, Makrocare, India

Global Implementation of a Full Service Provision eTMF Software and Services: A Case Study
Martina M. Duevel, DrSc, PhD
Senior GCPM ONC, eTMF Process Owner Representative, Bayer Pharma AG, Germany

#342 Track 07C – Technology/Data/Records and Submissions

Related Interest Area(s): CR, ST, RA

2:00–3:15PM | Level: ■ | Format: SYMPOSIUM
Room 201C | *CME, Pharmacy, and Nursing*

Big Data in Health Care and Life Sciences

CHAIRPERSON

John Piccone
Lead Partner Life Sciences Strategy and Analytics, IBM Watson Health

SPEAKER(S)

IBM Watson Health: Creative Innovation of Health Care and Life Sciences
John Piccone
Lead Partner Life Sciences Strategy and Analytics, IBM Watson Health

Exploiting Big Data in Precision Medicine
Amrita Basu, PhD
Genomics and Computational Biology Lead, Health and Life Sciences, Lockheed Martin Information Systems & Global Solutions

The Big Data Gap: Harnessing Big Data to Accelerate Clinical Development
Srinivas Karri, MSc
Director, Clinical Warehousing Cloud Strategy, Oracle Corporation, United Kingdom

#343 Track 08 – Regulatory Affairs

Related Interest Area(s): RA, PPLC, SP

2:00–3:15PM | Level: ■ | Format: SESSION
Room 201B | *CME, Pharmacy, and Nursing*

Strategies, Enablers, and Barriers to Medicine Development in the Emerging Markets: The 2025 Global Regulatory Landscape

CHAIRPERSON

Prisha Patel, MSc
Manager, Global Development Programme, Centre For Innovation In Regulatory Science (CIRS), United Kingdom

SPEAKER(S)

Industry Perspective
Joseph C. Scheeren, PharmD
Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care AG, Switzerland

WHO Perspective on Medicines Development in the Emerging Markets
Mike Ward
Coordinator, Regulatory Systems Strengthening, EMP, World Health Organization (WHO), Switzerland

#344 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD, CmbP

2:00–3:15PM | Level: ■ | Format: FORUM
Room 103A | *CME and Nursing*

Companion Diagnostics: Driving New Business Models for Successful Outcomes

CHAIRPERSON

Patrick Phillips
Chief Executive Officer, Health Decisions, Inc.

Panelists

Robert Bilkovski, MD, MBA
Head, Medical and Clinical Affairs, Abbott Molecular

Kelly R. Pitts, PhD
Vice President, Research & Development, Site Manager - Colorado Operations, Corgenix, Inc.

#345 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PPLC

2:00–3:15PM | Level: ■ | Format: FORUM
Room 202AB | *CME, Pharmacy, and Nursing*

Are State Consumer Fraud Lawsuits Encroaching on FDA's Regulatory Authority?

CHAIRPERSON

Lisa M. Dwyer, JD
Partner, Member of the FDA and Life Sciences Group, King & Spalding

Panelists

JB Van Hollen, JD
Former State Attorney General for Wisconsin, Van Hollen Consulting, LLC

Sheldon Bradshaw, JD
Partner, FDA and Life Sciences Practice; Former Chief Counsel, FDA, King & Spalding

#346 Track 11 – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): CR

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

Room 204A | *CME and Nursing*

Anticipating and Responding to Challenges in Issue Management

CHAIRPERSON

Susan V. Callery-D'Amico, BSN
Vice President, R&D Quality Assurance, AbbVie Inc.

SPEAKER(S)

Controlling the Killer KRI: New Solutions to Address Protocol Deviations
Kenneth Wu, MBA, MS
Consultant, Kenneth Wu and Associates

FDA Perspective
Jean M. Mulinde, MD
Senior Policy Advisor, Division of Clinical Compliance Evaluation, Office of Scientific Integrity, Office of Compliance, CDER, FDA

#347 Track 12 – Pharmaceutical Quality

Related Interest Area(s): RA

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

Room 111AB | *CME and Nursing*

Global Harmonization: Non-ICH Regions

CHAIRPERSON

Mark Rosolowsky, PhD
Vice President, Global Regulatory Sciences, CMC, Bristol-Myers Squibb Company

SPEAKER(S)

The Challenges Handling Postapproval Changes in Latin America
Maria Cristina Mota, MBA
Director, Scientific Regulatory Policy and Intelligence - Latin America, AbbVie Inc.

The New Postapproval Regulations from ANVISA
Ivone Takenaka, PhD, MSc
Associate Director, GRSB-CMS and LATCAN Regulatory Expert, Bristol-Myers Squibb Company

Opportunities for Improved Access to Safe and Efficient Medicines
Maria Guazzaroni Jacobs, PhD
Director, Quality and Regulatory Policy (QRP), Pfizer Inc

#348 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): CEHTAEbM

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

Room 107AB | *CME, Pharmacy, and Nursing*

Interpreting Meaningful Change on PROs: When to Talk, When to Use Cumulative Distribution Functions, and When to ROC

CHAIRPERSON

Marian M. Strazzeri, MS
Mathematical Statistician, Office of Biostatistics, Office of Translational Sciences, CDER, FDA

Panelists
Scott Komo
Mathematical Statistician, Office of Translational Sciences, CDER, FDA

Cheryl D. Coon, PhD
Principal, Outcometrix

#349 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

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

Room 109AB | *CME, Pharmacy, and Nursing*

Measuring the Effectiveness of Risk Minimization: Principles and Regional Requirements

CHAIRPERSON

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Real World & Late Phase Research, Quintiles Inc., United Kingdom

SPEAKER(S)

Risk Management Plans and Risk Minimization: What Have We Learned and Where Is It All Going?
Shelley Gandhi, MS
Strategic Advisor, Pharmacovigilance & Drug Safety, NDA Group, United Kingdom

CIOMS IX and the Theory of Assessing Effectiveness
Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Real World & Late Phase Research, Quintiles Inc., United Kingdom

Additional Risk Minimization Measures for EU Centrally Authorized Products, 2006-2014: A Qualitative and Quantitative Review
Annalisa Rubino, PhD
Director of Risk Management Epidemiology, Oxon Epidemiology, United Kingdom

#350 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

2:00–3:30PM Level: ■ Format: SESSION
Room 108A *CME, Pharmacy, and Nursing*

Evaluating the Impact of Adverse Event Information from Solicited Programs on Benefit-Risk Profiles: Is It Worth the Effort?

CHAIRPERSON

Bruce A. Donzanti, PhD
Senior Group Director, Global Pharmacovigilance Policy, Genentech, A Member of the Roche Group

SPEAKER(S)

Industry Survey on Pharmacovigilance Oversight of Solicited Programs
Jamie Portnoff
Vice President, Foresight Group International

A Regulatory View of ICSR Reporting Requirements for PSPs
Mick Foy
Group Manager, Vigilance Intelligence and Research Group, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Pragmatic Compliance: A QPPV View of PSPs
Sue Rees, MS
EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd., United Kingdom

Organized Data Collection Systems: A Pure Compliance Challenge or More?
Heike Schoepper, MD, PhD, MBA
Head of Global Drug Safety, GDS Regions, Merck KGaA, Germany

#351 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, CR

2:00–3:15PM Level: ■ Format: SESSION
Room 108B *CME, Pharmacy, and Nursing*

Emergent Study Designs and Analysis Methods Addressing Issues Associated with Pediatric Clinical Studies

CHAIRPERSON

Tammy Massie
Mathematical Statistician, Office of Equal Opportunity and Customer Outreach, National Institutes of Health (NIH)

SPEAKER(S)

Enhancing Pediatric Clinical Trial Feasibility: Focus on the Use of Bayesian Statistics
Earl Seltzer, MBA
Associate Therapeutic Strategy Director, Quintiles

Panelist
Lisa A. Kammerman, PhD, MS
Senior Statistical Science Director, AstraZeneca

#352 Track 16 – Professional Development

Related Interest Area(s): SP

2:00–3:15PM Level: ■ Format: FORUM
Room 102AB *CME, Nursing, and PMI PDUs*

From Mistakes to Success: Lessons Learned from Organizational Change Management Programs

CHAIRPERSON

Diane Cooney
Senior Consultant, Paragon Solutions

SPEAKER(S)

Managing Change for Large-Scale Projects
Elizabeth Rager, MA
Corporate Entity Information Officer, Penn Medicine

Leading Global Change Management
Walter Hinz, MBA
Senior Director, Celgene Corporation

#353 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): RD, CR

2:00–3:00PM Level: ■ Format: SESSION
Room 103C *CME and Nursing*

The Utility of Natural History Studies in Drug Development and Approval

CHAIRPERSON

James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

SPEAKER(S)

FDA Draft Guidance and the Utility of Natural History Studies in the Development of Drugs for Rare Diseases
Jonathan C. Goldsmith, MD, FACP
Associate Director for Rare Diseases, Office of New Drugs, CDER, FDA

Considerations in the Use of National History Studies: Development and Registration Perspective
Camilla Veronica Simpson, MS
Group Vice President Regulatory Affairs, BioMarin Pharmaceutical Inc.

Use of Historical Controls to Support Drug Approvals
James E. Valentine, JD
Associate, Hyman, Phelps & McNamara, PC

#354 Track 22 – Engage and Exchange

Related Interest Area(s): CR

2:00–3:00PM Level: ■ Format: WORKSHOP
Exhibit Hall A *No CE available*

Protocol Optimization: Making It Real

CHAIRPERSON

Robert L. Ferendo, RPh
Service Owner SemioClinical, Eli Lilly and Company

Facilitators
Virginia Nido, MS
Head, Industry Collaborations, Genentech, A Member of the Roche Group

Stacy J. Tegan
Manager, Regulatory Technology Consulting, Accenture Accelerated R&D Services

Bryan Yee
Strategic Planning and Operatiaons Senior Manager, Amgen Inc.

3:00–4:00PM

Refreshment Break in Exhibit Hall

#355 Track 20 – Innovation Theaters

Related Interest Area(s): CP

3:25–3:55PM | Level: ■ | Format: SESSION

Exhibit Hall B | *No CE available*

DBMS Innovation Theater: Safety Data Delay is a Risk-Enhanced Signal Detection With Customized MedDRA and Drug Grouping Queries

#356 Track 22 – Engage and Exchange

Related Interest Area(s): PM

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

Exhibit Hall A | *No CE available*

Let's Enjoy Global Stakeholder Management

CHAIRPERSON

Atsushi Tsukamoto, PhD, MSc, PMP
Senior Director, R&D Strategy and Coordination Group, Planning and Management Department, Daiichi Sankyo Co., Ltd., Japan

#357 Track 01 – Clinical Operations

Related Interest Area(s): RA, CR, PPLC, EC, IT

4:00–5:15PM | Level: ◆ | Format: SESSION

Room 108B | *CME, Pharmacy, and Nursing*

The Internet of Things and Clinical Research: Privacy, Security, and Ethical Aspects

CHAIRPERSON

Ellen Kelso
Executive Director, Chesapeake IRB

SPEAKER(S)

Does "Big Data" for Enhanced Recruiting Invade Patient Confidentiality?
Lea Studer
Senior Vice President of Marketing Communications, SCORR Marketing

#358 Track 02 – Project /Portfolio Management and Strategic Planning

Related Interest Area(s): PM, PETD

4:00–5:00PM | Level: ● | Format: WORKSHOP

Room 102AB | *CME, Nursing, and PMI PDUs*

Don't Shoot the Messenger: Techniques for Delivering the Hard Messages

CHAIRPERSON

Diane Neiman, MBA
Director, Global Project Management, Merck & Co., Inc.

Facilitator
Karla Childers, MS
Senior Director, Strategic Projects, Office of the Chief Medical Officer, Johnson & Johnson

#359 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, QC, RD, IT

4:00–5:15PM | Level: ■ | Format: FORUM

Room 111AB | *CME and Nursing*

Addressing Dysfunction in Provider Prequalification: A New Model to Streamline Processes, Improve Quality, and Reduce Risk

CHAIRPERSON

Dawn M. Niccum, BSN, MS, RN, PMP
Associate Director, Quality, Endocyte

Panelists
Marta Haley Fields, MBA
Senior Director, Compliance and Quality Systems, Seattle Genetics, Inc.

Mitchell A. Katz, PhD
Head of Clinical Research and Drug Safety Operations, Purdue Pharma L.P.

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

Sean Y. Kassim, PhD
Director, Office of Study Integrity and Surveillance, Office of Translational Sciences, CDER, FDA

#360 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): BT, CMC/GMP, QA/QC, RD, CR, PM

4:00–5:00PM | Level: ■ | Format: SESSION

Room 105AB | *CME and Nursing*

Biomarkers and Sample Stability: Bottlenecks in Study Planning, Ensuring Sample Stability as the Key for Reliable Lab Results

CHAIRPERSON

Hermann Schulz, DrMed
Executive Vice President, Synlab Pharma Institute, Germany

SPEAKER(S)

Piecing Together a Successful Biomarker Strategy: A Catalyst for Precision Medicine
Paul Travis
Executive Director, Medpace, Inc.

Ensuring Sample Stability When Handling Biomarkers
Hermann Schulz, DrMed
Executive Vice President, Synlab Pharma Institute, Germany

#361 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): SE, CR, ROD, RD

4:00–5:00PM | Level: ■ | Format: SESSION
Room 203AB | *CME, Pharmacy, and Nursing*

Protocol Endpoints: A Clear Map to Navigate the Yellow Brick Road and the End of Endpoint-Creep

CHAIRPERSON

Anne B. Cropp, PharmD
Vice President, Pfizer Inc

SPEAKER(S)

The ABCs of Writing Effective Clinical Study Protocols
Julia Forjanic Klapproth, PhD
Senior Partner, Trilogy Writing & Consulting GmbH, Germany

#362 Track 07 – Technology/Data/Records and Submissions

Related Interest Area(s): CDM, RA, QA/QC, EC

4:00–5:15PM | Level: ■ | Format: SESSION
Room 204C | *CME, Pharmacy, and Nursing*

Risk-Based Monitoring: Best Practices in Implementation for the Data Manager and Key Stakeholders

CHAIRPERSON

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

SPEAKER(S)

Lessons Learned in Implementing Risk-Based Monitoring and eSource: The Data Manager's Expanded Role
Vadim Tantsyura, DrPH, MA, MS
Director, Data Management, Target Health Inc.

Risk-Based Monitoring Best Practices for the Data Manager: Lessons Learned from Sponsors and Sites
Amita Malik, MS
Senior Manager, Product Management, Oracle Health Sciences

Data Quality Oversight
Erik Doffagne, MSc
Product Manager, CluePoints, Belgium

#363 Track 08A – Regulatory Affairs

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

4:00–5:15PM | Level: ■ | Format: SESSION
Room 201B | *CME, Pharmacy, and Nursing*

Expedited Reviews and Other Pathways to Speed Up Access to Medicines

CHAIRPERSON

Stella C.F. Blackburn, MD, MA, MSc, FFPM, FISPE, FRCP
Vice President, Global Head of Risk Management, Real World & Late Phase Research, Quintiles Inc., United Kingdom

SPEAKER(S)

Sooner or Later? Cost and Benefit of Utilizing Rolling Reviews in US and Japan
Toshiyoshi Tominaga, PhD
Associate Executive Director (for International Programs), Pharmaceuticals and Medical Devices Agency (PMDA), Japan

EU Adaptive Pathways Process
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency, European Union

Expedited Reviews and Using Postmarketing Data to Supplement Clinical Trials
Gerald J. Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER, FDA

#364 Track 08B – Regulatory Affairs

Related Interest Area(s): SP, RA, BT

4:00–5:15PM | Level: ■ | Format: SESSION
Room 204B | *CME and Nursing*

Cell and Gene Therapies: Current Global Landscape

CHAIRPERSON

Gopalan Narayanan, MD, FFPM, FRCP
Biologics and Advanced Therapies Expert, NDA Group, United Kingdom

SPEAKER(S)

Examining the Global Regulatory Environment and Scientific Landscape for Gene Therapy Clinical Trials
Victoria Rocchi
Senior Regulatory Affairs Specialist, AnGes, Inc.

Regulation of Cell Therapy Products in Asia
Chao-Yi Wang, MSc
Director, Division of Medicinal Products, TFDA

New Approach to Development of Regenerative Medicines in Japan
Noriaki Murao, MS
Representative, NM Consulting, Japan

#365 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD

4:00–5:15PM | Level: ■ | Format: FORUM
Room 103A | *CME, Pharmacy, and Nursing*

Cross-Labeling of Drugs and Devices: How Can It Be Done?

CHAIRPERSON

Heidi F. Gertner
Partner, Hogan Lovells US LLP

Panelists
Lene Garde Sommer
Vice President, RA Devices, Novo Nordisk A/S, Denmark

Diane Macculloch Johnson, MS
Senior Director, North American Policy and Intelligence, Johnson & Johnson

John Barlow Weiner
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner, FDA

#366 Track 10 – Public Policy/Health Care Compliance/Law

Related Interest Area(s): PPLC, RA, CR

4:00–5:15PM | Level: ■ | Format: SESSION
Room 202AB | *CME, Pharmacy, and Nursing*

Infectious Disease Containment and Lessons Learned

CHAIRPERSON
Ekopimo O. Ibia, MD, MPH, FRCP
Director, Medical Safety Review, Merck & Co., Inc.; FDA Alumni Association International Network

SPEAKER(S)

How Can We Develop Medicinal Products for Emerging Disease?
Junko Sato, DrSc, PhD
International Coordination Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Regulatory Response and Pathways for Licensure of Ebola Virus Vaccines: FDA Perspective
Sara Gagneten, PhD
Associate Division Director, Policy, Office of Vaccines Research and Review, CBER, FDA

Ethical Perspective
Walter Straus, MD, MPH, FACP
Associate Vice President, Therapeutic Area Head, Clinical Safety and Risk Management, Merck & Co., Inc.

#367 Track 11A – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): QA/QC, CR

4:00–5:00PM | Level: ■ | Format: SESSION
Room 204A | *CME and Nursing*

Quality at the Edge(s): Design It Right and Keep It Going in Non-Interventional Studies

CHAIRPERSON
David William Fryrear, MSc
Senior Director, Clinical and Pharmacovigilance Quality Assurance, AbbVie Inc.

SPEAKER(S)

A Proactive QRM Framework that Breaks Down Functional Silos and Drives Higher Quality into Clinical Trials
Tim Strauss, MS
President, Quality Solutions, QI Path

Sponsor Oversight of Non-Interventional Research
Christine R. Sahagian, MS
Head, Clinical and Medical Quality Assurance and Compliance, Shire US Inc.

#368 Track 11B – Innovative Approaches to Ensuring Quality in Clinical Trials and Compliance to Good Clinical Practice (GCP)

Related Interest Area(s): GCP

4:00–5:00PM | Level: ■ | Format: SESSION
Room 201A | *CME and Nursing*

Conducting Trials in China

CHAIRPERSON
Daniel Liu, PhD, MSc
Chief Scientific Officer, Beijing Clinical Service Center, China

SPEAKER(S)

Overview of Steps to Doing a Clinical Trial in China
Daniel Liu, PhD, MSc
Chief Scientific Officer, Beijing Clinical Service Center, China

Risk-Based Monitoring and Enrollment Pattern Analysis: Efficient Approaches for the Assessment Required by CFDA
Wenjun Bao, PhD
Chief Scientist and R&D Manager, SAS Institute Inc.

CFDA Perspective
Fudong An
Vice Director General, Information Center, China Food and Drug Administration (CFDA), China

#369 Track 12 – Pharmaceutical Quality

Related Interest Area(s): QA/QC, MF, IT

4:00–5:15PM | Level: ■ | Format: SESSION
Room 109AB | *CME, Pharmacy, and Nursing*

Innovative and Emerging Technologies

CHAIRPERSON
Daniel Blackwood
Director, Pharmaceutical Science Technology and Innovation, Pfizer Inc

SPEAKER(S)

Process Validation for Lyophilized Drug Products: Developing a Program for Continued Process Verification
Karen Bossert, PhD, RPh
Vice President, Scientific Affairs, Lyophilization Technology, Inc.

Portable, Continuous, Miniature, and Modular: An Integrated Development and Manufacturing System for Solid Oral Dossage Forms
Daniel Blackwood
Director, Pharmaceutical Science Technology and Innovation, Pfizer Inc

API Particle Engineering: Bridging Primary and Secondary Processes for Continuous Oral Solid Dose Manufacturing
Sonja A. Sharpe, PhD
Technology Development Leader, Advanced Manufacturing Technologies, GlaxoSmithKline

#370 Track 13 – Comparative Effectiveness Research/Global Health Outcomes and Economics

Related Interest Area(s): PR, MDD

4:00–5:15pm | Level: ■ | Format: FORUM
Room 107AB | *CME, Pharmacy, and Nursing*

Pricing, Patient Access, and What's Next for Today's Biopharma and Devices

CHAIRPERSON

Jane Horvath, MHA
Market Access Lead, 3D Communications

Panelists

Matt Salo
Executive Director, National Association of Medicaid Directors

Michael Gray, MBA
Vice President and Chief Operating Officer, The Resource Group, Ascension

John Hoffman, MBA
Senior Director, Health Policy, Advocacy and Quality, Johnson & Johnson

#371 Track 14A – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP, CR

4:00–5:00pm | Level: ■ | Format: SESSION
Room 113A | *CME, Pharmacy, and Nursing*

FDA and PatientsLikeMe: Exploring the Use of Patient-Generated Data in Drug Safety

CHAIRPERSON

Ben Heywood, MBA
President and Co-Founder, PatientsLikeMe

SPEAKER(S)

Patient-Generated Data in Drug Safety
Sally Okun, RN
Vice President, Advocacy, Policy and Patient Safety, PatientsLikeMe

Systematic Exploration of Patient-Generated Health Data for Use in Postmarketing Safety Monitoring
Carol Pamer
General Health Scientist, Office of Surveillance and Epidemiology, CDER, FDA

FDA Perspective
Sonja Brajovic, MD
Medical Officer, Office of Surveillance and Epidemiology, CDER, FDA

#372 Track 14B – Clinical Safety and Pharmacovigilance

Related Interest Area(s): MW, CP

4:00–5:00pm | Level: ■ | Format: FORUM
Room 113C | *CME and Nursing*

Impact of the European Medicines Agency's Medical Literature Monitoring Service on Pharmacovigilance Processes

CHAIRPERSON

Vineet Kacker, PhD
Managing Director and Co-Founder, APCER Life Sciences, United Kingdom

SPEAKER(S)

EMA Medical Literature Monitoring Service: Impact on EU Pharmacovigilance
Vineet Kacker, PhD
Managing Director and Co-Founder, APCER Life Sciences, United Kingdom

Authority-Based Medical Literature Monitoring in the EU: Impact on US and Global Pharmacovigilance
Leonardo Ebeling, MD, PhD
General Manager, Dr. Ebeling & Assoc. GmbH, Germany

#373 Track 14C – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP, CR

4:00–5:15pm | Level: ■ | Format: SESSION
Room 113B | *CME and Nursing*

Safety Reporting Pitfalls and Successes for Oncology and Hematology Drugs

CHAIRPERSON

Tamy Kim, PharmD
Associate Director for Regulatory Affairs, Office of Hematology and Oncology Products, CDER, FDA

FDA Perspective
Suranjan De, MBA, MS
Deputy Director, Regulatory Science, Office of Surveillance and Epidemiology, CDER, FDA

A Large Pharma's Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting
Nina Stuccio, DO
Therapeutic Area Lead, Clinical Safety and Risk Management, Oncology and Bone, Merck Research Laboratories

#374 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST

4:00–5:00pm | Level: ■ | Format: FORUM
Room 108A | *CME and Nursing*

Design and Execution of Futility Analysis Using Real-World Case Studies: Key Considerations

CHAIRPERSON

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

SPEAKER(S)

The Futility of Futility Analysis
Imogene McCanless Dunn, PhD, MA, MS
Senior Vice President, Biometrics and Regulatory Affairs, Vtv Therapeutics

Design of Futility Analysis in a Phase 3 Clinical Trial
Feng Liu, MS, MSc
Manager, Statistics, GlaxoSmithKline

#375 Track 16A – Professional Development

Related Interest Area(s): PETD

4:00–5:00PM | Level: ■ | Format: SESSION
Room 112AB | *CME and Nursing*

Creating Competent Clinical Research Professionals Through Systematic Evidence Review

CHAIRPERSON

Lisa Palladino Kim, MS
Faculty, Rutgers, The State University of New Jersey

SPEAKER(S)

Using a Meta-Analytic Method to Build Rigorous Thinkers for Clinical Trial Sciences
James Scott Parrott, PhD
Associate Professor, Rutgers, The State University of New Jersey

CRO Perspective
Otis Johnson, PhD, MPA
Vice President, Feasibility & Clinical Informatics, ICON, Plc

#376 Track 17 – Rare/Orphan Diseases

Related Interest Area(s): ROD, CR

4:00–5:15PM | Level: ■ | Format: SESSION
Room 103C | *CME, Pharmacy, and Nursing*

Pediatric Rare Disease Drug Development

CHAIRPERSON

Kinnari Patel, PharmD, MBA
Vice President, Head of Regulatory, Pharmacovigilance, and Compliance, Rocket Pharmaceuticals

SPEAKER(S)

FDA Perspective
Mary Dianne Murphy, MD
Director, Office of Pediatric Therapeutics, Office of Special Medical Programs, FDA

THURSDAY, JUNE 30

Registration Hours:

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

8:00–9:00AM

Coffee and Light Refreshments

Room 108 Concourse

#401 Track 19A

DIAmond SESSIONS

Related Interest Area(s): RA

9:00–10:30AM | Level: ■ | Format: FORUM
Room 114 | *CME, Pharmacy, and Nursing*

EMA/FDA Question Time

CHAIRPERSON

Sabine Haubenreisser, PhD, MSc
Liaison to the US FDA, European Medicines Agency, European Union

Sandra L. Kweder, MD, FACP
Deputy Director, Liaison to the EMA, Office of International Programs, Office of the Commissioner, FDA

Panelists

Emer Cooke, MBA
Head of International Affairs, European Medicines Agency, European Union

Dara Corrigan
Associate Commissioner, Office of Global Regulatory Policy, FDA

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Jordi Llinares Garcia, MD, MSc
Head of Product Development Scientific Support Department, European Medicines Agency, European Union

Anabela Marcal, PharmD
Head of Compliance and Inspections Department, European Medicines Agency, European Union

Heidi C. Marchand, PharmD
Assistant Commissioner, Office of Health and Constituent Affairs, Office of the Commissioner, FDA

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

Isabelle Moulon, MD
Head of Patients and Healthcare Professionals Department, European Medicines Agency, European Union

#402 Track 19B

DIAmond SESSIONS

Related Interest Area(s): CR

9:00–10:30AM | Level: ■ | Format: FORUM
Room 103ABC | *CME, Pharmacy, and Nursing*

Protocol Development Is a Team Sport

CHAIRPERSON

Richard Murray, DrMed, MD, FACP
Vice President and Deputy Chief Medical Officer, Merck & Co., Inc.

Panelists

Steven Taylor, MBA
Chief Executive Officer, Sjogren's Syndrome Foundation

Andy Lee, MA
Senior Vice President, Head of Global Clinical Trial Operations, Merck & Co., Inc.

Christine Pierre, RN
President, Society for Clinical Research Sites

Michael Krams
Vice President, Quantitative Sciences, Janssen Pharmaceuticals, Inc.

10:30–10:45AM

Coffee Break

Room 108 Concourse

#403 Track 01 – Clinical Operations

Related Interest Area(s): CR, PC, RA

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 108B | *CME, Pharmacy, and Nursing*

Running Personalized Medicine Trials: Facts and Figures

CHAIRPERSON

Jane E. Myles, MS
Head, Operational Intelligence and Innovation, Genentech, A Member of the Roche Group

SPEAKER(S)

Challenge and Change in Personalized Medicines: A Survey of Industry Perspectives
Christopher Paul Milne, DVM, JD, MPH
Director of Research and Research Associate Professor, Tufts Center for the Study of Drug Development

FDA Perspective
Michael Pacanowski, PharmD, MPH
Associate Director for Genomics and Targeted Therapy, Office of Clinical Pharmacology, CDER, FDA

#404 Track 03 – Innovative Partnering Models and Outsourcing Strategies

Related Interest Area(s): OS, RD, SP

10:45AM–12:00PM | Level: ● | Format: SYMPOSIUM
Room 112AB | *CME and Nursing*

Bringing CRO Collaboration into the 21st Century

CHAIRPERSON

Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

SPEAKER(S)

Optimizing Collaboration Between Sponsors and CROs Using CTMS in Today's eClinical Landscape
Lynn Fraser, MS
Product Manager, BioClinica, Inc.

Outsourcing and the Clinical Data Mess, and Why It Isn't Acceptable
Matthew J. Kiernan, MBA
Partner, Pharmica Consulting

Building an Integration Platform for Collaborating with CROs
Srinivas Karri, MSc
Director, Clinical Warehousing Cloud Strategy, Oracle Corporation, United Kingdom

#405 Track 04 – Preclinical and Translational Development/Early Phase Clinical Development

Related Interest Area(s): PC, OS

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 107AB | *CME and Nursing*

Hot Button Protocol and Operational Issues Between Sponsors and Sites in Clinical Pharmacology Studies

CHAIRPERSON

Gary L. Steinman, MS
President, Medexetech

SPEAKER(S)

Tales from the Front Lines: An Introduction
Gary L. Steinman, MS
President, Medexetech

Panelists

William B. Smith, MD
President, New Orleans Center for Clinical Research

Mary L. Westrick, PhD
Adjunct Professor, University of Wisconsin

#406 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

Related Interest Area(s): MW, CR, CP, SUBS

10:45AM–12:00PM | Level: ◆ | Format: SESSION

Room 113A | *CME and Nursing*

Navigating Partnerships and Submissions: Best Practices for Successful Medical Writing Deliverables Involving Multiple Stakeholders

CHAIRPERSON

Tammy Franklin, MSc
Senior Director, Head of Global Medical Writing, UCB

SPEAKER(S)

Sponsor Companies as Partners: Tips for Creating a Successful Partnership for Medical Writing
Tammy Franklin, MSc
Senior Director, Global Medical Writing, UCB

A Specialized Strategic Medical Writing Partnership: A Case Study
Timothy D. Garver, PhD
Chief Operating Officer and Executive Vice President, Impact Pharmaceutical Services, Inc.

Partnerships in Action: Learning from Real-Life Submissions Involving Multiple Stakeholders
Angela Campbell, PhD
Principal Medical Writer, Shire Pharmaceuticals

#407 Track 07A – Technology/Data/Records and Submissions

Related Interest Area(s): EC, CDM, PPLC, RA, CR, IT

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

Room 111AB | *CME, Pharmacy, and Nursing*

Successful Application of Wearables and Remote Monitoring in Clinical Trials: Lessons Learned and Future Progress

CHAIRPERSON

John H. Bunch
Senior Innovation Project Manager, PPD

SPEAKER(S)

Internet of Medical Things (IoMT) and Clinical Development: Challenges and Opportunities
Yury Rozenman
Director, Business Development, Qualcomm Life

How to Get From Unknown Unknowns to Known Unknowns
Tilo Hache, MBA
Work Stream Leader Mobile Patient Data, Novartis Pharma AG, Switzerland

#408 Track 07B – Technology/Data/Records and Submissions

Related Interest Area(s): SUBS, CDM, IT, RA

10:45–11:45AM | Level: ● | Format: SESSION

Room 109AB | *CME and Nursing*

Securing Internet-Driven Collaboration in Drug Development

CHAIRPERSON

Mollie Shields-Uehling
President and Chief Executive Officer, Safe-BioPharma Association

SPEAKER(S)

Industry Perspective
Andrew Porter
Director of Enterprise Architecture, Merck & Co., Inc.

#409 Track 09 – Medical Devices/In Vitro Diagnostics and Combination Products

Related Interest Area(s): MDD, PPLC

10:45AM–12:00PM | Level: ● | Format: SESSION

Room 113C | *CME, Pharmacy, and Nursing*

Current Status of Genetic Testing in Medical Therapies: What Regulations We May Need in a Convergent Regulatory Environment

CHAIRPERSON

Joseph C. Scheeren, PharmD
Senior Vice President, Head Regulatory Affairs, Pharma and Consumer Health, Bayer Consumer Care AG, Switzerland

SPEAKER(S)

Patient Perspective
Sue Friedman
Executive Director and Founder, Facing Our Risk of Cancer Empowered (FORCE)

Industry Perspective
Morten Sogaard, PhD
Vice President and Head, Enterprise Scientific Technology Operations, Pfizer Inc

Regulator Perspective
Robert Schuck, PharmD, PhD
Clinical Pharmacologist, Genomics and Targeted Therapy, Office of Translational Sciences, CDER, FDA

#410 Track 14 – Clinical Safety and Pharmacovigilance

Related Interest Area(s): CP

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 113B | *CME, Pharmacy, and Nursing*

The Role of Big Data in Transforming the Detection of Adverse Drug Reactions

CHAIRPERSON
Rave Harpaz, PhD
Senior Research Scientist, Oracle Health Sciences

SPEAKER(S)

Harnessing Scientific Literature Reports for Pharmacovigilance: FDA Perspective
Alfred Sorbello, DO, MPH
Medical Officer, Office of Translational Sciences, CDER, FDA

Maximizing Data Sources for Signal Detection: Pharmaceutical Company Perspective
Amy Purrington, MD
Safety Surveillance Physician, Lead Immunology TA, Janssen Pharmaceuticals, Inc.

Social Media Mining for Public Health Monitoring and Surveillance
Representative Invited
Associate Professor, Department of Biomedical Informatics, Arizona State University

#411 Track 15 – Statistical Science and Quantitative Thinking

Related Interest Area(s): ST, CMC/GMP

10:45AM–12:00PM | Level: ■ | Format: SESSION
Room 108A | *CME, Pharmacy, and Nursing*

Nonclinical Statistics for Chemistry, Manufacturing, and Control: Case Studies and Regulatory Perspective

CHAIRPERSON
Surya P. Chitra, PhD, MBA
Consultant, Biostatistics and Statistical Programming, Savio Group Inc.

SPEAKER(S)

A Case Study of Statistical Analysis of Integration Site Assay in the Application of Gene Therapy
Shu Zhang, PhD
Statistician, GlaxoSmithKline

Overview of CMC Area Statistics
Cassie Dong, PhD
Mathematical Statistician, Division of Biometrics VI, Office of Translational Sciences, CDER, FDA

Quality by Design Case Studies for Biologics/Biosimilars
Charles Li, MS
Statistician, Teva Pharmaceuticals

#412 Track 18 – Global Regulatory

Related Interest Area(s): RA

10:45AM–12:00PM | Level: ■ | Format: FORUM
Room 114 | *CME, Pharmacy, and Nursing*

CDER Town Hall

CHAIRPERSON
Nancy D. Smith, PhD
Adjunct Professor, Temple University, FDA Alumni

Panelists

Leah Christl, PhD
Associate Director for Therapeutic Biologics, Therapeutic Biologics and Biosimilars, Office of New Drugs, CDER, FDA

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

John K. Jenkins, MD
Director, Office of New Drugs, CDER, FDA

Michael Kopcha, PhD, RPh
Director, Office of Pharmaceutical Quality, CDER, FDA

Theresa M. Mullin, PhD
Director, Office of Strategic Programs, CDER, FDA

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

Student Poster Session

Monday, June 27, 9:30AM–6:00PM | Posters will be displayed in Exhibit Hall A
*Award Ceremony at 5:30PM | DIA Booth #1425

This year's Student Poster Program features more than 25 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 at 5:30PM on Monday at the DIA Booth #1425.

M 01 A Gap Analysis of Marketers' Approach to Marketing of Pharmaceuticals and the Essential Functions of Marketing in Pharma 3.0
Sarthak Athavle, MBA
SPP SPTM, SVKM - NMIMS College, India

M 02 Factors Influencing Quality Decision Making in Medicines Development and Regulatory Review
Magdalena Bujar, MSc
University of Hertfordshire, United Kingdom

M 03 Analysis of Postmarket Safety Labeling Changes: Comparison of Expedited Versus Standard NDA Approvals
Adam Chin
Touro College of Pharmacy

M 04 The Key Issues of the Trial Subjects' Protection During First in Human and Bioequivalence Studies
Tetyana Kolodyezna
National University of Pharmacy, Ukraine

M 05 Risk-Based Monitoring: A Global Study Focusing on Perception and Merits Among Clinical Investigational Sites
Prajna Kumar, MLAS
Texila American University

M 06 Analysis of Off-Patent Pharmaceutical Price Increases: 2013-2016
Reshma Lakhram
Touro College of Pharmacy

M 07 Synergetic Prevention of Sudden Death by ACEI, Statin and Gliflozin in Type 2 Diabetes: A Simulation Study
Hai-Ha Le, DrPH, MPharm
Claude Bernard Lyon 1 University, France

M 08 Formulary Processes of Major Countries
Yen Ping Lim, MPharm
National University of Singapore, Singapore

M 09 Evaluation and Characterization of Health Economics and Outcomes Research in SAARC Nations
Manthan Mehta
Topiwala National Medical College & BYL Nair Charitable Hospital, India

M 10 Factors That Affect Market Share of Biosimilars Against Reference Biologics
Christopher Milan
Touro College of Pharmacy

M 11 Best Practices for the Design and Dissemination of Patient Medication Information: A Systematic Review
Rebecca Mullen, MS
Northwestern University

M 12 Impact of Smartphone Use in Health Care by Providing Smartphones to Patients: A Systematic Review
Mehdi Namil
University of North Texas Health Science Center

M 14 Pediatric Opiod Exposures and Poisonings: Prevalence and Characteristics
Anisha Patel, MS
Virginia Commonwealth University School of Pharmacy

M 15 Identifying Symptoms and Functional Impact Reported by Persons with Multiple Sclerosis: A Qualitative Literature Review
Mira Patel, MS
University of Arizona

M 16 Direct-to-Consumer Television Marketing of Oncology Products in the US
Shivani Shah
Rutgers, The State University of New Jersey

M 17 Unique Pharmaceutical Market and Pricing System in Japan: Suggestions to Global Pharma for Effective Market Penetration
Shoyo Shibata, RPh
Keio University, Japan

M 19 Adherence to Guideline on Use of Analgesics in Patients with First Myocardial Infarction Event: A Stepped-Care Approach
Myung Suk Yang, MPharm
Chung-Ang University, Republic of Korea

M 20 Three Decades Research Advances in Pharmaceutics and Drug Delivery Systems: A Global View of Big Data
Weixiang Zhang, MSc
University of Macau, Macao

M 21 Benefit-Risk Assessment of HPV Vaccination Program in Japan
Tomoko Matsumoto
Gifu Pharmaceutical University, Japan

M 22 Trends in Endpoint Selection in Clinical Trials of Advanced Breast Cancer
Seung Yeon Song, MPharm
Chung-Ang University, Republic of Korea

M 23 Global Effects of FDA Guidance Requiring Evaluation of Cardiovascular Risk in New Antidiabetic Therapies on Drug Development
Daichi Mori
Gifu Pharmaceutical University, Japan

M 24 Evaluation of the Appropriateness of Mupirocin Prescription in the Ambulatory Setting
Jinuk Suh, MPharm
Chung-Ang University, Republic of Korea

M 25 Do Clinical Trials Conducted in India Match its Health Care Needs? An Audit of Two Clinical Trials Registries
Mansi Chaturvedi
Seth GS Medical College and KEM Hospital, India

M 26 Do Drugs Interact Together in Cardiovascular Prevention? A Meta-Analysis of Powerful Randomized Controlled Trials
Mor Fall, DrPH, PharmD, MPharm, MSc, RPh
University Cheikh Anta Diop, Senegal

M 27 Evaluation of Public Awareness and Impact of the Turkish Regulatory and Reimbursement Processes on Patients' Access to Medicines
Emel Mashaki Ceyhan, MBA, MPharm
Cardiff University, Turkey

The content noted on this page was made available to DIA as of May 24, 2016.

Professional Poster Sessions

Selected Life Sciences Professionals from all fields related to the mission of DIA will participate in this year's Professional Poster Program. There will be various oral presentations where poster authors will deliver a five to eight minute overview of their work. Presentations will be held in the Poster Area located in Exhibit Hall Entrance A.

Professional Poster Session 1 | Tuesday, June 28, 9:00AM–5:00PM

T 01 Cost Effectiveness Analysis of HLA-B5801 Genotyping in the Treatment of Gout Patients with Chronic Renal Insufficiency
Gaeun Kang, MD
Chonnam National University Hospital, Republic of Korea

T 02 Practical Aspects of Developing, Implementing and Using Facilitated Regulatory Pathways (FRPs) in the Emerging Markets
Lawrence Liberti, MS, RPh, RAC
Centre For Innovation In Regulatory Science (CIRS)

T 03 Sponsor Attitudes and Behaviors on Patient Recruitment: Insights from Line Management Clinical Operations Personnel
Dan McDonald
Imperial

T 04 Missing ePRO Data: Impacts on Clinical Trial Results
ORAL PRESENTATION SCHEDULED: Session 1A 9:40–9:50AM
Elisa Holzbaur, PMP
Almac Group

T 05 Compare the Quality of Case Reports Originating from Social Media with Spontaneous Case Reports by Evaluating Case Attributes
Samarth Parikh, PharmD
Janssen Pharmaceutical Companies of Johnson & Johnson

T 06 Logistics and Distribution Challenges: Emerging Pharma Markets
Harshal Patil, MBA
Cognizant, United Kingdom

T 07 Strong Considerations for Self-Reporting Prospective Suicidal Ideation Using the eC-SSRS
Huda Shalhoub, PhD
ERT

T 08 Cost Drivers of a Hospital Acquired Bacterial Pneumonia and Ventilator Acquired Bacterial Pneumonia (HABP/VABP) Phase III Clinical Trials
Stella Stergiopoulos
Tufts Center for the Study of Drug Development

T 09 Albuminuria in Cardiovascular Outcome Trials: Balancing Event and Recruitment Rates
ORAL PRESENTATION SCHEDULED: Session 1A 10:00–10:10AM
Rafal Ziecina
Quintiles, United Kingdom

T 10 Teething Problems of Global Harmonization with Regard to Bioequivalence Assessment: Proton Pump Inhibitors
E. Dennis Bashaw, PharmD
FDA

T 11 Bridging the Gap: The Need for a Paradigm Shift in Clinical Trial Design to Ensure Continued Patient Access to Medicines
ORAL PRESENTATION SCHEDULED: Session 1A 10:10–10:20AM
Richard Macaulay, PhD
PAREXEL Access Consulting, United Kingdom

T 12 Special Safety Considerations for Gene Therapy Products in Global Clinical Development
ORAL PRESENTATION SCHEDULED: Session 1B 12:00–12:10PM
Colleen Davenport, PhD
AnGes, Inc.

T 13 Going Beyond Data Virtualization: Advancing Research with a Transformational Informatics Platform
ORAL PRESENTATION SCHEDULED: Session 1B 12:10–12:20PM
Rick Hart
BioStorage Technologies, Inc.

T 14 The Conundrum of Fracture Risk in Users of Proton Pump Inhibitors: A Retrospective Analysis
Elena Dubcenco, DrMed, MS
Robarts Clinical Trials Inc./University of Western Ontario, Canada

T 15 Impact of Risk Evaluation Mitigation Strategy on Use of Erythropoiesis-Stimulating Agents
Kristen Hollingsworth, PhD, MBA, MPH
Johnson & Johnson

T 16 Best Practices for Medical Review Process in Clinical Research
Joshua Zhang, MD, PhD
Celldex

T 17 Mobile CRAs: Transforming Clinical Monitoring Processes through Mobile Technology
ORAL PRESENTATION SCHEDULED: Session 1B 12:20–12:30PM
Xiu Wei Lim
Quintiles, Malaysia

T 18 Comparing the Equivalence of EQ-5D-5L PROM Across Paper and Electronic Modes of Administration
ORAL PRESENTATION SCHEDULED: Session 1B 12:30–12:40PM
Chris Watson, PhD
Exco InTouch, United Kingdom

T 19 Stack, Swarm, Arc: Data Visualizations
Michelle Thompson
FDA Quality and Regulatory Consultants, LLC

T 20 US Outcomes-Based Drug Pricing: A Fad or the Future?
Michelle Hoiseth
PAREXEL International

T 21 Risk Assessment of Sites Through Risk-Based Monitoring (RBM): Do Your Monitors Agree? A Joint Case Study
Nick Hargarden, PhD, MSc
Algorics

T 22 Comparative Strengths of Public and Commercial Clinical Trials Databases: A Case Study
Diane Webb, MA
BizInt Solutions

T 23 Patient Reported Outcomes: Comparison of Required Data Cleaning Efforts for ePRO Versus Paper
ORAL PRESENTATION SCHEDULED: Session 1B 12:40–12:50PM
Jennifer Ross, MEd, MS
Almac Clinical Technologies LLC

T 24 Patient Recruitment on Social Media: a Qualitative Analysis of Strategies by Pharmaceutical Companies on Facebook and Twitter
ORAL PRESENTATION SCHEDULED: Session 1B 12:50–1:00PM
Joseph Fiore
Merck & Co., Inc.

T 25 Cultural Adaptation of the TOMMORROW Cognitive Battery in Russia, Switzerland, and Italy
Alexandra Atkins, PhD
Neurocog Trials

T 26 The Impact of Regulatory Policy on the Development of Clinical Trials in Taiwan
Jessica Chou
TCDE

T 27 So You Want to Influence Stakeholders...Now What? How Outreach Programs can Advance Clinical Research
Jui Shah, PhD
National Institutes of Health (NIH)

T 28 **Maximizing Awareness of Post-PharmD Opportunities in Industry Through Targeted National and Regional Recruitment Initiatives**
Lucie Vu, PharmD, MSc
MCPHS University

T 29 **Risk of Asthma Attacks is Increased in Association With Nonsteroidal Anti-Inflammatory Drugs Adjusting for Season Effects**
Takashi Ando
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

T 30 **Identifying TPPs and Establishing CQAs to Support Commercial Product Specifications**
Carrie Shults
Lyophilization Technology, Inc.

T 31 **Comparison of Feature Encoding Methods for Automated Document Classification in Adverse Event Detection**
Joshua Ainsley, PhD
Fino Consulting

T 32 **Disrupting Clinical Trials in The Cloud**
Eric Morrie, MBA
ClinCapture

T 33 **Utilization of National Webinars to Reach Students for Educational Opportunities: A Two Year Analysis**
Kun Yang, PharmD
MCPHS University

T 34 **Signal Analysis of Adverse Drug Reactions: Signal Detection/ Evaluation Method Formulation Using Important Risk Visualizer™**
Masahide Nakajima, PhD
Mitsubishi Tanabe Pharma Corporation, Japan

T 35 **Bridging Study Evaluation in Taiwan**
Tai Wai Shun, MD
TCDE

T 36 **Reduce Training Redundancies to Improve Clinical Trial Efficiency**
Rebecca Hummel
CNS Healthcare

T 37 **Use of a Mobile Robot to Facilitate Long Distance Professional Development Meetings For Post-Doctoral Fellows**
Ramya Mathew, PharmD, RPh
Rutgers, The State University of New Jersey

T 38 **Electronic Document Presentation During a Japan PMDA Inspection**
Camilla Lau, PMP
Gilead Sciences

T 39 **Bangladesh: A New Frontier for Global Clinical Trials**
Wasif Khan, MD, MLAS, AHIP
ICDDR,B, Bangladesh

T 40 **What's in a Number? Differences in Enrollment Rate Calculation Methodologies for Clinical Trial Planning**
Earl Seltzer, MBA
Quintiles Transnational Corp

T 41 **Enabling Global Regulatory Submission Project and Portfolio Management**
Matthew Pazdernik, MBA
Merck & Co., Inc.

T 42 **Talimogene Laherparepvec: Advanced Therapy Medicinal Product (ATMP) – A Distinct Risk Management Plan**
Heba Abdullah, MD
Amgen

T 43 **Evidence for Empirical Power Law Scaling in Adverse Event Profiles**
Shaun Comfort, MD, MBA
Genentech, A Member of the Roche Group

T 44 **Current Japanese Diabetic Mellitus Prevalence and Glucose Clamp Studies for Global Anti-Diabetic Development**
ORAL PRESENTATION SCHEDULED: Session 1A at 9:50–10:00AM
Eunhee Chung
SOUSEIKAI Global Clinical Research Center, Japan

T 45 **Evolution of e-System to Support Needs of Agile Pharmaceutical Company: A Case Study of Growing Together**
Mikhail Samsonov, MD, PhD
R-Pharm, Russian Federation

T 46 **Do Environmental Parameters Influence the Prediction of the Placebo Response?**
Dominique Demolle, PhD
Tools4patient, Belgium

T 47 **True Globalization of the PSMF and Why It's a Useful Tool for Non-EU Pharmaceutical Companies**
Beverly Gow
PrimeVigilance, United Kingdom

T 48 **Best Practices for Development or Migration of Patient-Reported Outcome Measures for use on Multiple Data Collection Modes**
Mabel Crescioni, DrPH, JD, LLM
Critical Path Institute

T 49 **Establishment of Foreign Adverse Event Reporting System in Korea (KAERS-foreign)**
Hyun-Kyung An, MPharm, RPh
Korea Institute of Drug Safety & Risk Management, Republic of Korea

T 50 **US Trends in Drug Pricing Policy: Past, Present and Future**
Fenan Solomon, PharmD
Rutgers, The State University of New Jersey

T 51 **A Comparison of CDRH Review Times of Original PMA Applications for Products Classified as Combination versus Non-Combination**
Irene Darras, PharmD
Rutgers, The State University of New Jersey

T 52 **Evaluating the Level of Medical Information Provided for Health Care Professionals on Consumer Care Websites**
Alisha Couto, PharmD
Rutgers, The State University of New Jersey

T 53 **Calling All Patients: Using a Clinical Call Center to Perform Disease Activity Assessments to Support Treating RA to Target**
ORAL PRESENTATION SCHEDULED: Session 1B 1:00–1:10PM
Kristin Hanson, PharmD, MS
UBC: An Express Scripts Company

Professional Poster Session 2 | Wednesday, June 29, 9:00AM–4:00PM

W 01 **Clinical Development in Regulated and Unregulated Markets: Understanding Safety Reporting Requirements**
Sanjeev Miglani, MD
APCER Life Sciences

W 02 **End-to-End Change Control: An Integral Approach to Product Changes, Submissions, and Variation Management**
Denis Fung, PhD, MBA
Navitas Life Sciences Limited, United Kingdom

W 03 **Use of Text Analytics for Extraction of Evidence-Based Safety and Toxicity Findings from Textual Dossiers**
Rohini Patil
Cognizant Technology Solutions Corporation, United Kingdom

W 04 **A Value-Driven Decision Making for Drug Development Strategy**
ORAL PRESENTATION SCHEDULED: Session 2A 9:40–9:50AM
Masanori Ito, PhD
Astellas Pharma Global Development Inc.

W 05 Unusual Data Pattern Analysis in a Large Pharmaceutical Company
ORAL PRESENTATION SCHEDULED: Session 2A 9:50–10:00AM
Julie Appel, MSc
Novo Nordisk A/S, Denmark

W 06 Design of Physicochemical Compatibility Studies for Sterile Injectable Products: Key Lessons from Recent Filings
Eli Zavialov, PhD
Johnson & Johnson

W 07 Effectively Evaluating Risk Minimization: Mitigating the Risk of Inadequate Assessments
Steve Mayall, PhD
Pope Woodhead & Associates Ltd., United Kingdom

W 08 Increasing the Efficiency of Investigator-Initiated Research in China
Qing Gu, PhD
Pfizer Investment Co., Ltd., China

W 09 Molecular Pathology and Standardized Testing Plays a Central Role in the Development of Targeted Drugs and Tissue CDx in Oncology
Thomas Henkel, PhD
Targos Gmbh Biomarker Services

W 10 Process and Pitfalls of Preparing Breakthrough Therapy Designation Documents
Robin Whitsell
Whitsell Innovations, Inc.

W 11 Integral Authoring: A New Paradigm for Data-Driven Structured Authoring of Documents in the Life Sciences Industry
Romuald Braun, MSc
uanotau GmbH, Switzerland

W 12 Tipping Point Sensitivity Analysis in Continuous Asthma Quality of Life Questionnaire Endpoint
Tulin Shekar, MSc
Merck & Co., Inc.

W 13 Switching Endpoints Based on an Interim Analysis
David Bristol, PhD
Statistical Consulting Services, Inc.

W 14 Evaluating REMS Burden: A Comparative Time Analysis of Three Options for REMS Stakeholders to Perform Mandatory REMS Tasks
ORAL PRESENTATION SCHEDULED: Session 2A 10:00–10:10AM
Jennifer Chapman
Celgene Corporation

W 15 Applications of Expanded Access/Compassionate Use Programs for Evidence Generation
ORAL PRESENTATION SCHEDULED: Session 2A 10:10–10:20AM
Marielle Bassel
UBC: An Express Scripts Company, Canada

W 16 An Investigation Into the Distribution of BRCA 1/2 Mutation/Ness Breast and Ovarian Cancer Populations
Bhavish Lekh, MSc
Quintiles, United Kingdom

W 17 Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names
Lubna Merchant, PharmD
FDA

W 18 Quality Consistency Assessment for Botanical Medicines using Chromatographic Fingerprint
Cassie Dong, PhD
FDA

W 19 Implementing and Monitoring the Use of Interactive Risk Communications
Mark Perrott, PhD
Pope Woodhead and Associates Ltd., United Kingdom

W 20 Digital Health Networks as a Change Agent of Public Perceptions for Clinical Trials
ORAL PRESENTATION SCHEDULED: Session 2B 12:00–12:10PM
Jessie Lee, MA
Quintiles, Singapore

W 21 Utilizing Simulations to Enhance Randomization Methodology Decision Making
ORAL PRESENTATION SCHEDULED: Session 2B 12:10–12:20PM
Kevin Venner
Almac Clinical Technologies

W 22 Best Practices for Pregnancy Outcome Monitoring in the Post Marketing Environment
Maureen McGee, BSN, RN
Merck & Co., Inc.

W 23 Use of Juvenile Animal Studies to Support Oncology Medicine Development in Children
Dinah Duarte, PharmD, MSc
INFARMED, Portugal

W 24 Innovation in Regulatory Science: Development and Validation of an Instrument for Assessing the Quality of Decision Making
Stuarrt Walker, PhD
Center For Innovation in Regulatory Science (CIRS)

W 25 Industry-Based Pharmacists and Moonlighting: Remaining Current in Clinical Practice
Joseph Fulginiti, PharmD
Rutgers, The State University of New Jersey

W 26 Impact of Internal Data Review and Source Data Review on Overall Data Integrity
Ron Taylor
Seattle Genetics, Inc.

W 27 Is the World's Third Largest Pharmaceutical Market Ready for Patient-Centric Clinical Trials?
ORAL PRESENTATION SCHEDULED: Session 2B at 1:30–1:40PM
Saumya Nayak, MSc
Quintiles East Asia Pte. Ltd., Singapore

W 28 Development of a Matching Dictionary Between Lay and Corresponding Scientific Terms to Detect Web Reported Adverse Events
ORAL PRESENTATION SCHEDULED: Session 2B 12:20–12:30PM
Manon Exposito
Universal Medica, France

W 29 SC Influence on the Cost of Conducting Clinical Trials and Impact on Pricing of Related Services: Evidence from a Pilot Study
Srinivas Pai Raikar
Quintiles East Asia Pte Ltd., Singapore

W 30 Implementing Neurocognitive Testing in Clinical Trials: Facilitating Rater Administration With an iPad-Based App
Brian Saxby, PhD
NeuroCog Trials

W 31 Impact of Biosimilars in Clinical Practice and Clinical Research: Results of Questionnaire-Based Survey
Nithin Sashidharan
Pharm-Olam International, India

W 32 Geo-Political Analysis of Phase 3 Clinical Trial Recruitment: Changes in 2015
Colin Miller, PhD
Brackendata

W 33 A Comparison of Single-Dose Pharmacokinetics Studies in Subjects with Various Degrees of Renal Impairment
Julie Massicotte
Algorithme Pharma Inc., Canada

W 34 Urodynamic Measurement of Urethral Closure Function in Healthy Japanese Women: A Single Dose Study of Duloxetine
ORAL PRESENTATION SCHEDULED: Session 2B at 1:20–1:30PM
Yumi Inoue
SOUSEIKAI Global Clinical Research Center, Japan

W 35 Comparison of Manual Versus Automated Redaction Techniques for Clinical Submission Documents
ORAL PRESENTATION SCHEDULED: Session 2B 12:30–12:40PM
Rashmi Dodia
MMS Holdings, Inc.

W 36 The Influence of Atipic Antipsychotic Drugs on Vas Deferens in Mice
Pelin Tanyeri, DrMed, MD
Sakarya University, Turkey

W 37 Development of Novel Compounds for the Treatment of Intractable Epilepsy
Ming-Shian Tsai, PhD
NTU

W 38 Patient Preference for Electronic Patient Reported Outcomes: Assessment in Patients with Psoriatic Arthritis (PsA)
Celeste Elash, MS
ERT

W 39 Novel Use of a Medication Event Monitoring System to Track Rescue Medication Use in a Trial of a New Meloxicam Drug Product
ORAL PRESENTATION SCHEDULED: Session 2B 12:40–12:50PM
Clarence Young, MD
Iroko Pharmaceuticals, LLC

W 41 Engaging Patients with eClinical Technology: Incorporating Patient Preferences into Osteoarthritis Management and Care
Laura Khurana
ERT

W 42 Adaptive Design in Dose Selection Study of Next-in-Class NNRTI
ORAL PRESENTATION SCHEDULED: Session 2B 12:50–1:00PM
Natalia Vostokova, PharmD
IPHARMA LLC, Russian Federation

W 43 Pooled Continued Access Protocol for Oncology Experimental Therapeutics No Longer in Development
Daphne Farrington, MSc
Eli Lilly and Company

W 44 Social Listening for a New Product Launch and Beyond: How Does the Conversation Change Over Time?
Laurie S. Anderson, PharmD
GlaxoSmithKline

W 45 Real-Time Monitoring of the Digital Patient in Clinical Trials
Michael Phillips, PhD
ICON, Ireland

W 46 Proof of Concept for the Development of Digital Biomarker using Raw Actigraphy Data from a Wrist Wearable Device
Louis Smith, MSc
ICON Plc, Ireland

W 47 Testing for Bioequivalence in Higher-Order Crossover Designs: Two-at-a-Time Principle Versus Pooled ANOVA
Pina D'Angelo, MSc
Novum Pharmaceutical Research Services

W 48 Regulatory Turnaround Makes India an Increasingly Attractive Location for Clinical Research
ORAL PRESENTATION SCHEDULED: Session 2B 1:10–1:20PM
Suneela Thatte, MBA, MPharm
Quintiles Research india Pvt Ltd, India

W 49 Integrated Solution to Improve Eligibility Fraction and Time Factor in Patient Recruitment for Clinical Trials
ORAL PRESENTATION SCHEDULED: Session 2B 1:00–1:10PM
Nihar Parikh, PMP
Citiustech Inc.

W 51 Predicting Future State and Business Drivers of Safety System Upgrades based on Safety Database Upgrade and Industry Trends
Amanda Bowles MS
Deloitte Consulting

W 52 Visualizing Patients' ADaM Data via SAS and R
Bella Feng, PhD, MS
Amgen, Inc.

AWARD WINNERS

DIA Inspire Awards recognize significant individuals or group accomplishments in the discovery, development, or life cycle management of biopharmaceutical, device, or related therapeutic health care products, and/or exceptional volunteer contributions to advancing DIA's Mission and Vision.

GLOBAL INSPIRE AWARDS

Evaluated and selected by the DIA Fellows. Approved by DIA Board of Directors.

DNDi Drugs for Neglected Diseases *initiative*

President's Award for Outstanding Contribution to Global Health
Drugs for Neglected Diseases *initiative*

The Drugs for Neglected Diseases *initiative* (DND*i*) is a patient-needs driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable medicines for neglected diseases that afflict millions of the world's poorest people.

DND*i* focuses on developing new treatments for the most neglected patients suffering from diseases such as sleeping sickness (or Human African Trypanosomiasis), leishmaniasis, Chagas disease, malaria, specific filarial diseases, and paediatric HIV. The initiative's primary objective is to deliver 11 to 13 new treatments by 2018 and to establish a strong R&D portfolio for these diseases.

Global Connector
Toshiyoshi Tominaga, PhD
Associate Executive Director for International Programs
Pharmaceuticals and Medical Devices Agency

Excellence in Service
Isabel Drzewiecki
Managing Partner, JID Consulting

DIA Author(s) of the Year Award

Therapeutic Innovation & Regulatory Science (TIRS), DIA's official peer-reviewed scientific journal, identifies an article each year that has made a significant impact in advancing medical product development and recognizes the authors of that article as leaders in their field with the DIA Author(s) of the Year Award. This article and its authors 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.

Evaluating Source Data Verification as a Quality Control Measure in Clinical Trials Nov 01, 2014 48: 671-680
Nicole Sheetz, PharmD; Advisor of Clinical Development Innovation and Innovation Adoption, Eli Lilly and Company
Brett Wilson, BSP; Head, Monitoring Excellence, Bristol-Myers Squibb
Joanne Benedict, MS; Senior Advisor, Genentech, A Member of the Roche Group
Esther Huffman, BS; Associate Director, Global Strategic Operations, Bristol-Myers Squibb
Andy Lawton, ASTAT; Head of Biometric and Data Management, Boehringer Ingelheim
Mark Travers, PhD; Global Head, Monitoring Excellence, Merck
Patrick Nadolny, MS; Vice President, Product Management, Data & Analytics Services, PAREXEL
Stephen Young, MA; Senior Director of Transformation Services, OmniComm
Kyle Given, BA; Principal, Strategic Consulting Services, Medidata Solutions
Lawrence Florin, MBA; Clinical Leader, Life Sciences, Cognizant

REGIONAL INSPIRE AWARDS: AMERICAS

Parent Project Muscular Dystrophy
LEADING THE FIGHT TO END DUCHENNE

Outstanding Contribution to Health in the North America Region
Parent Project Muscular Dystrophy

Parent Project Muscular Dystrophy (PPMD) is the largest most comprehensive nonprofit organization in the United States focused on finding a cure for Duchenne muscular dystrophy—their mission is to end Duchenne. PPMD invests deeply in treatments for this generation of people affected by Duchenne and in research that will benefit future generations. They advocate in Washington, DC, and have secured hundreds of millions of dollars in funding. They demand optimal care and strengthen, unite, and educate the global Duchenne community. Everything PPMD does—and everything they have done since their founding in 1994—helps people with Duchenne live longer, stronger lives.

Excellence in Service
Stacey Fung, PharmD
Associate Director, Medical Communications
Genentech, A Member of the Roche Group

Excellence in Service
David Schubert
Vice President of Regulatory and Quality
Stealth BioTherapeutics

Excellence in Service
Kenneth VanLuvanee
President and Chief Executive Officer
Virtual Regulatory Solutions, Inc.

Leader of Tomorrow
Philip Masaitis, PharmD Candidate 2017
Philadelphia College of Pharmacy, University of the Sciences

FELLOWS OF DIA CLASS OF 2016

Fellow of DIA
Per Spindler, DVM, E-MBA, MSc
DIA Past President;
Director, Biopeople
University of Copenhagen

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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:

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107	Fatal Drug Trials in Phase 1: Understanding Risk, Subject Safety, Timelines, and Cost	0286-0000-16-615-L04-P	Knowledge
108	Drug/In Vitro Diagnostic Device Advertising and Promotion: Unapproved Combination Product or Awareness?	0286-0000-16-526-L01-P	Knowledge
110	Updates and Pending Issues in the US Biosimilar Environment	0286-0000-16-544-L01-P	Knowledge
111	Global Regulatory Harmonization in Asia: Is a New Trend Occurring?	0286-0000-16-551-L04-P	Knowledge
113	Clinical Developments in Immuno-Oncology, Part 1 of 2: Science, Current Methodologies, and Achievements	0286-0000-16-554-L01-P	Knowledge
114	Bringing the Trial to the Patient: Making the Patient Voice Central from Trial Design Onward	0286-0000-16-604-L04-P	Knowledge
115	Clinically Relevant Specifications: Translating Voice of the Patient Into Quality Attributes of the Product	0286-0000-16-605-L04-P	Knowledge
119	Narrative Medicine: Innovative Techniques for Including the Voice of the Patient in Clinical Trials	0286-0000-16-589-L04-P	Application
121	Rare Disease Clinical Trials: Coping with Unique Challenges	0286-0000-16-602-L01-P	Knowledge
124	Risk-Based Monitoring in Clinical Trials	0286-0000-16-518-L05-P	Knowledge
125	Patient Recruitment in Rare Diseases: Ideas and Framework for Out-of-the-Box Exploration	0286-0000-16-520-L01-P	Knowledge
126	Hope Is Not a Strategy: Quantifying Knowledge for Better Decision Making in Clinical Development	0286-0000-16-596-L04-P	Knowledge
129	Delivering Value Through Medical Information Metrics	0286-0000-16-530-L04-P	Knowledge
130	Take Two Aspirin and Text Me in the Morning: Technology Suited for 20,000 Virtual Patients on the PCORI Aspirin Trial	0286-0000-16-535-L04-P	Application
132	Electronic Implementation of New PRO Measures to Assess Treatment Benefit in Irritable Bowel Syndrome Trials: Lessons Learned	0286-0000-16-540-L01-P	Knowledge
133	Take Advantage of Global Expedited Pathways: Breakthrough, Sakigake, PRIME!	0286-0000-16-543-L04-P	Knowledge
134	How Can We Utilize Mobile Health for Better Quality of Life and Medical Economy?	0286-0000-16-561-L04-P	Knowledge
135	Clinical Developments in Immuno-Oncology, Part 2 of 2: Clinical Implementation of Biomarkers	0286-0000-16-562-L01-P	Knowledge
138	Risk Communication and Management: The Art of Communicating Risk - Challenges and Best Practices	0286-0000-16-599-L04-P	Knowledge
139	Measuring the Impact and Influence of Patient Input on Regulatory and Health Technology Assessment Decision Making: What Are the Key Considerations?	0286-0000-16-568-L04-P	Knowledge
140	Understanding, Developing, and Implementing an Anticipated Events Review Process: Adoption of the FDA IND Rule on Safety Reporting Requirements	0286-0000-16-576-L05-P	Knowledge

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203	Next Generation Collaborations: Transforming the Industry	0286-0000-16-609-L04-P	Knowledge
207	Advancing the Appropriate Use of Mobile Clinical Trials: The Clinical Trials Transformation Initiative	0286-0000-16-513-L04-P	Knowledge
212	Special Populations in Clinical Pharmacology Studies	0286-0000-16-524-L05-P	Knowledge
213	FDA Enforcement Update: Advertising and Promotion	0286-0000-16-527-L04-P	Knowledge
215	Exploring the Use of Virtual Technologies Within Medical Affairs Organizations	0286-0000-16-603-L04-P	Knowledge
218	Lessons Learned from Eight Years of Drug Development Tool/Novel Methodology Qualification	0286-0000-16-548-L04-P	Knowledge
219	Regulatory Science Considerations Applying to Novel Combinations of Biologics and Bifunctional Biologics Development	0286-0000-16-552-L01-P	Knowledge
221	Envision the Future: How Big Data and Artificial Intelligence Change Our Regulatory Environment	0286-0000-16-555-L04-P	Knowledge
222	Valuing the Clinical Trial Patient	0286-0000-16-566-L01-P	Knowledge
223	Global Harmonization: Current ICH Quality Initiatives	0286-0000-16-567-L04-P	Knowledge
224	Identifying Patient-Centered Outcomes for Use in Observational Research: Why and How	0286-0000-16-569-L01-P	Knowledge

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225	One Size Does Not Fit All: Best Practices for Right-Sized Signal Management Systems	0286-0000-16-600-L04-P	Knowledge
227	Unique Global Regulatory Considerations and Drug Development Incentives in Rare Disease and Orphan Drug Development	0286-0000-16-590-L01-P	Knowledge
236	Expanded Access: Ethical, Regulatory, and Policy Challenges and Considerations	0286-0000-16-522-L04-P	Knowledge
238	Prescription Drug Marketing Regulatory Primer	0286-0000-16-528-L04-P	Application
241	Disease Interception: Shifting the Paradigm from Treatment to Prevention of Disease	0286-0000-16-547-L01-P	Knowledge
242	Regulatory Challenges in the Development of Combination Products Involving Digital Technology	0286-0000-16-556-L04-P	Knowledge
243	Patient Involvement Today and Tomorrow: What's in It for Patients?	0286-0000-16-563-L04-P	Knowledge
246	Valuing the Signal and the Noise in Health Care Horizon Scanning	0286-0000-16-574-L04-P	Knowledge
247	Fit for Purpose and Modern Validity Theory in PROs	0286-0000-16-575-L01-P	Knowledge
248	Mind the Gaps: The Science of Designing, Implementing, and Evaluating Benefit-Risk Communication for Medicinal Products	0286-0000-16-580-L04-P	Knowledge
250	Open-Label, Long-Term Extension Studies: Study Designs and Ethics	0286-0000-16-583-L04-P	Knowledge
252	Capturing Real-World Data in Rare Diseases	0286-0000-16-591-L01-P	Knowledge
253	Update from Health Canada	0286-0000-16-613-L04-P	Knowledge
254	CBER Town Hall: State of the Center and Plans for the Future	0286-0000-16-595-L04-P	Knowledge
257	Mobile Apps for Clinical Trials: DIY or AMAZON Strategy? When to Build, When to Buy	0286-0000-16-514-L04-P	Knowledge
260	A Risk-Benefit Approach to Planning Early Clinical Development	0286-0000-16-598-L04-P	Knowledge
261	Marketing After Amarin and Pacira	0286-0000-16-529-L04-P	Knowledge
262	Solving Challenges and Employing Best Practices in Medical Information Contact Centers	0286-0000-16-531-L04-P	Knowledge
263	Patient Centricity in Clinical Trials	0286-0000-16-536-L04-P	Knowledge
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265	Enabling Innovative New Endpoint Measurement Using Mobile Technology	0286-0000-16-541-L04-P	Knowledge
266	Perspectives on Expanded Access to Investigational New Drugs	0286-0000-16-545-L01-P	Knowledge
271	The Things Kids Say: Clinical Outcome Assessments in Pediatric Clinical Trials	0286-0000-16-570-L01-P	Knowledge
272	How Can We Build Reliability and Quality When Outsourcing Pharmacovigilance?	0286-0000-16-577-L04-P	Knowledge
273	Improving Adverse Drug Reaction Information in Product Labels	0286-0000-16-587-L04-P	Knowledge
274	Statistical Issues in the Evaluation of Biosimilars	0286-0000-16-588-L04-P	Knowledge
276	Using Input from Patient Communities to Develop PRO Instruments	0286-0000-16-592-L04-P	Knowledge

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302	Europe and the US: Making Outcomes-Based Health Care Possible	0286-0000-16-610-L04-P	Knowledge
308	Patient Recruitment Workshop: Survey Results and Practical Application	0286-0000-16-519-L01-P	Application
314	Transforming Clinical Protocols into a Digital Platform: Driving Quality and Efficiency End-to-End	0286-0000-16-539-L04-P	Knowledge
315	Enhancing Pediatric Product Development in a Global Regulatory Environment: Extrapolation and Modeling and Simulation, Oh My!	0286-0000-16-549-L01-P	Knowledge
316	What's Your Preference? The Emerging Importance of Patient Preference Elicitation	0286-0000-16-553-L01-P	Knowledge
317	Global Medical Device Development: Regulatory Concordance or Discordance?	0286-0000-16-558-L04-P	Knowledge
321	Office of Pharmaceutical Quality Update	0286-0000-16-606-L04-P	Knowledge
322	Real-World Evidence in Drug Development: Creating the Right Environment for Enhanced Pre-Launch Evidence	0286-0000-16-571-L01-P	Knowledge
323	Social Listening for Pharmacovigilance: Practical Considerations and Challenges for Implementation	0286-0000-16-578-L04-P	Knowledge
324	Implementing Adaptive Designs Involves Greater Teamwork	0286-0000-16-584-L05-P	Knowledge
326	FDA Rare Disease Town Hall	0286-0000-16-608-L01-P	Knowledge
333	Hearing the Patient Voice in Pharma and What Patients Want You to Know	0286-0000-16-517-L04-P	Knowledge
335	Multi-Ethnic, Special Populations, and Patient Diversity in Clinical Trials	0286-0000-16-521-L04-P	Knowledge
336	Effect of International Reference Pricing on Planning for Global New Product Launches	0286-0000-16-597-L04-P	Knowledge
338	Evolving Methods in Pain Trials: Evaluating Abuse Deterrence, Drug Interactions, and Appropriate Patient Selection	0286-0000-16-525-L01-P	Knowledge

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Born from customer need, AgilePV is an intuitive, secure, and validated pharmacovigilance solution that helps companies mitigate risk and enhance visibility within their pharmacovigilance practice. Consisting of four applications—Adverse Event Intake and Staging, Partner Data Reconciliation, RMP Tracking and Safety Signal Tracking—plus an advanced analytics platform, AgilePV provides a better path to global patient safety.

Almac
Booth: 1035
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Almac Group is an established contract development and manufacturing organization with a strong reputation for innovation, quality and customer service. Comprehensive solutions range from R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply, IRT technology (IVRS/IWRS) through to commercial-scale manufacture. The global company is privately owned and has grown organically over 40 years employing approximately 3,600 highly skilled personnel.

Alpha Clinical Systems
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Website: www.alphaclinicalsystems.com

Alpha Clinical Systems is an e-clinical solutions provider. Our web-based integrated technology solutions framework, provides a global platform for trial management. Our products suite includes Study Designer, Study Monitor and Electronic Source Document (ez-SourceDocx) system (iPad/android friendly), also integrated are our ePIC and ePRO, which streamlines and accelerates the entire clinical trial process in an efficient, expedited and cost effective manner.

Alpha IRB
Booth: 842
Phone: 949-218-5522

Amazon Gift Cards
Booth: 2257
Contact: Andre Chernih
Phone: 206-435-3695
Website: www.amazon.com

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American Solutions for Business
Booth: 737
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American Solutions for Business (ASB) is your single source for all your marketing, clinical research, and pharmaceutical branding needs. ASB was founded in 1981 as a forms distributor, but we have continuously evolved throughout the years to become a leading provider of packaging, commercial print, direct mail, patient awards, promotional items, branded apparel and branded ecommerce storefronts. Stop over to booth #737 and say hello to one of our experienced team members.

AMPLEXOR Life Sciences
Booth: 1354
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AMPLEXOR helps pharmaceutical, medical device and biotechnology organizations launch products and break new markets. Its solutions and services expedite the creation and delivery of consistent, compliant and high-quality content–both physical and digital–across all target countries. Its services include technology consultancy, implementation and management services, as well as technical writing, translation and linguistic validation services, and creation and management of marketing assets.

ANCILLARE

Ancillare, LP
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Ancillare is the leader in end-to-end global clinical trial ancillary supply chain management services for pharmaceutical, biotechnology, CRO and research medical companies. We are fully equipped to manage all aspects of the clinical trial supply chain from start to finish. Ancillare is headquartered in USA (Horsham, PA) with regional offices in Europe (Milton Keynes, UK) and Asia-Pacific (Singapore). For learn more, visit Ancillare.com.

AnovaFill
Booth: 1854
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APCER Life Sciences
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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory, and technology resources to ensure that patients receive the safest, most effective therapies possible.

Appian Corporation
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Applied Clinical Trials/ Pharmaceutical Executive
Booth: 901

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Website: www.appliedclinicaltrialsonline.com and www.pharmexec.com

Applied Clinical Trials is the authoritative, peer-reviewed resource and thought leader for the global community that designs, initiates, manages, conducts and monitors clinical trials. Industry professionals learn effective and efficient solutions to strategic and tactical challenges within the tightly regulated, highly competitive pharmaceutical environment.

Aquila Solutions, LLC
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ArisGlobal
Booth: 1925

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ArisGlobal is the leading provider of integrated solutions for PV & safety, regulatory affairs, clinical development, & quality & compliance for medical communications. Life science companies using ArisGlobal's solutions can better build & maintain the trust they need with their customers, medical practitioners & regulatory bodies around the world.

arivis
Booth: 1840

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arivis is a market leading software company focused on the life sciences industry. With a broad product portfolio, our solutions address industry and academic environments. Our solutions and services allow customers to easily navigate the complex clinical and regulatory pathways on the way to successful drug approvals. Our solutions are delivered via a simple, predictably priced, rapidly deployed SaaS platform.

Arriello Ireland Limited
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We provide Strategic Advice, underpinned by Regulatory Affairs, Pharmacovigilance, Medical Writing and Translation services. As an established European-based service provider, we facilitate access into Europe and CIS, alongside other key markets. With our experience and project management expertise, we act as a natural extension of your Regulatory and Pharmacovigilance team.

Artcraft Health
Booth: 834

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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

ARUP Laboratories
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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
Booth: 630

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The Asia CRO Alliance aims to provide clinical trials support to small and medium-sized pharma, biotech, medical device companies as well as multinational CROs. This innovative partnership was created to meet the demand for more options for conducting Asian clinical trials. Through its strong presence in Asia, the Asia CRO Alliance believes that it can help serve the demand by providing flexibility in its services and local expertise while working closely with sponsors and multinational CROs.

August Research
Booth: 1907

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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, Poland, Romania, Serbia and Slovakia, with office-based clinical staff. With more than 14 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.

Axiom Real-Time Metrics Inc.
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Know More. Know it Sooner. Act Faster. Axiom delivers intuitive, powerful and cost-effective eClinical solutions and services. Services include: DM, Biostats and PV. Our eClinical suite, Axiom Fusion, delivers innovative end-user focused, unified functionality and modules. Fusion Delivers: EDC, DM, IWRS, CTMS, Inventory Management, IVR, Patient Portal, AE/SAE Tracking, Safety Database, Central Lab, Imaging, eTMF, and 24/7 Project and Clinical Data Reporting. Axiom: The Results oriented partner.

AxxiTRIALS (Litéra)
Booth: 2357

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Litéra AxxiTRIALS' unique, fully automated, site communication portal and study management tools accelerate clinical trials and significantly reduce study costs. By leveraging ubiquitous technology, email/SMS, cloud, and familiar website design, global Site users easily review (and e-sign) documents, complete e-learning, and access central e-binders and other resources. CRO and Sponsor staff save substantial time with compliant, computerized document exchange, workflows, surveys and reporting.

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BARC Global Central Laboratory
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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.

Barnett International
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Barrington James
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BBK Worldwide
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With more than three decades of experience across a wide variety of therapies and medicines, BBK Worldwide is the global leader in patient recruitment for the clinical trial industry. BBK's latest innovation is the introduction of adaptive recruitment – a new specialty in clinical trial marketing proven to protect global enrollment integrity, specifically within a changing or threatened landscape. BBK is a privately held, women owned business, headquartered in Needham, Mass.

Beijing Clinical Service Center
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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.

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Bioclinica Clarity Bar
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Clinverse, Inc. architected the industry's first end-to-end technology solution that automates the financial lifecycle of global clinical trials. Powered by our secure technology platform, our solution standardizes clinical finance and manages millions of financial transactions across the globe, including clinical site payments. Used by leading BioPharma companies, our clients benefit from reduced workload, time, and costs gained through automation and unprecedented transparency and workflow.

BioFortis, Inc.
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BioFortis provides technology-enabled solutions in clinical trial sample and consent tracking. Utilized in 1000+ biomarker-driven trials, we enable study teams to monitor the health of trials from a sample-centric perspective across the distributed ecosystem of sites, labs, vendors, and biobanks. Our solutions allow you to 1) improve trial execution by reducing sample logistics issues and regulatory risks; 2) increase utilization of precious patient samples; 3) reduce costs for banked samples.

Biomedical Systems
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Biomedical Systems is a premier global provider of centralized diagnostic services to pharmaceutical, medical device, biotech, and CRO's in support of sponsors' regulatory requirements to meet their primary and secondary clinical trial endpoints. Our comprehensive solutions include cardiac safety, pulmonary function, imaging, eCOA and scientific affairs. Our corporate headquarters is located in St. Louis, MO. Our EU headquarters is located in Brussels, Belgium.

BioPharm Insight
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BioPharm Insight is your definitive guide to the global biopharma community, combining an online business intelligence system of comprehensive market analytics and key industry contacts with an independent investigative journalism news service. As part of the Financial Times Group, BioPharm Insight is also an acclaimed independent journalist team with a proven track record of breaking forward-looking and competitive business intelligence 6-12 months ahead of mainstream press.

BioPoint, Inc.
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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.

Biorasi
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bioskin® is a full-service contract research organization (CRO) specialized in dermatology. We plan and conduct clinical trials for pharmaceuticals, medical devices, food supplements and advanced/professional cosmetics. bioskin® is offering all core services for management of Phase I-IV trials with healthy volunteers and patients.

BioStorage Technologies Inc.
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BioStorage Technologies, Inc., a subsidiary of Brooks Automation, is the premier, global provider of comprehensive sample management solutions for the bioscience industry. Offering flexible onsite and offsite storage models, the company provides a complete lifecycle of sample management solutions including sample management consulting, temperature-controlled storage facilities, sample bioprocessing and ISIDOR®, a transformational technology solution.

BioTelemetry Research
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Before being acquired in 2012, Cardiocore became the world's most comprehensive core lab focused solely on cardiac safety. Now a division of BioTelemetry, Inc. (NASDAQ: BEAT), we are a member of the world's largest cardiac data network - processing over 2 billion heartbeats a day. In addition to cardiovascular monitoring, we have expanded in two areas. First, advanced imaging services for clinical trials. And second, in spirometry, where we have created an exclusive alliance with Vitalograph.

BIOVIA
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QUMAS, now part of BIOVIA from Dassault Systèmes, is the leader in Compliance and Quality Management Solutions for the Life Sciences industry, with more than 270 global customer deployments and domain expertise in regulatory compliance since 1994. BIOVIA QUMAS provides software solutions for Electronic Document Management (SOPs, QA Docs.), Electronic Process Management (CAPA, Deviation, Change Control, Audit), eCTD & Submission Management.

BizInt Solutions, Inc.
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BizInt Smart Charts software helps information analysts create, customize and distribute competitive intelligence reports and visualizations from drug pipeline, clinical trial, patent and gene sequence databases. Our new BizInt Smart Charts for Clinical Trials software helps you create polished reports integrating trials intelligence from the leading commercial and public databases -- Citeline TrialTrove, Cortellis, Adis Clinical Trials Insight, ClinicalTrials.gov, EudraCT, and WHO ICTRP.

Blinded Diagnostics
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Blinded Diagnostics is a contract service organization providing same day lab test results for global clinical trials. We offer over 100 test analytes on accurate and proven point of care diagnostics systems. To see the test menu visit www.pointofcaresearch.com or for more information on our services go to www.blindeddiagnostics.com

BloodCenter of Wisconsin
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BloodCenter of Wisconsin is a world-renowned specialty Reference Lab specializing in hematology, oncology, transplantation and immunology. Our medical and scientific expertise, and leading edge testing platforms set us apart from the typical central lab and other esoteric labs. We support preclinical and phase I-IV trials, including: specialty laboratory testing, custom assay development, specimen collections, sample storage and electronic data transfer.

BlueCloud® by HealthCarePoint
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BrackenData
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Bristol-Myers Squibb
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Bristol-Myers Squibb is a global BioPharma company firmly focused on its mission to discover, develop and deliver innovative medicines to patients with serious diseases. Around the world, our medicines help millions of people in their fight against such diseases as cancer, cardiovascular disease, hepatitis B and hepatitis C, HIV/AIDS and, rheumatoid arthritis.

Bynder
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ByteGrid
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C3i Healthcare Connections
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C3i Healthcare Connections, a division of Telerx, is an industry-leading BPO specializing in the multi-channel engagement of patients, healthcare professionals and enterprise personnel via a network of global contact centers. Our unique customer-centric approach has made us the partner of choice for some of the world's most trusted brands. In this ever-changing healthcare climate, our integrated solutions give our clients a unique advantage. We deliver the ultimate experience www.c3ihc.com.

CAC Croit Corporation
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Cambridge Healthtech Institute
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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 Educational Services, Cambridge Meeting Planners and CHI's Media Group, which includes news websites and e-newsletters including Bio-IT World and Clinical Informatics News.

Canfield Scientific, Inc.
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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) and in the United States (Mystic, CT).

Cardinal Health
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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.

Catalent Pharma Solutions
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Celerion
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Celerion leverages over 40 years' experience, 600 clinic beds, and locations in NA, EU and Asia, to conduct and analyze First-in-Human, clinical Proof-of-Concept and dose response in patients, cardiovascular safety assessments, ADME and NDA-enabling clinical pharmacology studies. Celerion provides expertise on clinical data analysis as well as small and large molecule bioanalytical assay services. Regulatory, drug development and program management complement Celerion's service offerings.

Cenduit, LLC
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As an IRT specialist, Cenduit sees things others don't. We have the expertise to empower sponsors for success with a completely personalized system that puts them in control of their clinical trials. With the needs of investigator sites and patients top of mind, Cenduit offers clinical supply chain intelligence and clinical operations know-how through its IRT-driven services: patient randomization, drug supply management, patient reminders, and materials forecasting.

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.

Chesapeake IRB
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Chesapeake IRB provides central, independent ethical review services throughout the US and Canada with one seamless submission process. AAHRPP accredited since 2004, Chesapeake is known for creating innovative and adaptive solutions including the fully compliant, electronic IRB management platform (CIRBI) which streamlines protocol submissions, decreases investigator review turnaround and results in greater efficiency, transparency and quality.

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Cincinnati Children's Research Foundation — Booth: 1634
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CitiusTech Inc. — Booth: 637
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Clinical Ink — Booth: 1004
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Patient organizations are key stakeholders in helping DIA achieve its mission and vision. Through the Patient Fellowship Program, DIA is working to ensure that the "voice of the patient" is heard globally in every facet of the life cycle management of pharmaceuticals, medical devices, and related health care products. Stop by our booth to meet with 20 patient fellows and learn more about the DIA Patient Fellowship Program.

DITA Exchange

Booth: 1652
Contact: Jim Nichols
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Phone: 302-310-7138
Website: www.ditaexchange.com

DitaExchange simplifies the way organizations create, manage, share and deliver important documents with Dx4™ - DitaExchange's structured authoring solution built to run on the SharePoint platform. By helping companies produce and maintain important information quickly and by following compliance guidelines, employees spend less time keeping up with regulations and more time reaching company goals.

DLTA

Booth: 2356
Business Suite: BS 5
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Website: www.druglifecycle.com

Aurotech is focused on simplifying work. By simplifying work processes, we aim to positively impact the lives of the people we work with, their employees and their patients. Our immediate focus is the development of the Drug Lifecycle Tracking Application (DLTA) - druglifecycle.com. With years of experience working directly with the FDA, we understand the challenges facing the industry. We have assisted organizations like yours overcome those challenges through enterprise work management.

Dohmen Life Science Services

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Website: www.dlss.com

DLSS provides intelligent outsourcing to biopharma and medical device companies. With the broadest suite of services in the industry, DLSS has helped more than 600 companies connect more closely with their customers, grow their business and realize their vision. Whether it's navigating regulatory requirements, commercializing products, managing daily operations or providing patient-centric care for the rare disease community, DLSS helps our clients advance with speed, scale and certainty.

Dora Wirth (Languages) Ltd.

Booth: 955
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Website: www.dwlanguages.com

In-house medical expertise, a proven track-record of dedication to the life science sector, and a strong commitment to quality and service all combine to make DWL your reliable partner for global translation solutions. DWL has over 50 years' experience in providing translation services and language consultancy in the following specialist areas: • Regulatory Affairs • Clinical Research • Biotechnology • Medical Devices • Legal • Manufacturing • Medical Publishing • Marketing Communications

Dr. Ebeling & Assoc. GmbH

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Headquartered in Hamburg, Germany, Dr. Ebeling & Assoc. GmbH is a CSO with experience in regulatory and quality and compliance consulting as well as in project and data management, providing a wide range of services in the area of regulatory and medical affairs, pharmacovigilance for the pharmaceutical, biotech, generic drug and medical device industry and GCP. If you need an EU-QPPV or EU Legal Representative - we have the experience to support you!

DrugDev

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DrugDev is a technology company which provides cloud-based solutions to help sponsors, CROs and investigators do more clinical trials together. Built around the largest global network of active opted-in investigators, DrugDev's unified solutions suite optimizes site selection and startup, investigator payments and clinical operations. DrugDev also serves as the trusted third-party host of the revolutionary Investigator Databank and powers the TransCelerate Investigator Registry.

DSG, Inc.

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Phone: 484-913-0210
Website: www.dsg-us.com

DSG, Inc. celebrates over 25 years of full service clinical trial data collection and management with a fully integrated suite of innovative technology solutions: Award-winning eCaseLink EDC & DSG Designer for Enterprise licensing using CDISC standards; Risk Based Monitoring, eSource, specialized Clinical Data Management services, IWRS Randomization and Clinical Supply, Drug Safety, Patient Profiles, ePRO, CTMS, Site Payment, Protocol Violations, and digital on-demand Clinical Printing software.

Duke Clinical Research Institute

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Website: www.dcri.org

The Duke Clinical Research Institute (DCRI) offers the full-service operational capabilities of a major contract research organization combined with clinical expertise, academic leadership, and business acumen that translates into targeted and sound research results. The DCRI... From Thought Leadership to Clinical Practice.

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DZS Clinical Services and Software/ClinPlus Booth: 2009
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Email: bborysko@clinplus.com
Website: www.clinplus.com

DZS is led by an experienced team of clinical development experts and offers industry leading software including EDC and CTMS. Whether you are looking for CRO services or better data transparency using our ClinPlus® platform, DZS can help you manage your trial with customized control from start to finish. With full-service clinical capabilities, a broad range of engagement models, and a full suite of software tools, DZS is your direct line to improved trial efficiency and high-quality data.

EastHORN Clinical Services in CEE, Ltd. Booth: 1406
Contact: Iain Gordon Phone: 44-7738-6738
Email: iain.gordon@easthorn.eu
Website: www.easthorn.com/geographical-reach

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EDETEK, Inc. Booth: 1249
Contact: Jian Chen Phone: 609-720-0888
Email: info@edetek.com
Website: www.edetek.com

EDETEK, a proud CDISC Registered Solution Provider, provides innovative end-to-end data management solutions. Key products and services include eClinical (EDC, IWRS, Patient Recruiting, Site Management, Study Calendar, Financial Management), Conform (Metadata Repository, Data Integration, Standardization, Analysis, Reporting), and eSubmission Solutions. We deliver quality services in every aspect of trial design, conduction, analysis, and regulatory submission.

EGeen International Corporation Booth: 2440
Contact: Philip Vorwald Phone: 443-255-8420

Elite Research Network, LLC Booth: 1600
Contact: Christopher Hoyle Phone: 843-849-7382
Email: choyle@eliteresearchnetwork.com
Website: www.eliteresearchnetwork.com

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. We have earned a reputation for quick study start up time lines, high enrollment and providing our clients with quality data. Our sites utilize central IRBs.

Elite Research Staffing Booth: 2254
Contact: Jill Laufer Phone: 844-984-7200
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Website: www.eliteresearchstaffing.com

Elite Research Staffing is a small, niche research staffing agency focusing on placing contract clinical trials staff. With over 15 years' personal industry experience, we can provide the best and brightest talent this industry has to offer. Elite also offers the utmost in personalized service, 24/7, with a single point of contact. And because we are a small, niche agency, our overhead is much lower than other agencies, and those savings are passed on to our clients.

EMB Statistical Solutions, LLC Booth: 1141
Contact: Brenda Bishop Phone: 816-522-6340
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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".

endpoint Booth: 501
Contact: Ryan Keane Phone: 415-531-5917
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Enforme Interactive Booth: 1752
Contact: Eric Delente, CEO Phone: 301-788-1900
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Enforme Interactive Inc. has been producing electronic systems for informed consent for global studies since 2005. Enforme's SecureConsent system improves patient comprehension, regulatory compliance, & raises efficacy by making remote, centralized oversight possible. The flexible system supports numerous consent workflows and global regulatory environments as the forms and processes can be customized according to individual client, study & site requirements. It can run on virtually any device.

ENNOV Booth: 1255
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ePatientFinder
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European Medicines Agency
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The European Medicines Agency is a decentralised agency of the European Union, located in London. It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. EMA protects public and animal health in 28 EU Member States, as well as the countries of the European Economic Area, by ensuring all medicines available on the EU market are safe, effective and of high quality.

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FDA Office of New Drugs
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The Office of New Drugs (OND) within FDA's Center for Drug Evaluation & Research (CDER) is responsible for providing regulatory oversight for investigational studies during drug development and making decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. We also provide guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.

FDA Office of Women's Health
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The U.S. Food and Drug Administration Office of Women's Health addresses the health issues of the nation's women by funding scientific research, collaborating with national organizations to sponsor outreach efforts, and disseminating free publications on a variety of topics including diabetes, medication safety, menopause, heart disease, and mammography.

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FOMAT Medical Research
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Formedix Inc.
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Frenova Renal Research
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Global Clinical Trials. LLC
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Greenphire is the leader in global clinical trial payment solutions. Greenphire's best-in-class solutions optimize clinical trial performance by simplifying and streamlining payment processes from sponsors and CROs to sites and patients. Visit Greenphire at booth 2317.

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As a pioneering and leading commercial clinical laboratory in China, KingMed is accredited by CAP (13 disciplines), ISO15189, ISO/IEC17025, ISO9001, NGSP Level 1 Laboratory, and follows GLP, US 21 CFR Part 11, ICH-GCP and other applicable laws and regulations. KingMed provides clinical tests, consumable materials management, logistic service and specimen management services for clinics, hospitals, international pharmaceutical companies, CROs and biotech companies.

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H&J CRO Int'l (a.k.a. ShujuMetrics) is a premier full service CRO offering efficient global clinical trial solutions. Established in 2003 in China, with over 20 domestic branch offices and HQ in the USA in New Jersey, we specialize in data management, clinical trial management, regulatory affairs, SAS programming, biostatistics, and medical writing. With combined 24/7 operation, on-shore in the USA and off-shore in China, we deliver, prompt, high quality services, at an exceptional value.

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Health Decisions CRO+ is a full-service CRO providing excellence in every aspect of clinical research. We are the customer-focused specialty CRO of choice for biopharma, diagnostics, precision medicine and medical device companies. For 27 years, we have consistently delivered clinical development success for our sponsors through our people, performance and transparency. Our clinical experts look forward to meeting you at booth 1143. For additional information visit www.healthdec.com.

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HighPoint Solutions solves the toughest IT challenges facing companies in the highly regulated life sciences and healthcare industries by providing our clients with practical IT strategies and solution implementations and giving them direct access to the people and technology that get things done. Since 2000, our 700+ consultants have provided business consulting and technology solutions that continue to deliver business value and competitive advantage to more than 170 clients nationwide.

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iCardiac Technologies, Inc. is an industry-leading centralized core laboratory for cardiac safety and respiratory services. Its high-precision cardiac safety assessment methodology has set a new standard for precision and accuracy in all phases of clinical trials. The company serves 8 of the top 10 global pharmaceutical companies, as well as numerous small and mid-sized pharma and biotechnology firms.

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Inflamax Research is a global CRO with clinical research facilities in both Canada and the US. We offer both Phase I Clinical Pharmacology and Late Phase Global Clinical Research Services. Site experience includes the performance of over 800 studies from Phase I to Phase IV in several therapeutic areas. Inflamax offers a full spectrum of services from Clinical trial management, sites qualification and initiation, study design, data management, biostatistics and medical writing.

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Mayo Validation Support Services (MVSS) is a service line within Mayo Clinic's Department of Laboratory Medicine and Pathology. We facilitate collaborations between Mayo Clinic scientists and industry or academic partners related to clinical validations, acquisition of biospecimens, laboratory testing to support clinical trials, or validation of new technologies.

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Contact: Jonathan Catley
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Website: www.mdconnectinc.com

MD Connect is a digital marketing healthcare agency (over 1,000,000 patient leads driven) that accelerates clinical trial patient recruitment through high volume, cost-efficient digital strategies. Leveraging multiple digital media (search, social, display, mobile, video, content, etc.), lead qualification strategies (through websites, landing pages, online screeners) and an advanced lead tracking solution, we provide qualified patient leads into your clinical trial at the lowest possible cost.

Med Fusion
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med fusion, an integrated Molecular Center of Excellence (MCOE) and clinical trials organization, delivers support to healthcare providers and biotech/pharmaceutical companies to consistently meet the needs of patients. Our clinical trials experience supports healthcare providers and biopharmaceutical partners with a hypothesis-to-conclusion suite of services.

Med-Con Technologies LLC
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Med-Con Technologies, LLC is the management and marketing organization for MedSked (medsked.com), a unique adherence solution that directs patients at the point-of-use to follow their drug therapy. We partner with all segments of the pharma industry, and MedSked today is a leading adherence tool for global clinical trials. In 2016, Med-Con has introduced the "MedSked Mobile" app, which uses the patient's smartphone to provide remote monitoring and time-stamp notification of medication usage.

MedDRA MSSO
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MedDRA is a clinically validated terminology used for encoding adverse events for the biopharmaceutical industry and regulators. The MSSO maintains MedDRA and provides support services (e.g., training, data conversion, consulting).

Medical Vigilance Solutions, Cincinnati Children's
Booth: 1435
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Medical Vigilance Solutions (MVS) specializes in Pharmacovigilance, Medical Communications and 24/7 Contact Center Services supporting pharmaceutical, biotech, medical device and consumer health organizations. With 30 years of industry experience, MVS provides comprehensive outsourced solutions that fit seamlessly into your process. Let's get started. 855-752-3742

Medidata Solutions Worldwide
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Medidata is the leading global provider of cloud-based solutions for clinical research, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® platform brings new levels of productivity and quality to the clinical testing of promising medical treatments, helping life science organizations conduct their clinical trials faster, with less risk and with lower costs.

MEDIX
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Medix Clinical Research delivers quality trials on time and under budget through a sustainable workforce solution. Through projecting your needs and pipelining potential talent, we can provide your organization the flexibility and agility you need to tackle new projects. In addition, through our Medix Match process, we will enable you to match the aptitude, culture fit, skills and experience of our candidates to your top performers.

MedNet Solutions, Inc.
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MedNet Solutions is a leading healthcare technology company specializing in electronic data solutions designed for the global life sciences community. Since 2001, MedNet's flexible and intuitive cloud-based eClinical systems have been trusted by pharmaceutical, medical device, biotechnology and Contract Research Organizations (CROs) around the world. Visit our booth to see iMedNet eClinical...an affordable solution that allows sponsors and CROs to quickly and easily build their own studies.

Medpace Inc.
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Medpace is a leading global full-service clinical research organization providing Phase I-IV core development services. With expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced teams to execute at every level of the company's operations, providing complete and seamless drug development services. Medpace operates with 2300+ employees and clinical trial experience in over 50 countries.

MedPoint Digital, Inc.
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MedPoint Digital develops specialty eClinical platforms for clinical trial portals, interactive modules, virtual investigator meetings, and mobile patient apps. Our digital solutions enable sites, sponsors and CROs to be more productive, with online study training, study eBinders (eISF), digital study alerts and SUSARs, visit guides, single sign-on and metrics displays.

Medrio
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Medrio offers an eClinical software platform with a fully hosted EDC system. Our revolutionary CloudEDC™ technology allows studies to be built in days, not months, with no required programming. Our mobile eSource suite, mSource, supports event- and subject-based workflows, offline data entry, and Patient Reported Outcomes. Medrio serves all study phases, but with over 500 Phase I trials, our m1 application leads the way in early phase trials. Medrio costs up to 75% less than other EDC solutions.

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MedTrials
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MESM provide Global Equipment Solutions to the Clinical Trials industry. Currently supporting clinical studies in over 70 countries, MESM take care of all aspects of the medical equipment, consumables and related products for studies from initial enquiry through to end of study removal. MESM have officially partnered with Abbott and Abaxis to announce the launch of QRTD (Quantitative Real Time Diagnostics) for use of their diagnostic devices/services for the global clinical trials market.

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MonitorForHire.com
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Montrium is a knowledge based company, that focuses on leveraging its deep understanding of GxP processes and technologies to provide cost-effective solutions to life science organizations. Montrium's industry leading SharePoint Solution, Montrium Connect, offers a truly collaborative and compliant document and quality management environment on the cloud or on-premise. Montrium is a Global Leader in Cloud-based Compliance Solutions and GxP Consulting Services for the Life Sciences

Morningside Translations
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NACS Inc. is a complete resource for GMP contract manufacturing & scalable custom production needs. NACS offers end-to-end production services including prototype development, scalable production(s), complete automation, contract manufacturing, and turnkey production delivery. NACS is focused on scalable solutions allowing the market to pull future capital expenditures.

National Association of Veterans' Research and Education Foundations
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Formed in 1992, the National Association of Veterans' Research and Education Foundations (NAVREF) is the 501(c)(3) nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), are authorized by Congress to provide flexible funding for research and education at VA facilities nationwide. Currently, NAVREF has 82 members.

NCGS Incorporated
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NCGS, Inc. is a full-service, international CRO. We have been in business for 32 years, have helped with 33 approved products, and have ZERO 483s or other warnings from the FDA, EMA, or other global agency. We are a privately-held, WBENC Certified company with a family-like culture. NCGS offers our Sponsors only tenured teams with very low turnover, creating a level of collaboration that is second to none and necessary to overcome issues that are inevitable in clinical trials.

NCT Linguistics
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NCT Linguistics provides translation, interpretation and training services for clinical trials conducted worldwide. As a division of NeuroCog Trials, we have over 15 years of experience translating scientific documents, communicating with sites, and training raters in 30+ countries. NCT Linguistics has more than 500 highly skilled linguists - many of them holding advanced degrees and experienced in all phases of clinical trials. Our stringent certification process is recognized globally.

Neuroscience Trials Australia
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Neuroscience Trials Australia is a niche contract research organization specializing in all aspects of neuroscience clinical research and product development. We work on global or local projects. As a business within The Florey Institute of Neuroscience and Mental Health (The Florey), our staff has global management expertise in all phases of clinical research including studies sponsored by pharmaceutical and device companies, the biotechnology industry and granting bodies.

New Orleans Center for Clinical Research — Booth: 1408
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NOCCR / VRG is an academic hospital based research company. We conduct research in a wide range of medical specialties for the pharmaceutical, biotechnical and device industries. NOCCR Knoxville is primarily a 52 bed Phase I unit, well suited for conducting first-in-human trials. VRG and NOCCR New Orleans are primarily focused on conducting later phase studies.

Next Phase Research — Booth: 912
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Nextrials, Inc. — Booth: 1955
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Website: www.nextrials.com

Nextrials provides innovative software solutions for clinical research. Prism®, Nextrials' EDC system, offers integrated randomization, inventory management, laboratory data management, and ad hoc reporting. Nextrials E2E TM solution integrates with EHR systems providing cleaner data and reduced monitoring requirements. These tools allow sponsors to accelerate time to market and lower costs. Nextrials is now part of PRA Health Sciences, a global full-service CRO.

NNIT — Booth: 1843
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NNIT is one of Europe's leading consultancies in the development, implementation, validation and operation of IT for the life sciences industry. We create value for our clients by treating their IT as if it were our own and, of course, we meet the industry's strictest requirements for quality. For over a decade, we have applied the latest advances in technology to make our clients' software, business processes and communication more effective.

Norav Medical — Booth: 745
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NORAV is a market leader in fully integrated electrocardiography devices, cardiovascular information and PACS systems (CVIS), and pioneers in cloud-powered analytics and research solutions. Our comprehensive suite of wired and wireless ECG instruments, software, and services enable high-performance cardiology workflows, and optimal integration of clinical and research data. LUMEDX and NORAV products and services are utilized throughout the world for research and healthcare.

Nova Language Services Ltd. — Booth: 733
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Nova Language Solutions helps life science, contract research and healthcare organizations overcome challenges surrounding mission critical communications. We welcome the opportunity to get to know you better and show you what we have to offer to solve your patient recruitment, linguistic validation, medical devices and regulatory compliance multilingual challenges. NOVA is a specialised ISO 9001:2008 and UNE EN 15038 certified multilingual medical communication company.

November Research Group — Booth: 1107
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November Research Group is a software development company focused on providing commercial applications for product vigilance. Our team has been developing software in this space for over 20 years and has participated in the development of AERS, Argus, and PRIMO Regulatory. Our software portfolio includes applications to: streamline case intake, utilize mobile AE/PC intake tools, facilitate business user access to product vigilance data and provide analytic solutions built on Big Data platforms.

Novotech — Booth: 1939
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Internationally recognized as the leading Australian CRO, Novotech is a full service clinical CRO with operations in Australia, across the Asia Pacific and South Africa. We assist biotechnology and pharmaceutical companies bring new products to market by offering a full range of ICH compliant clinical services from first human exposure through to completion of Phase III trials.

Nuventra Pharma Sciences — Booth: 1849
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Ocala Research Institute — Booth: 2430
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Ocala Research Institute has been an active site in North Central Florida since the year 2000. We have the ability to conduct trials from Phase I to IV in a wide range of medical disciplines. In addition to our headquarters in Ocala, Florida, United States of America, we have sites in Central America, South America, and the Caribbean.

Ocasa Logistics Solutions — Booth: 2234
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With over 30 years of experience developing Logistics Solutions worldwide, OCASA's Bio-Pharmaceutical logistic service offers tailor made solutions for the Pharma industry including export, import, distribution, fulfillment, and temperature controlled warehousing for: Diagnostic Specimens, Medication/Vaccines, Experimental Drugs, Controlled Substances, Dangerous Goods, and Medical Supplies.

OmniComm Systems, Inc. — Booth: 2201
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Online Business Applications
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Online Business Applications provides advanced software solutions for the Pharmaceutical, Biotechnology, and Medical Device industries in the areas of Medical Communications and Drug Safety. We utilize proven leading-edge technologies, anticipate our clients' needs, and deliver solutions that exceed expectations.

OpenClinica
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OpenClinica provides cloud-based research solutions to capture high quality clinical data and engage research participants. Leveraging the power of open source and open standards, the OpenClinica platform has powered thousands of clinical trials involving millions of patients worldwide. Learn more at www.openclinica.com.

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Oracle Health Sciences
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Orbis Clinical
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Orlando Clinical Research Center
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Paragon Solutions is an advisory consulting and systems integration firm that supports the entire drug development lifecycle, from pre-clinical through commercialization, as well as corporate functions. We partner with clients to define and deliver optimal business outcomes by applying proven methodologies, technology frameworks and best practices to successfully blend people, process and technology.

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Patient Genesis
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Patient Genesis empowers organizations to create, share and transfer knowledge to patients during the informed consent process. We recognize that health care providers need to educate, inform and consent patients from globally diverse social and economic backgrounds. That's why we've created the ConsentNowTM electronic Informed Consent (e-ICF) platform.

PCI Pharma Services
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PCM TRIALS
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Pharmaceutical Packaging Professionals is an Australian based clinical trial manufacturing, warehousing and distribution CRO, servicing international pharmaceutical companies. PPP has TGA audited cGMP facilities in Australia offering finished product manufacturing services, packaging and labelling and controlled warehousing and distribution of clinical trial supplies. The company has been providing these services for 6 years and has acted as a central depot for more than 200 clinical studies.

Pharmaceuticals and Medical Devices Agency (PMDA)
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The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that reviews applications for marketing approval of pharmaceuticals and medical devices, monitors product safety, and provides financial relief to people suffering from adverse drug reactions, in collaboration with the Ministry of Health, Labour and Welfare.

PharmaSeek Companies
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A group of interrelated businesses focused on expediting clinical research activities. Supporting businesses include PharmaSeek, an Investigative Site Network of 250 research sites, PatientWise, a patient recruitment and healthcare marketing firm, The Oncology Hub, a network connecting sites and sponsors for the conduct of oncology research, and PFS Clinical, a provider of outsourced administrative solutions.

PharmaSys, Inc.
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PharmaSys, Inc. is a full service compliance & consulting firm specializing in FDA regulated industries & offering a wide range of services including computer validation, audit services, compliance training, commissioning, equipment/process validation, & QA consulting. Visit us at www.pharma-sys.com or call (919) 468-2547.

PharmaVOICE
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PharmaVOICE magazine provides readers with insightful and thought-provoking commentary about the challenges and trends impacting the life-sciences industry in a multiple-perspective format through articles covering a range of issues from molecule through market. PharmaVOICE's more than 41,000 BPA-qualified subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, and White Papers.

Pharmica Consulting
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Pharm-Olam International Ltd.
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Pharm-Olam International is a multi-national contract research organization offering a wide range of comprehensive, clinical research services to the pharmaceutical, biotechnology and medical device industries. From Phase I to Phase IV, Pharm-Olam focuses on delivering the highest quality data, achieving targeted enrollment and meeting projected timelines. For further information about Pharm-Olam, please visit www.pharm-olam.com.

Phlexglobal Inc.
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Phlexglobal is a specialist provider of both industry leading eTMF technology solutions and expert TMF & eTMF technology-enabled services. Offering a unique combination of clinical trial knowledge, document management skills, regulatory understanding and technical expertise, we deliver a range of flexible, targeted solutions to meet business needs.

Pilgrim Quality Solutions
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Pilgrim Quality Solutions is a leading global provider of enterprise quality management software and services for the Life Sciences and other highly regulated industries. For more than 20 years, our solutions have automated thousands of processes that ensure the quality of life's most important products. Product quality and patient safety increase while risks decline. With Pilgrim Quality Solutions as your partner, you are prepared to succeed. For more information, visit www.pilgrimquality.com.

Pinnacle 21
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Pinnacle 21 is the industry leader in software and services for managing CDISC compliance, clinical data quality, and eSubmission readiness. Our industry-leading software (Pinnacle 21 Enterprise and Community, formerly OpenCDISC) and clinical data SME services help life sciences companies prepare regulatory submission data and documentation (Define.xml, SDTM & ADaM Reviewer's Guides), and health authorities (FDA and PMDA) efficiently validate and effectively review the data package.

Planet Pharma
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Planet Pharma is a professional staffing and recruitment company specializing in strategic solutions for the pharmaceutical, biotechnology, device and related industries. Planet Pharma provides experienced staff across numerous therapeutic and functional areas for all phases of the clinical trial process. Our service offerings include: - Contract / Contract-to-Hire - Permanent Placement - Functional Service Provider - Payrolling Services

PleaseTech Ltd.
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PleaseTech specializes in document co-authoring and review software. Our flagship product, PleaseReview, is a proven collaborative review and co-authoring solution for Microsoft Word and other document types and is used extensively by Life Sciences organizations. It facilitates controlled, simultaneous collaboration for the review and editing of documents, including comment and change reconciliation, review management and metrics, and accommodates both online and offline reviewers.

Polar Leasing Company, Inc.
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Polar Leasing offers a national rental fleet of temperature controlled test chambers and walk-in refrigeration units for the life sciences industry. Units are constructed of seamless fiberglass, ensuring a sanitary storage environment and ship from more than 75 US locations. All units are ground resting, available at almost any holding temperature. Units are delivered pre-wired, pre-assembled and ready to operate. No on-site assembly or refrigeration work is required at your location.

Pope Woodhead & Associates
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Pope Woodhead provides strategic consulting & integrated solutions to pharmaceutical companies. Honed to address client challenges posed by dynamic markets & regulatory environments, our consulting services cover all key strategic areas: o Benefit/risk management strategy, implementation & effectiveness o Real World Evidence strategy & implementation o Market Access Excellence & Strategy o Payer Engagement o Digital enablement & integration o Organisational Capability Building

PPD

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PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. With offices in 46 countries and more than 15,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help clients and partners bend the cost and time curve of drug development to deliver life-changing therapies that improve health. Visit us at www.ppdi.com

PQE

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PQE is a Global Life Science consulting firm specializing in the following services: • Data Integrity Assurance/Computer System Validation • Quality Assurance & Compliance • Qualification & Engineering • Regulatory Affairs Our unique capabilities enable companies to achieve and maintain compliance with FDA, EMA and other international regulatory bodies.

PRA Health Sciences

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As a leading CRO, PRA is transforming clinical trials through our people, innovation and transparency. We combine therapeutic and operational expertise with local knowledge to serve clients across all phases of drug development. Our successful history of helping to bring new drugs to market demonstrates our successful approach to clinical research.

Praxis Communications, LLC

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Praxis provides focused patient recruitment to the world's leading pharmaceutical and biotech companies. It's all we do. Each study is unique, and so is each Praxis patient recruitment campaign. We believe that understanding the patient for each study is key to developing a strategic campaign that resonates with your patient population. Visit www.gopraxis.com to learn more.

Precision for Medicine

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Precision for Medicine supports the discovery, development, clinical trial work, and implementation of biomarkers essential for targeting patients more precisely and effectively. This dynamic new field requires novel services that aren't currently offered by traditional research organizations. We provide an uncommon array of talent and services to enable our pharmaceutical and life sciences clients to take advantage of new advancements in science and stay ahead of regulatory changes.

Premier Research

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Premier Research is a leading clinical development company that helps highly innovative biotech and specialty pharma companies transform breakthrough ideas to reality. More than a CRO, we work with pioneers and original thinkers who are pursuing the most challenging areas of study in analgesia, CNS, rare diseases, oncology, and pediatrics. We're focused on smart study design for advanced medicines that allow life-changing treatments. It's what we do. Best.

PrimeVigilance

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PrimeVigilance is a dedicated pharmacovigilance & medical information service provider supporting pharma, biotech and generics companies in managing the global safety of their products from clinical development through to full post-marketing activities including many North American companies within their US, EU & international markets.PrimeVigilance's services range from full management and provision of safety operations, medical information to specialist consulting with +200 in house employees

ProPharma Group

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ProPharma Group provides pharmaceutical, biotechnology, and medical device clients access to worldwide, integrated medical information and pharmacovigilance services. By way of strategically positioned contact centers in the United States, the United Kingdom, and Australia, our specialists speak approximately 30 languages and have extensive industry experience. We take care of your customers with a high level of experience and professionalism. providing the support you need, when you need it.

Proteus Digital Health, Inc.

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To help researchers more effectively track and manage the use of medication during clinical trials, Proteus Digital Health has developed a novel system that continuously captures precise and timely data about medication adherence. Our solution provides deeper insight into drug efficacy and safety. It can also help to shorten trial duration, which can, in turn, reduce costs and increase trial success rates.

ProTrials Research, Inc.

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As a clinical research organization serving the pharmaceutical, biotechnology and device industries for more than 20 years, ProTrials professionals provide one of the industry's highest average years of experience. We offer a suite of services focused on clinical operations experience: • Experience in a broad range of therapeutic areas • Phase I-IV clinical trials • Highly-skilled project management services • Operational experience in North America and throughout Europe

Q2 Business Intelligence
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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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QARA BioPharma Solutions delivers a Dedicated, Comprehensive, and Unique Medical Writing service for the bio-pharmaceutical industry producing exceptional clinical and regulatory documents. Our consultancy services encompass global drug development, global medical affairs, and strategic drug development from drug inception to marketing. Our team has extensive experience in therapeutic areas including ophthalmology, dermatology, respiratory, oncology, endocrinology, and genetic diseases.

QPS, LLC
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Founded by Dr. Ben Chien in 1995, QPS is a GLP/GCP-compliant CRO that supports discovery, preclinical, and clinical drug development. We provide quality services in Neuropharmacology, DMPK, Toxicology, Bioanalysis, Translational Medicine, and Early & Late Phase Clinical Research to clients worldwide. Our 30+ regional laboratories, clinical facilities and offices are located in North America, Europe, India and Asia. For more information, visit http://www.qps.com.

Quality and Compliance Consulting, Inc.
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QC2 provides worldwide audit and consulting services, including: GCP, GLP, and cGMP Audits; Bioanalytical Laboratory Audits; Clinical Pathology Laboratory Audits; Sponsor, CRO, and Vendor Audits; Computerized System Validation Audits; Standard Operating Procedures Review and Preparation; GCP, GLP, QA, and SOP Training; and Consulting.

Quality Associates, Inc.
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Quality Associates, Inc., established in 1986 as an independent third party QA consulting company, specializes in GCPs and GLPs. Capabilities include all aspects of GCP and GLP QA work; e.g., site audits, site/CRO qualifications; data & report audits; database and master file audits; bio-analytical audits; training; computer system validation audits, etc. QAI has a staff of 8 auditors, all with various scientific experience. QAI maintains a GLP archive for storage of documents and specimens.

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Quanticate is a leading global biometrics focused Clinical Research Organization (CRO) primarily focused on the management, analysis and reporting of data from clinical trials and post-marketing surveillance. As Experts in Clinical Data, Quanticate provides high quality teams that offer efficient outsourcing solutions, including functional service provision (FSP) for clinical data management, biostatistics, SAS programming, source data verification, medical writing and pharmacovigilance.

QuantifiCare
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QuantifiCare started as a responsive full-services CRO for imaging. Seven of the top ten pharma companies, are routinely trusting QuantifiCare for their clinical trials. Over the years, we specialized in skin evaluation bringing our expertise to pharmaceutical, biotech and cosmetic industries. We provide dedicated 2D or 3D photographic hardware and our services include image procedure definition, Investigator training, image centralization, real time quality check and query resolution follow up.

Queensland Clinical Trials Network
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Working with Life Sciences Queensland Ltd (LSQ), QCTN is the primary point of contact for domestic and international organisations seeking to undertake preclinical and clinical research in Australia. QCTN's aim is to promote and raise the visibility of the Australian biopharmaceutical industry and life sciences service providers at a national and international level and to support them in building their capabilities and marketing activities.

Quintiles
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Quintiles (NYSE: Q) helps biopharma and other healthcare companies improve their probability of success by connecting insights from our deep scientific, therapeutic and analytics expertise with superior delivery for better outcomes. From advisory through operations, Quintiles is the world's largest provider of product development and integrated healthcare services.

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Quipment provides medical and laboratory equipment and supplies for clinical trials worldwide. In addition to catering more than 9,000 investigator sites per year, Quipment also offers cutting-edge tools to manage and track shipments, supplies & equipment calibrations real-time online.

Quorum Review IRB
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Quorum Review IRB is the first name in streamlined, service-centered independent ethics and regulatory review. Our service offerings include full study review in the U.S. and Canada, international ethics review, a specialized Phase I early engagement team, and unique processes to accelerate minimal risk research. Quorum works closely with institutions and researchers on studies from all over the world.

Radiant Research/Clinical Research Advantage
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Radiant Research has provided experienced research SITES to the pharmaceutical industry for over 22 years. Consisting of 77 US sites (stand alone as well as integrated), we are the country's largest Wholly Owned network of sites w/ fully integrated quality systems and standardized SOPS. We have enrolled in over 14,000 multi-therapeutic phase I-IV studies (including 500 VACCINES). 77+Sites 1 Company 1 Budget/Contract 1 Point of Contact 2.5 Million Patients Rapid Start Up Times Standardized SOPs

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Randstad Life Sciences is a leading staffing and recruiting partner to life sciences and biopharma companies throughout the U.S. We have more than 20 years of experience in finding top talent and make thousands on employer/candidate matches in project and full time jobs for roles in biopharma, chemical and cosmetics, food, manufacturing and testing, medical device, nutriceauticals and pharma.

Reed Technology
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Reed Tech provides a portfolio of SPL solutions including services for Rx, OTC and Biologics to make electronic submission compliance easy and less time consuming for manufacturers and distributors of drugs and biologics. We also offer Medical Device manufacturers services to meet FDA submission mandates for Unique Device Identifier data including data extraction and validation, submission preparation in SPL format, maintenance, content management, and Medical Device UDI information submission.

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Regxia Inc. is a unique Scientific and Regulatory Consulting Firm serving the pharmaceutical and biotech industries. Supporting products at all stages of development and throughout their lifecycle as part of overall project management or on a stand-alone basis. Regulatory; Clinical; Quality & Training Services: US-FDA, Health Canada, EMA: Dossier Compilation & Management; eCTD (compilation & publishing); CMC; CTAs, IND, NDS, ANDS, etc.; Monitoring; online ICH GCP Certificate Training.

ReSolution Latin America
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ReSolution is a regional niche CRO specialized in assisting Sponsors with their clinical research needs in Latin America. From one-off consultancy projects (Clinical Development Planning, Feasibility Studies, Regulatory Strategy) to Full Protocol Implementation and Study Execution, understanding local/regional idiosyncrasies and the demands of international studies, allows us to offer access to all the benefits the Latin American region has to offer (Enrollment, Quality, Timelines & Cost).

Rho, Inc.
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Rho is a full service CRO dedicated to enhancing the quality and speed of its customers' clinical trials through the highest levels of performance, accuracy, and scientific integrity. Rho contributes to the success of pharmaceutical, medical device, and biotechnology studies in a range of therapeutic areas.

Richman Chemical, Inc
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Ropack Inc.
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Ropack Pharma Solutions focuses on getting solid oral delivery forms to key value milestones and through to commercial launch quickly, flexibly, reliably. As a CDMO, we provide comprehensive clinical services: scale-up, comparator blinding, packaging, labeling, clinical supplies management and distribution. We shorten timelines by assisting with time-consuming documentation. Sourcing packaging locally and distributing from our Montreal and Long Island depots bring significant cost savings.

RR Donnelley Language Solutions
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RR Donnelley Language Solutions is a global translation service and technology provider. We help pharmaceutical, clinical research and healthcare organizations create, translate, harmonize and manage content in over 140 languages. Thanks to +25 years of experience, 6,000 linguists, ISO certified processes and a 24/7 service platform, we provide accurate, secure and fast translations. Our fully scalable solutions also include interpreting, TMS, dynamic website translation and much more.

RTI International **Booth: 2540**
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RTI Health Solutions (RTI-HS) provides consulting and research expertise to help pharmaceutical, biotechnology, diagnostics and medical device companies develop and commercialize their products.

Rundo International Pharmaceutical Research and Development Co., Ltd **Booth: 538**
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Rundo International was founded in 2004,the first Sino-foreign joint venture CRO in China. Rundo provides professional clinical research outsourcing and post-market consultancy services. Over the past 11 years since establishment, Rundo has carried out over 600 trials covering a wide range of therapeutic areas.

RURO, Inc. **Booth: 1536**
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RxLogix Corporation **Booth: 1305**
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Salesforce **Booth: 2130**
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SanaClis s.r.o. **Booth: 1537**
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SanaClis was founded in 2000 by seasoned industry experts all of whom have had executive level positions in leading pharma companies and large global CROs. SanaClis is a full-service CRO offering a comprehensive range of services for clinical trials in Central and Eastern Europe. SanaClis is one of the very few CROs offering customs brokerage, warehousing and distribution of clinical trial materials and by own professional staff, in addition to clinical monitoring and regulatory services.

SAP America, Inc. **Booth: 1728**
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Sarah Cannon, the global cancer institute of Hospital Corporation of America (HCA), 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.

SAS Institute Inc. **Booth: 1825**
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JMP® is the SAS® software designed for dynamic data visualization on the desktop. JMP Clinical shortens the drug development process by streamlining safety reviews of clinical trials data. It helps clinicians and biostatisticians migrate into the modern review environment using CDISC data. Intuitive dashboards create a visual framework for rigorous statistical analysis.

Schulman IRB **Booth: 1607**
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Schulman IRB provides high quality, rigorous IRB reviews for all research phases in North America via streamlined processes, customized technology and responsive customer service. We offer dedicated, AAHRPP-accredited IRB services for sponsors, CROs, sites and institutions and also offer CQA and HRP consulting via our partner Provision Research Compliance Services.

Scientific Commercialization LLC **Booth: 952**
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Scientific Commercialization is a boutique management consultancy that provides innovative services to life sciences companies in the areas of strategy, organizational design, process optimization, technology selection/implementation, business intelligence/analytics and human performance strategy. Since 2001, SC has completed over 300 consulting engagements with global and regional life sciences organizations, and offers SC-Insight, its highly regarded BI analytics dashboard.

Sharp Clinical Services
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Sharp Clinical Services is a leading provider of specialist clinical supply chain services, from drug product development and manufacturing services through to increasingly complex clinical supplies packaging, clinical labelling and clinical distribution services.

Smart Patients
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SNBL CPC is a 96-bed, full service clinical pharmacology research facility based in Baltimore, Maryland. Our team specializes in executing complex early phase clinical research studies, including adaptive design, proof of concept, challenge, TQT, and ethnobridging trials. SNBL CPC offers ancillary trial support services including protocol consulting and design, IRB submissions, laboratory services, data management, safety monitoring, and more.

Society for Clinical Research Sites - SCRS
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The Society for Clinical Research Sites (SRCS) was founded in 2012 in response to the growing need for a trade organization to represent the global voice and community of research sites within the clinical research enterprise. The goals of the Society include providing sites with resources, mentorship, and new ideas through a membership organization dedicated only to research sites.

Sonic Clinical Trials
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Sonic Clinical Trials is a wholly owned subsidiary of Sonic Healthcare Limited, one of the world's largest medical diagnostic companies. Sonic Clinical Trials is a dedicated central laboratory supporting all phases of clinical trials and ensuring the highest regulatory compliance. Services Offered: Central Laboratory Services include: Laboratory Testing, Protocol Management, Data Management, Sample Management and Blood Collection Services.

SOUSEIKAI Global Clinical Research Center
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SOUSEIKAI Global Clinical Research Center is one of the largest (400 beds) and oldest clinical research centers dedicated to clinical trials in Japan. Since 1986, we have been conducting pivotal Phase 0-IV clinical trials with many world leading pharmaceutical companies and CROs. Our specialties include auto glucose clamp studies, CNS studies, biologics, etc. We provide high quality, efficient, and safe Phase 0-IV studies, satisfying both our sponsors' needs and budget concerns.

Southern Star Research
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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.

Spark Therapeutics, Inc.
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Spark is a gene therapy leader seeking to transform the lives of patients with debilitating genetic diseases by developing one-time, life-altering treatments. Spark's initial focus is on treating rare diseases where no, or only palliative, therapies exist. Spark's validated gene therapy platform is being applied to a range of clinical and preclinical programs addressing serious genetic diseases.

Sparta Systems
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Sparta Systems, an industry leader of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. The Company's quality management platform solutions include TrackWise, Stratas and 123Compliance, providing customers a choice of on-premise and cloud offerings. Sparta Systems is a trusted standard among highly regulated industries to manage compliance, reduce risk and improve safety across the global enterprise.

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Spaulding Clinical Research, LLC is a global CRO providing Phase I - IV drug development services to the biotechnology and pharmaceutical industries. Spaulding Clinical Research operates a 200-bed Clinical Pharmacology Unit, Core ECG Laboratory and provides full Biometrics/Scientific Affairs Services.

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Splash Clinical, a wholly owned subsidiary of Teuteberg, Inc., is a global marketing services company specializing in Online and Social Media Marketing for Clinical Trial Patient Recruitment. We combine our extensive knowledge of online and social media marketing with rich analytics to create highly targeted campaigns that reduce the time and expense required to recruit patients. You can trust that our quality, knowledge, and customer service will help your clinical trial succeed.

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SDC is committed to providing experienced teams who will take ownership of your needs and are positively engaged in your projects. With biostatistics, clinical data management, and electronic data capture (EDC) services at our core, SDC also offers scalable full service clinical trial solutions via our diverse and complementary strategic partnerships. With experience on over 200 clinical trials and scalable services tailored to your needs, SDC is The Right Fit For You.

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Stefanini is an industry-recognized leader in IT outsourcing services, offering onshore, offshore & nearshore support to mid-size and large corporations. Service offerings include: IT help desk outsourcing, desktop managed services, IT asset management, SAP advisory, Microsoft SharePoint services, mainframe modernization, mobility services, and strategic staffing solutions. At a glance: 88 offices – 39 countries – 35 languages – 21,000 resources globally. www.stefanini.com

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For more than 20 years, Sterling IRB has helped lead the way in safeguarding the rights and welfare of clinical research participants. Our approach places the focus on your specific needs – complete with caring, responsive service and a single-point-of-contact you can always count on. Sterling IRB is fully accredited by AAHRPP, and has oversight capabilities in the U.S. and Canada. www.sterlingirb.com

Stiris Research Inc.
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Stiris Research Inc. is an entrepreneurial Clinical Trial Management CRO, providing both integrated team support and full-service management of Phase I-III clinical trials for the pharmaceutical and biotechnology industries. Stiris was formed as a result of listening to all of the stakeholders engaged in clinical trials, identifying their unmet needs and developing a unique, value-based approach to address those needs. This remains Stiris' approach for successful partnerships.

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Suvoda offers the industry's leading SaaS solution for patient randomization and supply management in clinical trials. Suvoda's Interactive Response Technology (IRT/IWRS) system combines the flexibility of a custom solution with the speed of a configurable platform, offering 4-week deployment, reimagined reporting, and easy integration.

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Symbio is a full-service CRO. Since 2002, we have been successfully managing Phase II-IV clinical trials. By partnering with our Sponsors, we are involved with strategic planning throughout the entire product development cycle. Therapeutic areas include dermatology, ophthalmology, women's health and internal medicine.

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Symphony Clinical Research, takes clinical study visits to patients where they live, work or play. We provide 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.

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Synchrogenix is a global regulatory and medical writing consultancy providing strategic solutions to address the industry's greatest regulatory challenges. We offer cross-functional expertise; nonclinical, clinical, CMC, and drug safety; and the only Artificial Intelligence-enabled solutions to meet transparency and disclosure requirements, including EMA Policy 70.

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Synex is a global CRO for both medical device and pharmaceutical products. We also support various steps of market entry in healthcare industry. By working with us, you will be offered integrated solutions which ensure successful market entry in Korea. With our experienced consultants, you will have the answers to questions concerning regulatory approval, clinical research, reimbursement listing, market research, and distribution clearly.

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Synexus US Clinical Research (formerly Research Across America) is an Independent Site Network-ISN (Non-SMO) that conducts Phase I through Phase IV and Post marketing trials utilizing their many regional multi-specialty sites. Our site locations include Dallas, El Paso and Plano TX, and New York, NY. The physicians affiliated with Synexus US have conducted over 1850 clinical trials since 1992. Our sites are under one corporate umbrella but have the flexibility of negotiating their own contracts and budgets.

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Syntel (Nasdaq:SYNT) is leading global provider of digital transformation, information technology and knowledge process services. Our 24,000+ employees worldwide combine deep industry knowledge, a flexible Global Delivery Model and a collaborative partnership approach to create innovative solutions, sustainable business value and competitive advantage for our clients. Learn more at www.syntelinc.com.

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SynteractHCR is a full-service CRO with a successful two-decade track record supporting biopharmaceutical and medical device companies through the clinical development process. We have conducted Phase I-IV studies on six continents and 60+ countries, in multiple therapeutic areas.

Target Health Inc.
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Target Health Inc., is full service CRO, with staff dedicated to all aspects of drug and device development including Regulatory Affairs (represent over 45 companies at the FDA), Strategic Planning, Clinical Research, Biostatistics, Data Management & Medical Writing. Target Health has a full suite of web based, 21 CFR part 11 compliant clinical trial software. 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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Tarius® Web Portals provide easy answers to your global FAQ's! Subscribing to Tarius enables online access to updated regulatory information on Human Drugs, Biologics, Medical Devices and IVDs across 100 countries. Excel-tables enable quick comparison across countries. Experts' summaries describe national regulatory procedures. Comprehensive compilations of local regulations ensure compliance. FDA Scientific Advisory Committee special reporting, Tarius SAC Tracker, keeps you informed.

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TCS is one of the largest pure-play professional services, consulting and business solutions organization in the world in terms of market capitalization. 13 of the top 15 pharma & biotech, & 8 of the top 10 medical device companies leverage TCS services which cover: CDM, biostatistics, medical writing, regulatory, drug safety, drug discovery, drug development, manufacturing, pharma sales and distribution. TCS has 350,000+ employees globally with 3900+ dedicated consultants in Clinical Services.

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As a CRO+, TRI possesses all the essential resources to offer first-class functional, project-based, and outsourcing services: quality operational, strategic, technical, and regulatory solutions, long-standing clinical trial expertise, and deep therapeutic knowledge. TRI offers health communication services such as multi-level event planning and execution, design and implementation of marketing and outreach campaigns, multimedia design, focus groups, surveys, trainings, and product launches.

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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.

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CRN is an innovative and dynamic clinical contractor and project resourcing provider. We support Sponsors/CROs with Clinical Professionals and Project Teams. Our solutions provide significant cost savings with an emphasis on quality and service delivery. If you are seeking clinical professionals or rewarding opportunities CRN sets the standard.

The Patient Recruiting Agency
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A full-service global patient recruiting/retention company supporting Investigators, CROs & Sponsors. Since 1999, TPRA has completed over 3,500 campaigns for over 150 indications. IN-HOUSE services: Copywriting Production & fulfillment of site kit materials Online & traditional (TV/radio/print) advertising production & media placement Website development with pre-screening Call pre-screening Text messaging RADIUS365™ online response, referral delivery and retention tracking, managing & reporting system

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Therapak is the global leader in providing 3rd party kit assembly and distribution services to pharmaceutical and laboratory organizations. Therapak's menu of services include assembly of lab convenience kits for collection of samples, temperature sensitive shipping systems, requisition and label printing and ancillary supply distribution direct to sites on a global basis. Therapak is a cGMP compliant organization with facilities in the US, UK and Singapore.

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Therapeutics, Inc. is The Dermatology CRO with unparalleled dermatology expertise & decades of experience. A full service CRO with numerous product approvals, TI designs and executes Ph1-4 multicenter trials in acne, psoriasis, dermatitis, rosacea, alopecia, tissue fillers, inflammation, & all pediatric/ adult derm categories. Guiding strategy, CMC, nonclin + clinical development, regulatory, trial management, DM+statistics, & life cycle management: concept, design, project planning/management.

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Thoughtsphere delivers industry leading data aggregation, Risk-Based Monitoring (RBM) and data quality based payments solutions through next generation data integration and analytics platform built on state of the art technologies. It encompasses interactive visualizations with actionable insights and review workflow to deliver RBM for clinical trials. Founded by thought leaders, the core management team has worked in the product and technology space for 20+ years in Life Sciences industry.

ThreeWire, Inc. **Booth: 1804**
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ThreeWire is a global patient recruitment, enrollment and management provider focused on accelerating patient recruitment and enrollment for the medical device, pharmaceutical, and biotech industries. We utilize a proven, flexible, systematic approach with measurable outcome-based strategies backed by performance-based pricing. Our customized recruitment programs provide valuable solutions for sponsors, CROs, sites and patients in North America, Europe, the Middle East, and Latin America.

TKL Research, Inc. **Booth: 803**
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TKL Research, Inc. is a full-service, Global CRO providing comprehensive trial management for Phase 1 - 4 studies. TKL now offers Pharmacovigilance Services and a fully renovated state-of-the-art Phase 1 and inpatient facility, located in Fairlawn, N.J. In addition, we have several specialized outpatient research clinics, conveniently located throughout the Metro Area. Since 1944, TKL has continued to deliver the highest level of services to Pharmaceutical and Biotech Industries.

TMS Health, A Xerox Company **Booth: 2437**
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TMS Health, A Xerox Company is a leading global provider of outsourced multi-channel contact center services specializing in the healthcare, pharmaceutical, and medical device industries. TMS Health is focused on delivering best-in-class customercentric programs designed to provide safe, accurate, and relevant information in a professional and efficient manner. We are dedicated to reaching, educating, influencing, and serving patients, customers, physicians, and pharmacists on behalf of our clients.

Total Clinical Trial Management **Booth: 742**
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Total Clinical Trials Management (TCTM), is an emerging contract research organization based in Dallas, Texas. TCTM has a unique perspective on emphasizing the relationship with the clinical research site as a primary driver for successful clinical trial completion. TCTM has a wide range of therapeutic expertise with recent areas of focus including pain, orthopedic injury, GI, dermatology, cosmetics, over-the-counter (OTC) and generic studies.

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TransPerfect Life Sciences specializes in supporting global development and commercialization of drugs, treatments, and devices designed to improve and save lives. Our comprehensive solutions include eTMF and eClinical technologies, paper TMF migration, pharmacovigilance and safety solutions, translation and language services, and call center support. With offices in over 90 cities worldwide, TransPerfect is the ideal partner to ensure that your global launch makes a global impact.

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TrialX is a clinical research software company based out of New York. We develop consumer-centric digital solutions to connect patients to clinical research. Our solutions include an award winning trial finder, a patient recruitment platform, mobile research study Apps built using Apple's Researchkit and big data solutions for clinical trial analytics

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Trifecta is a leading global clinical technology solutions provider, producing more than 350 live, on-demand, and web-based Investigator meetings each year in 87 countries. Trifecta's pioneering innovative training and portal solutions improve trial quality, speed study start-up and Site readiness, and improve workflow and communication between Sites, Sponsors and CROs.

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Trilogy is a medical writing consultancy focused specifically on clinical regulatory documentation. We work as an outsourcing partner for our clients: proactively planning, coordinating and writing their clinical documentation to meet aggressive timelines, with a readability that reduces the time for review and approval. We help pharmaceutical companies of all sizes, worldwide, to streamline their documentation process and make sure their documents communicate clearly and effectively.

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UBC unites unsurpassed experience in generating real-world evidence of product safety, value, and effectiveness, with the strength of its parent company, Express Scripts, one of the nation's largest healthcare companies. UBC leads the market in providing integrated, comprehensive periapproval, safety, and commercialization services.

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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.

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UF offers an online MS in Pharmacy with a concentration in Pharmaceutical Outcomes & Policy. Personalize your education with one of our four specializations: Managed Care Pharmacy Systems, Applied Pharmacoeconomics, Patient Safety in Medication Use, or Pharmaceutical Regulation. This online master's program is tailored for working professionals, making it more manageable to balance work, family & education.

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As part of University of the Sciences, Mayes College focuses on the integration of healthcare business and policy. Mayes 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.

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The University of Utah Clinical Trials Office was established with a mission to provide clinical investigators and sponsors with comprehensive support services, research tools, personnel and facilities to conduct clinical research studies. Our experience includes working with special populations including neonatal, pediatric, adolescent, young adult, pregnant and geriatric participants.We offer services from protocol design, IND/IDE submissions, site activation, close-out and analysis.

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Inspire. Engage. Transform. Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice.

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URSATEC stands for innovative developments in preservative-free pharmaceutical, medical device and cosmetic products such as oral and nasal sprays. Safe protection against contamination by microorganisms, even after the opening of a package, is guaranteed by the dual microbiological protection of the patented dosing systems 3K® and COMFORT®.

UTMB Sealy Center for Vaccine Development
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The University of Texas Medical Branch (UTMB) Sealy Center for Vaccine Development (SCVD) is a comprehensive vaccine center that develops and supports multidisciplinary programs in discovery, basic and applied research/preclinical development, clinical trials and clinical research, public health policy, community outreach and education/training. The Clinical Trials Group has experience with Phases I, II, III, and IV vaccine clinical trials, and access to pediatric and adult study populations.

Valesta Clinical Research Solutions
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Valesta Clinical Research Solutions helps organizations find skilled clinical research professionals at all career levels for project-based, contract-to-hire, and direct hire opportunities. Our dedicated Account Executives thoroughly understand the industry and work to provide resourcing solutions in areas including clinical data, clinical monitoring, medical writing, biometrics, and regulatory affairs.

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Validated Cloud is the leader in Quality forward GxP hosting cloud and support services. Purpose built for the specialized needs of the Life Sciences, open for audits, transparent operations. Our highly secure service is ISO 27001:2013 certified. A fully integrated Quality system built in accordance to 21 CFR Part 820 encompasses ISO 9001, HIPAA, 21 CFR Part 11, Annex 11 and ISO 27001. All activities have experienced Life Science Quality oversight. Audit and believe this can be done well.

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Veeva Systems is a leader in cloud-based software for the global life sciences industry. Veeva Vault is the first cloud-based regulated content management platform and suite of applications designed for life sciences. It spans clinical, regulatory, quality, medical, and commercial to ensure one trusted source for content and data across the enterprise. Veeva Vault provides the accessibility, visibility, and agility needed to speed time to market.

Verified Clinical Trials
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Verified Clinical Trials is a research subject clinical trials database registry designed to prevent dual enrollment and several key protocol violations critical to a clinical trials success. VCT will improve safety and data quality in clinical trials. This will reduce adverse events and placebo rates. VCT has many functions that enhance the trial experience and safety while reducing liabilities in many arenas. VCT is partnered with a great number of the world's largest research companies.

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Veristat is a full-service clinical research organization (CRO) with over 20 years of experience supporting pharmaceutical, biotechnology and medical device companies throughout the clinical trial and regulatory submission process . Our experts provide strategic consultation throughout your program, clinical operations support, safety management, data management and standards implementation, biostatistics, statistical programming, medical writing and regulatory submissions support.

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Vigilare a full service safety services organization providing pharmaceutical, biotechnology, & medical device companies with a full range of safety services in Radnor, PA. Quality is an integral driver for all our offerings. Pharmacovigilance personnel are highly educated healthcare professionals. Overarching QA Plan assures the highest level of consistency, continuity & quality of data. With 45 yrs industry leadership experience; we assure client projects are managed effectively & efficiently.

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Altasciences Clinical Research encompasses Algorithme Pharma, Vince & Associates Clinical Research and Algorithme Pharma USA, thereby making it one of the largest early phase clinical CROs in North America. With over 25 years of industry experience, Altasciences provides early phase clinical development services to an international customer base of biopharmaceutical and generic companies.

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VirtualScopics is a global imaging core lab with proven medical, imaging, operational and project management capabilities. Our expertise and experience includes integrating MRI, CT, DXA, PET, X-Ray, and ultrasound into the therapeutic areas of oncology, hematology, muscle disease, metabolic disease, and neuroscience for clinical trials.

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Vitalograph is an industry leading manufacturer of cardio-respiratory diagnostic medical devices for use in clinics and in pharmaceutical clinical development. Vitalograph provide Standardized Equipment and Centralized Services for Spirometry, Cardiac Safety and eCOA data collection. Vitalograph offer independent, quality over-read services by industry experts in accordance with regulatory, industry and protocol requirements. Vitalograph, providing data you can rely on by people you can trust.

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The Electronic Common Technical Document (eCTD) format will soon be required for submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

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Don't forget

Requirements for study data standards are also coming soon.

If you are beginning a study after December 17, 2016, make sure you understand FDA's new mandatory data standards for most CDER/CBER submissions.

Learn more at **www.fda.gov/ForIndustry/DataStandards/StudyDataStandards or Booth 1426.**

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