HELPING DELIVER LIFE
CHANGING THERAPIES

“We need more clinical trials and we need to keep innovating in clinical research.”

Teresa
Triple Negative Breast Cancer Survivor and Executive Director, Project Management, PPD

“I have diabetes and I’m happy to know that people are working to find a cure.”

Luke
12-Year Old Living with Type I Diabetes

At PPD, what we do impacts our clients, our employees and people around the world. We see the benefits of clinical trials firsthand and are committed to building strong partnerships with our clients. Because to us, clinical research isn’t just business — it’s personal.

Be part of the change. Visit PPD at Booth No. 701 and see how you can help change lives.

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### 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:**
- 9:00 AM - 5:00 PM  Exhibitor Registration

**Schedule:**
- 9:30 - 10:30 AM  Coffee Break (Exhibit Hall)
- 10:30 - 11:45 AM  Educational Opportunities
- 10:45 - 11:45 AM  Engage and Exchange Session (Exhibit Hall A)
- 11:30 AM - 2:00 PM  Luncheon (Exhibit Hall)
- 12:00 - 1:00 PM  DIA Community Meet & Eat (Exhibit Hall A)
- 12:00 - 1:45 PM  Innovation Row Tour (Room 104A)
- 1:30 - 3:30 PM  Exhibit Guest Passes
- 2:00 - 3:15 PM  Educational Opportunities
- 3:00 - 4:00 PM  Refreshment Break (Exhibit Hall)
- 4:00 - 5:15 PM  Educational Opportunities

#### SUNDAY, JUNE 26

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

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

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

**Monday, June 27**

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

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

#### Tuesday, June 28

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

**Schedule:**
- 7:00 - 8:00 AM  Coffee and Light Refreshments (Grand Hall & Room 108 Concourse)
- 8:00 - 9:30 AM  DIAMond Sessions
- 9:00 AM - 5:00 PM  Exhibit Hall Open

#### Wednesday, June 29

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

**Schedule:**
- 7:00 - 8:00 AM  Coffee and Light Refreshments (Grand Hall & Room 108 Concourse)
- 8:00 - 9:30 AM  DIAMond Sessions
- 9:00 AM - 4:00 PM  Exhibit Hall Open
- 9:30 - 10:30 AM  Coffee Break (Exhibit Hall)
- 10:45 - 11:45 AM  Engage and Exchange Session (Exhibit Hall A)
- 11:30 AM - 2:00 PM  Luncheon (Exhibit Hall)
- 10:30 - 11:45 AM  Educational Opportunities
- 10:45 - 11:45 AM  Engage and Exchange Session (Exhibit Hall A)
- 11:30 AM - 2:00 PM  Luncheon (Exhibit Hall)
- 3:00 - 4:00 PM  Refreshment Break (Exhibit Hall)
- 3:15 - 4:00 PM  Engage and Exchange Session (Exhibit Hall A)

#### Thursday, June 30

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

**Schedule:**
- 8:00 - 9:00 AM  Coffee and Light Refreshments (Room 108 Concourse)
- 9:00 - 10:30 AM  DIAMond Sessions
- 10:30 - 10:45 AM  Coffee Break (Room 108 Concourse)
- 10:45 AM - 12:00 PM  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!

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

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

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

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

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

ConvergeHEALTH by Deloitte | 5:15 PM
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. | 9:45 AM
Leveraging Patient Data and Historical Investigator Performance Data to Realize Faster Patient Recruitment

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

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

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

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

Wednesday, June 29

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

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

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

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

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

Thank You to our Media Partners

Let’s Continue to Recognize Study Volunteers as Partners in Clinical Research

Communicating Trial Results: Since 2011, CISCRP has worked with more than two dozen research sponsors to address the critical unmet need to provide non-technical clinical trial results summaries to study volunteers.

Patient Advisory Board Panels: These panels amplify patients’ voices and feedback on protocol design feasibility, recruitment communications, clinical trial medicine kits and technology solutions.

Visit ciscrp.org and contact us at support@ciscrp.org for more information.
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:
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.
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.
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
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
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

First Aid Center
First Aid is available for routine health problems and emergency care. The First Aid Center is located in 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.

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.

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!

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.

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.
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 8:00 AM and after 6:00PM
Tuesday, June 28 | Before 8:00 AM and after 5:00PM
Wednesday, June 29 | Before 8:00 AM and after 5:00PM
Thursday, June 30 | Before 9:00 AM 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.
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)**

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)**

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.

**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.

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

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/certificatoprograms.

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"

The content noted on this page was made available to DIA as of May 24, 2016.
### DIA 2016 TRACKS AND INTEREST AREAS

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### 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

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<td>A 60- or 75-minute blended presentation and panel discussion.</td>
<td>A 60- or 75-minute presentation delivered lecture-style from the podium.</td>
<td>A blend of three 20-minute presentations.</td>
<td>A 90-minute conceptual presentation delivered in an interactive/simulation or role playing format.</td>
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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

#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)

SATURDAY, JUNE 25–MONDAY, JUNE 27

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

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**#102 Track 01B – Clinical Operations**

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

8:30–9:45 AM  
Room 113A  
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

**Panelists**
- Susan Uptain, PhD  
  Head of Regulatory Affairs Operations, Baxalta
- David Robinson, PhD  
  Principal Consultant, Robinson Vaccines and Biologics LLC

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**#103 Track 01C – Clinical Operations**

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

8:30–9:45 AM  
Room 113B  
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.

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

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

8:30–9:45 AM  
Room 105AB  
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**
- Eva M. Finney, PhD, PMP  
  Director, Global Project & Alliance Management, Merck & Co., Inc.

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

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

8:30–9:45 AM  
Room 107AB  
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

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**#106 Track 03 – Innovative Partnering Models and Outsourcing Strategies**

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

8:30–9:30 AM  
Room 112AB  
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

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

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

8:30–9:45 AM  
Room 202AB  
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

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The content noted on this page was made available to DIA as of May 24, 2016.
#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**  
**Room 203AB**  
**Format: FORUM**  
**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

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

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

**8:30–9:45am**  
**Room 201C**  
**Format: SESSION**  
**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)
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
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
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
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

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

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

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

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

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

**Related Interest Area(s):** OS, RD

**10:45am–12:00pm**  
**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

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

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

**10:45am–12:00pm**  
**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. Krauer, 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
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

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

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 Milikan
  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  
**Exhibit Hall A**  
**Level:** ■  
**Format:** WORKSHOP  
**Interpreting Meaningful Change on PRO Instruments: Methods in Action**  
**Chairperson:**  
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  

#148  Track 20 – Innovation Theaters  
**Related Interest Area(s):** RA  
1:00–1:30PM  
**Exhibit Hall B**  
**Level:** ■  
**Format:** SESSION  
**PAREXEL Innovation Theater: Balancing Rapid Approval with Demonstration of Value**  
**Chairperson:**  
Larry Brilliant, MD, MPH  
Chairman, Skoll Global Threats Fund  

#149  Track 22 – Engage and Exchange  
**Related Interest Area(s):** PPLC, RA  
1:30–2:15PM  
**Exhibit Hall A**  
**Level:** ■  
**Format:** WORKSHOP  
**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  
**Exhibit Hall B**  
**Level:** ■  
**Format:** SESSION  
**Quintiles Innovation Theater: Evidence Optimization: Fueling Smarter Clinical Development and Value Generation**  
**Chairperson:**  
Larry Brilliant, MD, MPH  
Chairman, Skoll Global Threats Fund  

#151  Track 23 – Opening Plenary  
2:30–4:00PM  
**Ballroom AB**  
**Level:** ■  
**Format:** SESSION  
**Plenary Session and Keynote Address**  
**Opening Remarks**  
Hans-Georg Eichler, MD, MSc  
Senior Medical Officer, European Medicines Agency, European Union  

**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  

#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  
**Exhibit Hall B**  
No CE Available  
**BBK Innovation Theater: Reimagining the Patient Experience Through mHealth Technologies**  
**Chairperson:**  
Larry Brilliant, MD, MPH  
Chairman, Skoll Global Threats Fund  

#154  Track 20 – Innovation Theaters  
**Related Interest Area(s):** CP  
5:15–5:45PM  
**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

**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

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### #201 Track 19A

**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

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### #202 Track 19B

**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

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### #203 Track 19C

**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

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### #204 Track 21: Poster Presentations

9:40–10:20AM  No CE Available  
Exhibit Hall A  Professional Poster Session and Oral Presentations 1A

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The content noted on this page was made available to DIA as of May 24, 2016.
#205 Track 22 – Engage and Exchange

Related Interest Area(s): PETD

9:40–10:25am  
Format: WORKSHOP

Exhibit Hall A

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  
Format: SESSION

Exhibit Hall B

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  
Format: SESSION

Room 108A

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  
Format: FORUM

Room 108B

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

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

Related Interest Area(s): PM, PETD

10:30–11:45am  
Format: WORKSHOP

Room 102AB

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  
Format: SESSION

Room 105AB

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  
Format: FORUM

Room 111AB

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
Philiomena 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

#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

**SPEAKER(S)**
- Current Status of Big Data Use in the Health Care Sector: View from the Market
- Big Data Being Part of FDA eHealth Policy: Viewpoint of the Regulator
- Challenges of Big Data in the Regulatory Environment from the Legal Point of View

#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**

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

**CHAIRPERSON**
Herschel 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

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#227 Track 17 - Rare/Orphan Diseases
**Related Interest Area(s): ROD, RA**

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**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

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#228 Track 22 - Engage and Exchange
**Related Interest Area(s): CR**

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**Increase Value of Clinical Trials Through Impactful Branding**

**CHAIRPERSON**
Neil Weisman
Executive Vice President and General Manager, Continuum Clinical

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#229 Track 21: Poster Presentations

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**Professional Poster Session and Oral Presentations 1B**

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#230 Track 20 - Innovation Theaters
**Related Interest Area(s): CR, PT**

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

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#231 Track 22 - Engage and Exchange
**Related Interest Area(s): MW, SUBS**

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**Introduction to Structured Content**

**CHAIRPERSON**
Ann Rockley, MLIS
Chief Executive Officer, The Rockley Group Inc., 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

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#232 Track 20 - Innovation Theaters
**Related Interest Area(s): IT**

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**PRA Innovation Theater: Transforming EMR to EDC**

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*The content noted on this page was made available to DIA as of May 24, 2016.*
#233 Track 20 – Innovation Theaters

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

1:20–1:50pm  
**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  
**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  
**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  
**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  
**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  
**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 GxPTT 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 202B  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)
FDA Perspective
Bakul Patel, MBA, MSc
Associate Vice President, Regulatory Affairs - Devices, Sanofi US

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

Related Interest Area(s): PT

2:00–3:15pm  
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  
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  
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  
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  
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

#250 Track 15 – Statistical Science and Quantitative Thinking

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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

#248 Track 14A – Clinical Safety and Pharmacovigilance

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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

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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

#251 Track 16 – Professional Development

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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

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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

**Panelists**

Jeffrey Skene  
Division Chief, Monoclonal Antibodies, Health Canada

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#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

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#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

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#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**

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#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 Development 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

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#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

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3:00–4:00pm

**Refreshment Break in Exhibit Hall**
#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)**
- Thijs Van Iersel, MD
  Senior Director of Science, Early Development Services, PRA Health Sciences, Netherlands
- Gopalan Narayanan, MD, FFPM, FRCP
  Biologics and Advanced Therapies Expert, NDA Group, United Kingdom
- Thijs Van Iersel, MD
  Senior Director of Science, Early Development Services, PRA Health Sciences, Netherlands

**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)**
- Alexander Varond, JD
  Associate, Hyman, Phelps & McNamara, PC
- 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
- Jeffrey K. Francer, JD, MPA
  Vice President and Senior Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)

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

#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)**
- Dominick L. Albano, PharmD, MBA
  Vice President, Global Medical Information, Pfizer Inc
- 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)**
- Doug Bain
  Co-Chief Executive Officer / Chief Technology Officer, eClinicalHealth Ltd., United Kingdom
- Chris Watson, PhD
  Director of Product Strategy, Exco InTouch, United Kingdom
- Bruno Gagnon, MPharm
  Executive Consultant, Clinical Operations, Myokardia, Inc.

**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.
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 Ratcliffe, 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

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#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

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#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.

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#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

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#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

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The content noted on this page was made available to DIA as of May 24, 2016.
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. Eggman, 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
Room 204A

Making Quality Stick: Building a Complete Quality Culture
CHAIRPERSON
Coleen Giessner, 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
Room 111AB

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
Room 103A

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
Room 113B

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
Room 109AB

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
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
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, Vital Transformation, 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
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
9:40–10:20 AM
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
9:40–10:25 AM  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
9:45–10:15 AM  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
10:30–11:45 AM  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
10:30–11:45 AM  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
10:30–11:45 AM  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
10:30–11:45 AM  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

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

**Time:** 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

**Speakers:**

**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

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

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

**Time:** 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

**Speakers:**

**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

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#318  **Track 10 – Public Policy/Health Care Compliance/Law**

**Related Interest Area(s):** CR, PPLC

**Time:** 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)

**Speakers:**

**Industry Perspective**  
David Vulcano, MBA, RAC  
Assistant Vice President and Responsible Executive for Clinical Research, Hospital Corporation of America (HCA)

**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

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

**Related Interest Area(s):** CR, CDM

**Time:** 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.

**Speakers:**

**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

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

**Related Interest Area(s):** SP

**Time:** 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

**Speakers:**

**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
#321  **Track 12 – Pharmaceutical Quality**  
**Related Interest Area(s): CMC, RA**  
**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**  
**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**  
**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  

#324  **Track 15 – Statistical Science and Quantitative Thinking**  
**Related Interest Area(s): ST, CR**  
**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**  
**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  Format: FORUM
Room 103A

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  Format: SESSION
Room 201C

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  Format: WORKSHOP
Exhibit Hall A

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  Format: SESSION
Exhibit Hall B

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  Format: WORKSHOP
Exhibit Hall A

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  Format: SESSION
Exhibit Hall B

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  
**12:00–1:15pm**  
Exhibit Hall B  
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**  
Room 113A  
**LEVEL:**  
**FORMAT:** Forum  
**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**  
Room 113B  
**LEVEL:**  
**FORMAT:** Symposium  
**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**  
Room 113C  
**LEVEL:**  
**FORMAT:** Symposium  
**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**  
Room 105AB  
**LEVEL:**  
**FORMAT:** Session  
**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, RA, QC, GCP*

2:00–3:15pm  
**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  
**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  
**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  
**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

**Wednesday, June 29**

**2:00–3:00pm**  
**Room 204B**  
CME and Nursing

**eTMF: Selection, Implementation, and What’s Next?**

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

**SPEAKER(S)**

- Laxman Kumar Jakkala, Sr., PhD  
  Director, Global Quality Assurance, Makrocare, India

- Martina M. Duevel, DrSc, PhD  
  Senior GCPM ONC, eTMF Process Owner Representative, Bayer Pharma AG, Germany

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

**Wednesday, June 29**

**2:00–3:15pm**  
**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)**

- Amrita Basu, PhD  
  Genomics and Computational Biology Lead, Health and Life Sciences, Lockheed Martin Information Systems & Global Solutions

- Srinivas Karri, MSc  
  Director, Clinical Warehousing Cloud Strategy, Oracle Corporation, United Kingdom

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#343 Track 08 – Regulatory Affairs

**Wednesday, June 29**

**2:00–3:15pm**  
**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

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#344 Track 09 – Medical Devices/In vitro Diagnostics and Combination Products

**Wednesday, June 29**

**2:00–3:15pm**  
**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.

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

**Wednesday, June 29**

**2:00–3:15pm**  
**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
Wednesday, June 29

#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**

**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**

**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 (GRP), Pfizer Inc

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

**Related Interest Area(s): CEHTAEbM**

**2:00–3:15pm**

**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**

**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
Wednesday, June 29

#350 Track 14B – Clinical Safety and Pharmacovigilance

2:00–3:30pm  
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)
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

2:00–3:15pm  
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

2:00–3:15pm  
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

2:00–3:00pm  
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

2:00–3:00pm  
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 Operations Senior Manager, Amgen Inc.

The content noted on this page was made available to DIA as of May 24, 2016.
3:00–4:00PM

**Refreshment Break in Exhibit Hall**

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**#355 Track 20 – Innovation Theaters**
Related Interest Area(s): CP

3:25–3:55PM
Exhibit Hall B

**DBMS Innovation Theater: Safety Data Delay is a Risk-Enhanced Signal Detection With Customized MedDRA and Drug Grouping Queries**

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**#356 Track 22 – Engage and Exchange**
Related Interest Area(s): PM

3:15–4:00PM
Exhibit Hall A

**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

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**#357 Track 01 – Clinical Operations**
Related Interest Area(s): RA, CR, PPLC, EC, IT

4:00–5:15PM
Room 108B

**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

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**#358 Track 02 – Project/Portfolio Management and Strategic Planning**
Related Interest Area(s): PM, PETD

4:00–5:00PM
Room 102AB

**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

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**#359 Track 03 – Innovative Partnering Models and Outsourcing Strategies**
Related Interest Area(s): OS, QC, RD, IT

4:00–5:15PM
Room 111AB

**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

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**#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
Room 105AB

**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
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
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
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
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
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

#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 Doseage 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**

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**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**

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**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**

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**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**

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**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

**Panelists**
- FDA Perspective
  - Suranj 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**

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**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
THURSDAY, JUNE 30

Registration Hours:
8:00–11:00 AM Attendee and Speaker Registration

8:00–9:00 AM
Coffee and Light Refreshments
Room 108 Concourse

#375 TRACK 16A – PROFESSIONAL DEVELOPMENT  Related Interest Area(s): PETD
4:00–5:00 PM  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
4:00–5:15 PM  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

#401 TRACK 19A  Related Interest Area(s): RA
9:00–10:30 AM  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

Related Interest Area(s): CR

9:00–10:30 AM
Room 103ABC
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.

Coffee Break
Room 108 Concourse

10:30–10:45 AM

10:45–12:00 PM
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

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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.

#404 Track 03 – Innovative Partnering Models and Outsourcing Strategies

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

10:45 AM–12:00 PM
Room 112AB
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

10:45 AM–12:00 PM
Room 107AB
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

Coffee Break
Room 108 Concourse

10:30–10:45 AM

10:45–12:00 PM
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

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

The content noted on this page was made available to DIA as of May 24, 2016.
#406 Track 06 – Medical Communication/Medical Writing and Medical Science Liaisons

**Related Interest Area(s):** MW, CR, CR, SUBS

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**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

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#407 Track 07a – Technology/Data/Records and Submissions

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

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**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

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

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

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**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.

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

**Related Interest Area(s):** MDD, PPLC

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**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 Purrrington, 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  
  Shū 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

Stay Connected

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#DIA2016
**Poster Program**

**Student Poster Session**

*Monday, June 27, 9:30 AM – 6:00 PM | Posters will be displayed in Exhibit Hall A*

*Award Ceremony at 5:30 PM | 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 5:30 PM 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  
Texas American University

Reshma Lakhram  
Touro College of Pharmacy

**M 07** Synergistic 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 13** Pediatric Opioid 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
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 Stergiopoulou
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
Exco InTouch, United Kingdom

**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
Exco InTouch, United Kingdom

**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
Jessica Chou
TCDE

**T 25** So You Want to Influence Stakeholders...Now What? How Outreach Programs can Advance Clinical Research
Jui Shah, PhD
National Institutes of Health (NIH)

The content noted on this page was made available to DIA as of May 24, 2016.
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.
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 Whitself
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
Stuart Walker, PhD
Center For Innovation in Regulatory Science (CIRS)

W 25 Industry-Based Pharmacist 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
Algorithm 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 1:20–1:30 PM
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 12:30–12:40 PM
Rashmi Dodia
MMS Holdings, Inc.

W 36 The Influence of Atypical 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 12:40–12:50 PM
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 12:50–1:00 PM
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 1:10–1:20 PM
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 1:00–1:10 PM
Nihar Parikh, PMP
Citiustech Inc.

W 50 Predicting Future State and Business Drivers of Safety System Upgrades based on Safety Database Upgrade and Industry Trends
Amanda Bowles MS
Deloitte Consulting

W 51 Visualizing Patients’ ADaM Data via SAS and R
Bella Feng, PhD, MS
Amgen, Inc.
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.

**President’s Award for Outstanding Contribution to Global Health**

**Drugs for Neglected Diseases initiative (DNDi)**

The Drugs for Neglected Diseases initiative (DNDi) 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.

DNDi 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**

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**

**Outstanding Contribution to Health in the North America Region**

**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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3D Communications
Contact: Karen Johnson
Email: kjohnson@3dcommunications.us
Website: www.3dcommunications.us

3D Communications is preeminent in preparing pharma, biotech and device companies for FDA interactions, Advisory Committee meetings, and Market Access negotiations. We’ve provided strategic counsel and hands-on implementation for nearly 150 Advisory Committee meetings and submissions. Our services include messaging, scripting, Q&A, slide development, briefing book writing, and communications coaching.

4C Pharma Solutions LLC
Contact: Dr. Muhammad Ahmad
Email: info@4cpharma.com
Website: www.4cpharma.com

4C Pharma Solutions is an Oracle partner with fully implemented Argus, certified in ISO 9001:2008 & 27001:2013 excelling in Pharmacovigilance, Regulatory Affairs, Medical Writing, Healthcare Analytics and Clinical Staffing solutions. 4C provides comprehensive services including setting up processes, systems, certifications, trainings & operations. With our deep understanding of operational challenges from personal experience, we render the most optimal results saving your precious time for R&D.

AB CUBE
Contact: Claudine Richon
Email: claudine.richon@ab-cube.com
Website: www.ab-cube.com

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Accenture Accelerated R&D Services
Contact: Ellen Semple
Email: ellen.a.semple@accenture.com
Website: www.accenture.com/lifesciences

Accenture Life Sciences is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better patient outcomes. We provide end-to-end business services as well as consulting, outsourcing and technology projects around the globe in all strategic and functional areas. Accenture Life Sciences group connects >10,000 skilled professionals in >50 countries who are committed to helping our clients achieve their business goals and deliver better health outcomes.

ACM Global Central Laboratory
Contact: Mark Engelhart
Email: mengelhart@acmlab.com
Website: www.acmgloballab.com

ACM Global Central Laboratory specializes in delivering high quality central laboratory testing services designed to optimize clinical trial outcomes. Through a powerful combination of robust global capabilities, operational and scientific expertise and unsurpassed service, ACM Global acts as an extension of our clients’ clinical teams to develop and execute Smarter Testing strategies that deliver reliable outcomes for their clinical development programs.

Acurian, Inc.
Contact: Kirk McPoyle
Email: kirk.mcpoyle@acurian.com
Website: www.acurian.com

Acurian, a subsidiary of PPD, is the global leader and industry specialist offering ways to enroll trials faster and more cost efficiently. We do this by consistently giving clinical trial managers more consented patients per site, faster enrollment, and lower costs. For over 18 years, we have helped sponsors efficiently enroll and retain the patients they need. When you can’t afford a delay in patient enrollment, only Acurian can deliver the patients you need, when and where you need them.

ADAMAS Consulting LLC
Contact: Steve Bliss
Email: steve.bliss@adamasconsulting.com
Website: www.adamasconsulting.com

ADAMAS Consulting is the leading global provider of Quality Assurance and Quality Management System consulting services. With 19 years experience and a full-time staff of dedicated ADAMAS Auditors/Consultants—including former MHRA (GCP and PV) inspectors. We conduct audits across the entire GxP spectrum including sites, PV audits, lab, vendor audits, mock inspections, inspection readiness and training. With offices in the US, EMEA AND APAC we have the entire world covered. www.adamasconsulting.com

Adaptive Clinical Systems
Contact: Mitch Collins
Email: mitch.collins@adaptive-clinical.com
Website: www.adaptive-clinical.com

If you are struggling with integration of clinical study data from multiple systems and platforms, Adaptive Clinical Systems offers a simple, secure, validated, compliant, and cost-effective solution for clinical data integration. The Adaptive eClinical Bus, a cloud-based hosted service, will integrate with your EDC, ePRO, CTMS, Medical Imaging, IVR/IWR, and analytical/data visualization systems to ensure accurate and efficient transfer of clinical data for any study of any complexity.

Advanced Clinical
Contact: Kristin Kelley
Email: kkelley@advancedclinical.com
Website: www.advancedclinical.com

Advanced Clinical is an award-winning clinical development organization that provides global end-to-end services, including CRO, functional support, quality & validation, patient recruitment and retention, and strategic talent acquisition solutions for pharmaceutical, biopharmaceutical, biotechnology, and medical device organizations. Our mission is to deliver a truly better clinical experience for our clients.
Aerotek
Contact: Kathleen Zazzara
Email: kzzazara@aerotek.com
Website: www.aerotek.com
Aerotek is the #1 U.S. provider of clinical and scientific staffing and provides the highest level of service through our customized recruiting solutions. By understanding your industry, our specialized recruiters are aware of hiring trends and know how to identify the necessary skills for each position.

AgilePV
Contact: Dan Feith
Email: dan.feith@agilepv.com
Website: www.agilepv.com
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
Contact: Ellen Diegel
Email: ellen.diegel@almacgroup.com
Website: www.almacgroup.com
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Alpha Clinical Systems
Contact: Koshy Philip
Email: Koshy.Philip@alphaclinicals.com
Website: www.alphaclinicals.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
Contact: Koshy Philip
Email: Koshy.Philip@alphaclinicals.com
Website: www.alphaclinicals.com
Alpha IRB provides a comprehensive and transparent regulatory solution for all your IRB needs. From Protocol Development, New Application, Amendments, Inactive and Administrative closure, Alpha IRB monitors your trial and provides meaningful scores to indicate risk. Alpha IRB delivers a quick, easy and straightforward process.

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Email: www.amazon.com
Our customers use our cards as incentives, gifts and rewards for their employees, customers and partners. We help clients achieve a higher level of business performance — rewarding behavior, increasing engagement and cutting costs. We offer organizations a range of solutions that provide their target audience with value that can be used on Amazon.com without fees or expiration dates. We offer customizable digital and physical gift card options, email fulfillment, bulk codes, and an API.

American Solutions for Business
Contact: Michael Tornvall
Email: DIA2016@americanbus.com
Website: www.americanbus.com
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
Contact: Eric Haase
Email: eric.haase@amplexor.com
Website: www.amplexor.com
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.

Ancillary, LP
Contact: Mike Brown
Email: michael.brown@ancillare.com
Website: www.ancillare.com
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 more information, visit Ancillare.com.

AnovaFill
Contact: Katherine Brandt
Website: www.aftonscientific.com
AnovaFill prepares cGMP washed empty sterile vials, stoppers and seals (Ready-To-Fill®) for cGMP aseptic filling operations. Anova Vials™ are used in small clinical fills and approved commercial injectable drugs. Anova is inspected by both FDA and MHRA. Worldwide users of Anova Vials™ include small biotechs and major multinational pharmaceutical companies.

APCER Life Sciences
Contact: Jill Notte
Email: jillnotte@apcerls.com
Website: www.apcerls.com
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
Contact: Tara Burwell
Website: www.appian.com
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**Applied Clinical Trials/Pharmaceutical Executive**

- **Contact:** Melissa Devlin
- **Phone:** 203-523-6952
- **Email:** melissa.devlin@ubm.com
- **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**

- **Contact:** Joshua Boutwell
- **Phone:** 404-217-9213
- **Email:** jboutwell@aquilasolutions.us
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**ArisGlobal**

- **Contact:** Miko Arai
- **Phone:** 609-360-4052
- **Email:** marai@arisglobal.com
- **Website:** www.arisglobal.com

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**

- **Contact:** Gerard Bradley
- **Phone:** 480-269-8124
- **Email:** gerard.bradley@arivis.com
- **Website:** www.arivis.com

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**

- **Contact:** Alan White
- **Phone:** 35312544033
- **Email:** alan.white@arriello.com
- **Website:** www.arriello.com

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**

- **Contact:** Brian Schaechter
- **Phone:** 908-782-4921-4205
- **Email:** Bschaechter@artcrafthealth.com
- **Website:** www.artcrafthealth.com

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**

- **Contact:** Jonathan Lowe
- **Phone:** 801-583-2787
- **Email:** jonathan.lowe@aruplab.com
- **Website:** www.aruplab.com

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**

- **Contact:** Ali Burhani
- **Phone:** 603-7725-7500
- **Email:** info@asiacroalliance.com
- **Website:** www.asiacroalliance.com

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**

- **Contact:** Dana Niedzielska
- **Phone:** 359-2-971-4593
- **Email:** dniedzielska@augustresearch.com
- **Website:** www.augustresearch.com

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.**

- **Contact:** Christopher Kata
- **Phone:** 416-318-5588
- **Email:** solutions@axiom.cc
- **Website:** www.axiommetrics.com


**AxxiTRIALS (Litéra)**

- **Contact:** Susan MH Lewenz
- **Phone:** 336-375-2991
- **Email:** slewenz@litera.com
- **Website:** www.axxitrials.com

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.
BARC Global Central Laboratory
Contact: Ann De Smet
Email: ann.desmet@barclab.com
Website: www.barclab.com
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
Contact: Naiya Ganatra
Email: nganatra@barnettinternational.com
Website: www.barnettinternational.com
Leaders in Clinical Research Training Barnett helps clients get the most out of their research and development dollars by managing change effectively, improving organizational performance, and enhancing staff knowledge. The Barnett approach is a unique combination of strategy development and practical, hands-on implementation. The “Barnett Difference” is evident in our deep understanding of the clinical research process and in the rapid and tangible performance improvements we deliver.

Barrington James
Contact: Pippa Wilson
Email: ljackson@barringtonjames.com
Website: www.barringtonjames.com
Barrington James are a Global specialist recruitment consultancy with offices in the USA, Europe and APAC that works across the healthcare sector. Our structure, with separate divisions and dedicated consultants for the markets we serve ensures a thorough, professional and intelligent approach in both permanent and interim solutions. Our tailored methodologies include contingency database search and executive search.

BBK Worldwide
Contact: Joan F. Bachenheimer and Bonnie A. Brescia
Email: info@bbkworldwide.com
Website: www.bbkworldwide.com
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
Contact: Alex Liu
Email: liuxhong@clinicalservice.cn
Website: www.clinicalservice.cn
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.

Benchmark Research
Contact: Richie Kahn
Email: richardkahn@benchmarkresearch.net
Website: www.benchmarkresearch.net
Benchmark Research is a fully integrated network of sites with broad therapeutic experience and geographic reach. Standardized recruitment, retention, quality, training and site operations combined with Benchmark’s “One Voice” model offer unmatched efficiencies. In 2016, we opened our first Urgent & Family Care center which allows us to take on a wider variety of trials. Contact us today about making Benchmark Research sites the cornerstone of your next program.

Bioclinica
Contact: Kimberly Salgueiro
Email: kimberly.salgueiro@bioclinica.com
Website: www.bioclinica.com
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Bioclinica Clarity Bar
Contact: Jeff Rogers
Email: jrogers@clinverse.com
Website: www.clinverse.com
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Bioclinica
Contact: Steve Chen
Email: shchen@biofortis.com
Website: www.biofortis.com
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 gained through automation.

Bioclinica
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Exhibitor Directory

BioPharm Insight
Contact: Mike Reynolds
Email: mreyolds@infinata.com
Website: www.biopharminsight.com

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 GmbH
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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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BIOVIA
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BizInt Solutions, Inc.
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Blinded Diagnostics
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BloodCenter of Wisconsin
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BrackenData

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Clinical Trial Intelligence Solution software using analytics for decision making. Our analytics software provides you with an intuitive, easy to use interface with complete mouse-over logic and drill down function, leading to intelligence at your fingertips. BrackenData offers three unique software platforms: TrialFinder, ProtocolAnalytics, and ResearchAnalytics as well as customize packages for your individual needs. Our novel software was the Winner of the 2016 Microsoft BizSpark award!

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Bristol-Myers Squibb

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C3i Healthcare Connections

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Cambridge Healthtech Institute

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Canfield Scientific, Inc.

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Contact: Simon Venhuizen  
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Website: www.celerion.com  
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Cardinal Health  
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Contact: Alexandre Durand-Salmon  
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Website: www.banookgroup.com  
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).

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Contact: Leslie Sullivan-Stacey, JD  Phone: 513-636-3232
Email: leslie.sullivan-stacey@cchmc.org
Website: www.cincinnatichildrens.org/clinical-studies
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Clarinness  Booth: 628
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Clinical Practice Research Datalink (CPRD)  Booth: 2157
Contact: Amal Saleh  Phone: 442030806115
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Clinical Reference Laboratory  Booth: 900
Contact: Debbie Felice  Phone: 913-693-2550
Email: Deborah.Felice@crlcorp.com
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Content Analyst Company
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Contract Pharma
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Conversis
Contact: Mark Hooper
Email: mark.hooper@conversismedical.com
Website: www.conversismedical.com

Conversis Medical is a leading provider of translation and localisation services for the Life Science and Pharmaceutical Industry with a specialism in multi-national clinical trials. We offer medical translation services for clinical CRO, pharmaceutical companies and healthcare advertising agencies. We translate • all materials relating to patient access and retention • patient education and training materials • investigator materials • product marketing materials • product leaflets • web campaigns.

Cornerstone OnDemand Inc.
Contact: Rachel Lindsay
Email: rlindsay@csod.com
Website: www.cornerstoneondemand.com/life-sciences

Cornerstone OnDemand is pioneering solutions to help organizations realize the potential of a modern workforce. As a global leader in cloud-based learning and talent management software, Cornerstone is designed to enable a lifetime of learning and development that is fundamental to the growth of employees and organizations.

Costa Rican Investment Promotion Agency - CINDE
Contact: Lucia Gross
Email: lgross@cinde.org
Website: www.cinde.org

Costa Rica has emerged as a leading location for MedTech Investment. It ranks #1 in availability of engineers & scientists, and quality of specialized research in LATAM. (WEF 2015-2016). Incentives as low as 0% income tax, strong industry-academic collaboration and presences of +60 Medtech firms provide the ideal investment site. CINDE is a private, non-profit, responsible for the attraction of Foreign Direct Investment (FDI) into Costa Rica. Our services are free of charge.

CNS Healthcare Booth: 1150
Phone: 407-722-5219

Collaborative Consulting Booth: 2256
Phone: 781-565-2600

CompleWare Booth: 1442
Phone: 319-626-8888

Comprehend Systems Booth: 2231
Phone: 650-521-5449

Content Analyst Company Booth: 840
Phone: 703-391-8700

Contract Pharma Booth: 2139
Phone: 201-825-2552

ConvergeHEALTH by Deloitte Booth: 1901
Phone: 617-831-4164

Conversis Booth: 949
Phone: +44(0)1869-255820

Cornerstone OnDemand Inc. Booth: 2530
Phone: 310-752-0158

Costa Rican Investment Promotion Agency - CINDE Booth: 1257
Phone: 50-622-012-823
Covance Inc.
Email: covance.inc@covance.com
Website: www.covance.com
Covance Inc. is a global leader in contract research services, providing comprehensive clinical development solutions to biopharmaceutical companies. Our services include clinical trial design, statistical analysis, regulatory strategy, and site management. With over 33,000 employees worldwide, Covance is dedicated to delivering the highest quality of care and service to our clients. To learn more about our services and how we can help you achieve your clinical development goals, visit our website at www.covance.com.

CSSi
Contact: Chris Trizna
Email: ctrizna@cssienroll.com
Website: www.CSSiEnroll.com
CSSi is a leading provider of global patient recruitment solutions for the clinical research industry, delivering successful enrollment, on time, every time. CSSi is a member of the CRO Network and has been recognized for its innovative strategies and experienced team of recruitment professionals. With a focus on patient recruitment and study design, CSSi is committed to helping our clients achieve their research goals. Visit our website at www.CSSiEnroll.com for more information.

CTI Clinical Trial & Consulting Services
Contact: Allison Schroeder
Email: info@ctifacts.com
Website: www.ctifacts.com
CTI Clinical Trial & Consulting Services is a global, privately held, full-service CRO, delivering a complete spectrum of clinical trial and consulting services throughout the lifecycle of development. CTI's focused therapeutic approach provides clinical and disease area expertise in rare diseases & regenerative medicine/gene therapy, and several other areas. CTI has a passion for helping life-changing therapies succeed in chronically and critically ill patient populations.

CSOFT International Ltd.
Contact: Jessica Teng
Email: jessica.teng@cssoftintl.com
Website: www.cssoftintl.com
CSOFT International Ltd. is a leading provider of globalization and communication solutions to the Fortune 1000, ranging from translation and localization services to branding and market entry strategies. Recognized as one of the Top Innovative Companies in 2011 by IDC and one of the Top 5 Language Service Providers worldwide, CSOFT delivers fast and professional medical, IT and technical translation services into 100+ languages with ISO 13485:2003 quality.

Cu-Tech, LLC
Contact: Kathleen Ashenfelter
Email: kashenfelter@cu-tech.com
Website: www.cu-tech.com
Cu-Tech, LLC is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

Crucial Life Sciences Data Solutions
Contact: Andrew Sizelove
Email: info@clsdss.com
Website: www.clinicalstudio.com
Crucial Life Sciences (Clinical Studio), is a rapidly growing eClinical company focused on providing truly innovative technology tools to clinical research professionals. We are proud recipients of the 2015 SCDM NextGen Technology Innovation Award and are excited to share our technology and mobile strategy with the attendees of DIA!

Cu-Tech, LLC
Contact: Kathleen Ashenfelter
Email: kashenfelter@cu-tech.com
Website: www.cu-tech.com
Cu-Tech, LLC is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

CROee Inc.
Contact: Aoyagi Kiyoshi
Email: aoyagi@croee.com
Website: www.croee.com/en
CROee Inc. is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

Court Square Group/RegDocs365
Contact: Keith Parent, CEO
Email: sales@courtsquaregroup.com
Website: www.courtsquaregroup.com
Covance is a professional consultancy specializing in the needs of FDA regulated companies, including IT planning, network, security and project management. Covance has expertise in business process optimization, auditing and quality (including validation), clinical data services, application development, and provides secure cloud hosted and managed systems.

Cros NT
Contact: Mary Wieder
Email: mary.wieder@crosnt.com
Website: www.crosnt.com
CROS NT is a data centric Contract Research Organization for Phases I-IV and medical device trials. Our contribution starts in early phase for targeted eligibility searches to recruit participants. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.

CRScube Inc.
Contact: Eric Choi
Email: hwchoi@crscube.co.kr
Website: www.crscube.co.kr
CRScube is a No.1 Clinical Research Solutions provider in Korea. We provide integrated clinical research solutions; cubeCDMS, cubeIWRS,cubePRO, cubeSAFETY, cubeCTMS, and cubeBUILDER. As a total clinical research solution provider, CRScube has been engaged in > 400+ studies across all phases in many therapeutic areas > 90 pharmaceutical companies and over 10 CROs > 15,000 sites in 10 Asian countries including 300,000 subjects Please visit our website, to find out more about us. Thank you.

CSL Behring
Contact: Debbie Finer
Email: Debbie.finer@cslbehring.com
Website: www.cslbehring.com
CSL Behring is a leading global biotherapeutics company with a broad range of innovative plasma-derived and recombinant therapies. For over a century, we have been driven by our promise to save lives. Today, our therapies include those to treat coagulation disorders, primary immune deficiencies, and hereditary angioedema among others.

CTI Clinical Trial & Consulting Services
Contact: Allison Schroeder
Email: info@ctifacts.com
Website: www.ctifacts.com
CTI Clinical Trial and Consulting Services is a global, privately held, full-service CRO, delivering a complete spectrum of clinical trial and consulting services throughout the lifecycle of development. CTI's focused therapeutic approach provides clinical and disease area expertise in rare diseases & regenerative medicine/gene therapy, and several other areas. CTI has a passion for helping life-changing therapies succeed in chronically and critically ill patient populations.

CSOFT International Ltd.
Contact: Jessica Teng
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Website: www.cssoftintl.com
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CSSi
Contact: Chris Trizna
Email: ctrizna@cssienroll.com
Website: www.CSSiEnroll.com
CSSi, the leader in global patient recruitment solutions for the clinical research industry, delivers successful enrollment, on time, every time. Through its innovative enrollment planning and full-service patient recruitment solutions, CSSi is able to reduce the costs and timelines associated with recruitment of subjects for clinical studies.

CRF Health
Contact: Dana Perotti
Email: info@crfhealth.com
Website: www.crfhealth.com
CRF Health is the leading provider of electronic Clinical Outcome Assessment (eCOA) solutions for global clinical trials. With experience in more than 800 trials, over 100 languages and across 74 countries, CRF Health’s TrialMax eCOA solutions consistently demonstrate the industry’s highest data accuracy, patient and site compliance, and patient retention.

CROee Inc.
Contact: Aoyagi Kiyoshi
Email: aoyagi@croee.com
Website: www.croee.com/en
CROee Inc. provides proprietary products and service to pharmaceutical companies and contract research organizations to facilitate the identification, selection and management of human subjects for clinical trials in Japan, China, Korea, and Taiwan. (culturally adaptive patient recruitment service) One of the proprietary products is “The Seikatsu-Kojo” Patient Database of 700,000+ categorized by medical history, that allows for targeted eligibility searches to recruit participants.

Covance Inc.
Contact: Andrew Sizelove
Email: info@clsdss.com
Website: www.clinicalstudio.com
Crucial Life Sciences (Clinical Studio), is a rapidly growing eClinical company focused on providing truly innovative technology tools to clinical research professionals. We are proud recipients of the 2015 SCDM NextGen Technology Innovation Award and are excited to share our technology and mobile strategy with the attendees of DIA!

Cu-Tech, LLC
Contact: Kathleen Ashenfelter
Email: kashenfelter@cu-tech.com
Website: www.cu-tech.com
Cu-Tech, LLC is a full-service CRO, celebrating over two decades of premier service to the pharmaceutical industry, specializing in Dermatology clinical trials management, conduct, and monitoring. Cu-Tech professionals offer a complete array of services and consultation to the client from the inception to completion of a project. We maintain an extensive database of the finest dermatologists in North America and abroad. Our clients can attest to our personal hands-on approach.
At Cytel, we’re helping shape the future of drug development. As the world’s largest Biometrics CRO, our dedicated teams are here to help you address an array of critical clinical research challenges. Whether you face a complex statistical issue or the need for biometrics and trial implementation from knowledgeable collaborators, Cytel has skilled experts available when you need them. More at cytel.com

Dacima Software, Inc
Contact: Dr. John Podoba
Email: john.podoba@dacimasoftware.com
Website: www.dacimasoftware.com

Dacima Software Inc. is a leading innovator in Electronic Data Capture technology. Dacima Clinical Suite is a flexible and powerful, web-based EDC software with features and capabilities that allows for the rapid creation of sophisticated and elegant eCRFs without the need for programming expertise. The software includes a features and options for the configuration of different study designs, including RCTs, observational studies, patient registries, web surveys, ePRO and patient diaries.

Data Matrix
Contact: Anna Davydova
Email: adavydova@oct-clinicaltrials.com
Website: www.dm-matrix.com

Data Matrix is a full service Data Management and Statistics company with our own software platform - Matrix CDMS. Matrix CDMS is an EDC, IWRS, CTMS, and E-Diary application on one platform. The software is a fully validated and 21 CFR Part 11 compliant product. Data Matrix team provide a complete range of DM and Statistics services from CRF development to final study report preparation. Data processed by Data Matrix team has been successfully used for FDA and EMA applications.

DataArt
Contact: Daniel Piekarz
Email: Daniel.Piekarz@dataart.com
Website: www.dataart.com

DataArt is a technology consulting firm that designs and builds custom software systems. We partner with clients to create and support innovative solutions that help businesses become a lasting success in the marketplace. To every project, we bring a combination of industry knowledge, unique company culture and some of the best technical talent in the world. Our clients’ business outcome is the true measure of our success and pushes us to find creative solutions to the most difficult problems.

Datapharm Australia Pty Ltd
Contact: Luke Edington
Email: luke.edington@datapharmaustralia.com
Website: www.datapharmaustralia.com

Run your clinical trials in (or from) Australia: • Up to 45% R&D tax credit offered by the Australian Government. • Australia’s speedy regulatory approval process • World class Australian health professionals and scientists. Datapharm (Full Service CRO) has the local knowledge, resources, experience, & innovative technology with FDA compliant processes, to provide our Clients access to the advantages of the Australian clinical trial environment. We also seek other CROs who need Australian presence.

DATATRAK International, Inc.
Contact: Dorothy Radke
Email: Dorothy.Radke@Datatrak.com
Website: www.datatrak.com

DATATRAK is an industry-leading provider of digital Clinical solutions and services. DATATRAK simplifies clinical trials with software that responds to the unique needs of each trial. From data gathering and analysis to submission, we eliminate redundandy and the need for revalidation, provide real-time data views, and a robust tool set to analyze stored data instantly, right through the interface, at the site, trial, cross-trial or enterprise levels. Safely accelerate your trial with DATATRAK.

Datatrial
Contact: Julie Wright
Email: julie.wright@datatrial.com
Website: www.datatrial.com

Datatrial believes that life science organizations should have access to one solution to collect and report on all of their clinical research data and that all users should have access to an easy to use, speedy system that intuitively leads them through patient enrollment, patient visits and more. Our mission is to utilize our experience and expertise to offer study sponsors a compliant and fully validated solution for their data capture needs.

DaVita Clinical Research
Contact: Adam Patton
Email: DCRmarketing@davitac.com
Website: www.davitacclinicalresearch.com

For 30 years, DCR has used its extensive database and real-world healthcare experience to assist client companies in the design and execution of clinical trials. From our two hospital-based Phase I clinical trial units to our extensive investigator network, we provide clinical trial support across therapeutic areas including ESRD, CKD, cardiovascular, diabetes, and others. Our capabilities span the product lifecycle and include real-world data and medical communications.

DBMS Consulting, Inc.
Contact: Sunil G. Singh, CEO
Email: info@clinicalserver.com
Website: www.clinicalhosting.com, http:www.clinicalserver.com

dsNavigator support is not available, and your team is hemorrhaging, regulatory consequences hang over your head, what to do. DBMS has proven solutions to stop the bleeding, a leader in the implementation of centralized Medical Coding systems. We can write the prescription for you. The FDA discovering safety issues with your products you are not.... at risk for the 483. DBMS has a tool that can empower medical monitors to manage MedDRA and WHOdrug custom queries to better address RISK....... CQT

DDI LLC
Contact: Mahesh Malneedi
Email: mahesh@ddismart.com
Website: www.ddismart.com

DDI, a prominent technology partner to the life sciences industry has built its solution competency with a unique blend of functional and domain expertise to serve the technology needs of global clients. Our Products that are in Clinical and Regulatory are fully validated and provide best ROI. Our solutions include ClinMetanoia (vendor oversight, trial optimization) & TULA (Risk Management), MPDsmart (IDMP).
As the premier professional community for the health care product development ecosystem, DIA provides global players a neutral and transparent forum for the exchange of ideas and collaboration by offering access to tools, resources, and networking opportunities for extending debate and discussion to advance scientific and medical innovation.

**DIA Patient Engagement Booth**
Contact: Elizabeth Lincoln  
Email: Elizabeth.Lincoln@DIAglobal.org  
Website: www.DIAglobal.org

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**
Contact: Jim Nichols  
Email: jim nichols@ditaexchange.com  
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**
Contact: Matt Mitchell  
Email: matt.mitchell@aurotechcorp.com  
Website: www.dlta.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**
Contact: Herb Lee  
Email: Herbert.Lee@dlss.com  
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.**
Contact: Kim Shouler  
Email: info@dwlanguages.com  
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**
Contact: Dr. Leonardo Ebeling  
Email: info@ebeling-assoc.com  
Website: www.ebeling-assoc.com

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**
Contact: Cindy Murray  
Email: solutions@drugdev.com  
Website: www.drugdev.com

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.**
Contact: Jack Minster  
Email: jminster@dsg-us.com  
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. ... A 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**
Contact: Melissa Clark  
Email: melissa.a.clark@dm.duke.edu  
Website: www.dcrl.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.
DZS Clinical Services and Software/ClinPlus  Booth: 2009
Contact: Bob Borysko and Greg Ambra  Phone: 732-764-6969
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
Founded in Prague in 2004, EastHORN is one of the leading CROs in Central and Eastern Europe. Present in Germany, Austria and 17 countries in the CEE region, our experience is driven largely by the availability of patient populations in CEE and covers areas such as oncology, cardiology, gastroenterology, immunology, ophthalmology, rheumatology, nephrology, metabolic, central nervous system, women's health disorders and paediatric indications.

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.

EGene International Corporation  Booth: 2440
Contact: Philip Vorwald  Phone: 443-255-8420
EElite 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
Email: jill@eliteresearchstaffing.com
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
Email: BBISHOP@EMBSTATS.COM
Website: www.EMBStats.com
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
Email: rkeane@endpointclinical.com
Website: www.endpointclinical.com
Endpoint is an innovative company focused on providing interactive response technology (IRT) systems and solutions to support the life sciences industry. endpoint’s proprietary IRT system PULSE® provides non-technical users with the necessary tools to design and deploy customized IRT solutions in just four weeks. Endpoint’s founding team has been developing IRT systems since 1998. See how our flexible IRT solution meets the unique needs of any clinical trial at www.endpointclinical.com.

Enforme Interactive  Booth: 1752
Contact: Eric Delente, CEO  Phone: 301-788-1900
Email: info@secureconsent.com
Website: www.secureconsent.com
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
Contact: Jim Wade  Phone: 336-613-4887
Email: jim.wade@ennov.com
Website: www.ennov.com
With over 15 years’ experience and 500 clients worldwide, Ennov makes the most integrated, cost-effective and user-friendly software for Life Sciences. Our 4 mobile solutions: Quality, Regulatory, Clinical and Pharmacovigilance integrate with your workflow to help you reach your compliance and productivity goals faster, with no IT skills required.

Entimo AG  Booth: 2131
Contact: Jörn Bilow  Phone: 49-30-520024-100
Email: bil@entimo.de
Website: www.entimo.com
Entimo, a life sciences and regulatory informatics company, provides superior quality software products and reliable services which streamline the clinical development processes. entimICE® Integrated Clinical Environment is a completely metadata-driven and modular enterprise solution. It provides: - Data and metadata repository - Standards management - Data transformation to CDISC SDTM, ADaM and other models - Statistical computing environment - Data consistency checks - Define.xml generation
ePatient Enroll, Inc. Booth: IR2
Contact: Devon Parks Phone: 888-251-7688
Email: info@epatientenroll.com
Website: www.epatientenroll.com

ePatient Enroll is a global patient recruitment firm specializing in digital enrollment solutions. Leveraging our eCentric Platform™ we connect clinical trial teams to ePatients for study feasibility, clinical recruitment and subsequent retention services. Our patient-centric model has helped sponsors enroll for multiple therapeutic areas including Dermatology, Allergy, Endocrinology, Asthma, Pain Management, Gastroenterology, Ophthalmology, Oncology, and many more.

ePatientFinder Booth: 2507
Contact: James Foster Phone: 512-593-5005
Email: jfoster@epatientfinder.com
Website: www.epatientfinder.com

ePatientFinder is an opportunity for physicians to connect their patients with life changing treatment opportunities of which they were previously unaware. Through our platform, we deliver information about novel preventative treatments including clinical trials to physicians and their patients. Our vision is to ensure that every patient is made aware of their treatment options because not knowing is not acceptable.

ePharmaSolutions Booth: 1215
Contact: Cara Deieso Phone: 609-945-0109
Email: cdeieso@wcgclinical.com
Website: www.epharmasolutions.com

ePharmaSolutions (ePS) is a leading provider of e-clinical solutions that improve the way that clinical trial sites are selected, trained, activated, and managed. By applying fresh thinking to difficult problems, we deliver clever, technology-enabled solutions that empower biopharmaceutical companies, contract research organizations and investigator sites to “un-complicate” the chaos of clinical trial management.

EPS Holdings, Inc. Booth: 1933
Contact: Askold Kozbur Phone: 1-708-657-4321
Email: akozbur@epsgr.com
Website: www.eps-holdings.co.jp/en

EPS Holdings, Inc. is a comprehensive provider of clinical research outsourced solutions. EPS operates in Japan, China, South Korea, Singapore, Taiwan, Thailand, Philippines, Australia, New Zealand, Malaysia, Vietnam, India, Indonesia, and Hong Kong. EPS Group Companies provide R&D support to pharmaceutical, biotech, and medical device companies. EPS also provides SMO, IT, Professional Support Call Center, Pre-clinical Study Agent, and Contract Sales Organization services.

ERT Booth: 509
Contact: Sheryl Walder Phone: 215-972-0420
Email: eresearch@ert.com
Website: www.ert.com

ERT is a leading provider of high-quality patient safety and efficacy endpoint data collection solutions for use in clinical drug development. ERT delivers solutions in: Centralized Cardiac Safety including ambulatory blood pressure monitoring (ABPM), Respiratory Services, Clinical Outcome Assessments (COA) – ePRO, eClinRO, eObsRO, Suicidality Risk Assessment, and related consulting. ERT is a global organization with headquarters in Philadelphia, PA & offices in the U.S., U.K., Japan, & Germany.

ETQ, Inc. Booth: 2252
Contact: Angela Lodico Phone: 516-293-0949
Email: info@etq.com
Website: www.etq.com

ETQ is the leading Quality, EHS, Operational Risk and Compliance management software provider for identifying, mitigating and preventing high-risk events through integration, automation and collaboration. At the core of ETQ’s framework is a compliance management platform that enables organizations to implement best in class compliance processes configured to meet their existing processes, create new compliance processes and automate and control their compliance ecosystem.

Eurofins Booth: 516
Contact: Elena Logan Phone: 717-925-6145
Email: Elena.Logan@eurofinsus.com
Website: www.centralab.eurofins.com

Eurofins Central Laboratory: Results that matter. At Eurofins, we are proud to call our central lab services hardcore. Central laboratory testing is our sole focus and 100% resource dedicated. We are the most devoted group of professionals available to execute and array of services ensuring that any clinical trial sample is collected, transported, managed, analyzed, reported and stored to meet the objectives of your study. With worldwide coverage – let us take you to the next level.

European Medicines Agency Booth: 1432
Contact: Beatrice Fayl von Hentaller Phone: 44-20-3660-8426
Email: beatrice.fayl@ema.europa.eu
Website: www.ema.europa.eu

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.

EUROTRIALS Booth: 2039
Contact: Cláudia Carvalho Phone: 351-21-382-54-40
Email: claudia.carvalho@eurotrials.com
Website: www.eurotrials.com

EuroTrials is a privately held full-service CRO with more than 20 years of experience, specialized in clinical research and scientific consultancy in Europe and Latin America. EuroTrials has been validated by international R&D companies and has several Master Agreements. Our services span from Clinical Research to Epidemiology, Regulatory Affairs, Pharmacovigilance, Health Economics, Data Management and Biostatistics.

EvaluatePharma USA Inc. Booth: 916
Contact: Drew Matthews Phone: 617-573-9450
Email: drew.matthews@evaluategroup.com
Website: www.evaluate.com

Evaluate is the trusted provider of life science commercial intelligence for R&D, commercial teams and their advisors. We deliver quality, timely, must-have data and insights, and give expert support to help our clients make better decisions. We cover the pharmaceutical, biotech, medtech sectors & clinical trials. Our Custom Services group delivers project based, expert analytical and data services. Vantage, our award-winning editorial team, offers data-driven news, commentary and analysis.
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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.
Fountain Medical Development Ltd. (FMD)  
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We are a Contract Research Organization (CRO) offering data management, biostatistics, statistical programming, CDISC compliant eSubmission, pharmacovigilance, medical writing, and clinical operations to the pharmaceutical, biotechnology, and medical device industries worldwide. In addition, we provide regulatory affairs services in China and South East Asia. We continuously strive to raise the standard of excellence through accuracy and efficiency.

Frenova Renal Research  
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Email: research@fmc-na.com  
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Frenova Renal Research is your only clinical development partner dedicated exclusively to renal research. We offer complete Phase I-IV clinical services and exceptional bioinformatics capabilities, along with a world-class network of resources and access to 390,000+ active CKD and 183,000+ active ESRD patients. Trust the partner that’s completely renal — Frenova!

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Website: www.gene.com

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Email: marketing@formedix.com  
Website: www.fdanews.com

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Flex Databases  
**Booth: 1642**  
Contact: Pelageya Grosheva  
Website: www.flexdatabases.com

Flex Databases is a software provider specializing in automation and enhancement of business processes in clinical trials. We offer a unique platform which allows combining traditional features related to management of clinical trials with the functionality for running internal pharma companies and CRO processes as well as a capability to manage financial data and invoicing.

FOMAT Medical Research  
**Booth: 1056**  
Contact: Beatriz Morales Medical  
Website: www.fomatmedical.com

FOMAT Medical Research is pioneering clinical research in Latin America. By directing the clinical research department for several of the largest hospitals continent-wide and possessing the professional expertise to assist pharmaceutical companies and/or contract research organizations with local regulatory agencies, it has enabled them to reach their project goals rapidly and successfully.

Foresight Group International AG  
**Booth: 1343**  
Contact: Scott Fonseca  
Website: www.foresightgroup.com

Foresight Group is a worldwide management and technology consulting company focused exclusively on drug safety and risk management services and solutions. We provide hosted safety solutions and specialize in PV process design and optimization, safety database implementation, ad hoc and custom reporting, signal management, risk management and inspection readiness and response.

Formedix Inc.  
**Booth: 2434**  
Contact: Mark Wheeldon  
Website: www.formedix.com

Formedix is a leading supplier of clinical trial automation software and services based on CDISC standards. CRO, pharma and biotech organizations work with Formedix to conduct clinical trials more efficiently, automating manual and time-consuming tasks. Our clients benefit from significant reduction in study setup time, build automation of all market-leading EDC systems, coupled with optimized study conduct and analysis, and streamlined submissions. Your clinical trials automated. Everywhere.
Global Clinical Trials, LLC  
Contact: Nataliya Katsnelson  
Email: nkatsnelson@gctrials.com  
Website: www.gctrials.com  

GCT is a full-service clinical CRO, headquartered in Princeton, NJ, with operations in Eastern Europe and Russia. We have been performing clinical research in this rapidly emerging regions since 2001 within GCP/EMA-FDA standards and this year comes the 15th anniversary of our successful business. With individual approach to each client, flexible pricing, fast patients’ recruitment, and high quality clinical development services we won the reputation of a trusted and reliable partner.

Global Instrumentation LLC  
Contact: James DeMaso  
Website: www.GlobalInstrumentation.com  

Global Instrumentations M12R ECG acquisition units combined with the M12A Enterprise application provide a turn-key solution to meet the requirements of clinical research. This platform supports a seamless exchange of ECG data from investigator sites to a centralized location including the export of FDA-HL7 data.

Global Language Solutions  
Contact: Inna Kasatkina  
Website: www.globallanguages.com  

Global Language Solutions (GLS) is an ISO 9001:2008 and ISO 17100 (formerly EN 15038) certified translation company specializing in pharmaceutical and clinical research translations in 100+ languages. Our regulatory experts and medical linguists have the knowledge that regulated industries demand plus extensive experience translating protocols, ICFs, labels, patient-reported outcomes (PROs), clinical trial agreements, websites, IVR/IWR & EDC applications. GLS is a certified WBE founded in 1994.

GlobalCare Clinical Trials, LTD  
Contact: Gail Adinamis  
Website: www.globalcarect.com  

GlobalCare conducts study visits (eg. blood draws, drug admin) at patients’ homes or other convenient locations via its global network of traveling clinicians to facilitate trials in a variety of indications and all phases and age groups. Globalcare’s patient-centric approach provides faster patient recruitment and better compliance/retention.

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Contact: Brandon Underwood  
Website: www.globalsubmit.com  

GlobalSubmit offers software solutions and regulatory publishing services to facilitate the delivery of high-quality, compliant regulatory submissions to global health agencies. We are introducing products for life sciences document management and regulatory information management in 2016. Headquartered in Philadelphia, we have regional offices in Boston and Research Triangle Park, NC.

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Contact: Kim Mason  
Website: www.gobalto.com  
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Green Key Resources  
Contact: Kim York  
Email: kimy@greenkeyllc.com  
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Greenphire  
Contact: Emily Forgash  
Email: emily.forgash@greenphire.com  
Website: www.greenphire.com  

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.

Guangzhou KingMed Center for Clinical Laboratory Co. Ltd.  
Contact: Shuzhuang Peng  
Email: gz-pengshuzhuang@kingmed.com.cn  
Website: www.kingmed.com.cn  

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.

H&J CRO International, Inc.  
Contact: Dr. Diane Y. Ding, MD.  
Email: dingyu@hjcro.com  
Website: www.shujumetrics.com  

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.

Hangzhou Tigermed Consulting Co., Ltd.  
Contact: Jenny Zhang  
Email: jenny.zhang@tigermed.net  
Website: www.tigermed.net  

Hangzhou Tigermed Consulting Co., Ltd. is a leading clinical research organization based in Hangzhou, China. We offer a wide range of clinical research services, focusing on oncology and other difficult-to-treat diseases. With over 10 years of experience, Tigermed has successfully completed thousands of clinical trials in China and internationally.

HCL America Inc.  
Contact: Abhishek Singh  
Email: contact.lsh@hcl.com  
Website: www.hcltech.com  

HCL is a $6.8Bn leading global technology and IT enterprise. Founded in 1976, HCL is one of India’s original IT garage start-ups. The HCL team consists of over 105,000 professionals of diverse nationalities, who operate from 31 countries including over 500 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. Its range of offerings includes product engineering, custom applications, BPO, IT infrastructure services and SI.
## Health Decisions, Inc.
**Booth: 1143**  
**Contact:** Leslie Hammill  
**Phone:** 919-967-1111-520  
**Email:** lhammill@healthdec.com  
**Website:** www.healthdec.com

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.

## HighPoint Solutions
**Booth: 1053**  
**Contact:** Danielle McDowell  
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**Email:** danielle.mcdowell@highpointsolutions.com  
**Website:** www.highpoint-solutions.com

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.

## Hurley Consulting Associates Ltd.
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For over 25 years, Hurley Consulting Associates has specialized in Finding Solutions for its clients’ regulatory and commercial development needs. We have successfully guided more than 40 products to market. With our unique expertise to prepare global regulatory submission documents, we integrate nonclinical, clinical and CMC evaluations; perform data analyses and develop regulatory strategies. We can serve as your U.S. agent for the entire IND through NDA process.

## iCardiac Technologies
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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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ICON plc is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. The Company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. ICON currently has approximately 10,600 employees, operating from 83 locations in 38 countries. Further information is available at www.iconplc.com

## Imperial
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Imperial is a Clinical Research Support organization focused on optimizing patient and site outcomes. Comprised of Patient Engagement, Site Readiness & Support, and Clinical Translation services, and with 60 years of global operational experience (over 100 countries) in 40+ therapeutic indications, Imperial delivers customized patient engagement programs, ISO-certified translation of over 100 languages, and site readiness and support services using the latest technology.

## IMS Health
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## INC Research
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INC Research (Nasdaq:INCR) is a leading global contract research organization (“CRO”) providing the full range of Phase I to Phase IV clinical development services for the biopharmaceutical and medical device industries. Leveraging the breadth of our service offerings and the depth of our therapeutic expertise across multiple patient populations, INC Research connects customers, clinical research sites and patients to accelerate the delivery of new medicines to market.

## Indica Labs
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**Website:** www.ISRreports.com

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Inflamax Research Inc.  
Contact: Stephane Marin  
Email: smarin@inflamaxresearch.com  
Website: www.inflamaxresearch.com

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.

Informa Pharma Intelligence  
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Email: irene.fitzgerald@informa.com  
Website: www.pharmaintelligence.informa.com

Informa Pharma Intelligence is the trusted partner of the top 50 global pharma companies and the top 10 CRO’s — providing timely intelligence and insight to make authoritative decisions. Our connected team of journalists, researchers and analysts are based around the globe. Drawing on a foundation of high quality proprietary data you can trust that the insights gained through our solutions have the level of precision needed to make forward focused decisions with confidence.

Information Builders, Inc.  
Contact: Ann Mahoney  
Email: ann.mahoney@ibi.com  
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Innovaderm Research Inc.  
Contact: Anne-Marie Gaulin  
Email: amgaulin@innovaderm.ca  
Website: www.innovaderm.ca

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Integrated Clinical Systems, Inc.  
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Email: eherbel@i-review.com  
Website: www.i-review.com

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Email: toshea@intralinks.com  
Website: www.intralinks.com

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Email: aar@ipharma.ru
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JAF Consulting Inc
Contact: Joseph Franchetti
Email: info@jafconsulting.com
Website: www.jafconsulting.com
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Jazz Pharmaceuticals Inc.
Contact: Romy Alhadef
Email: romy.alhadef@jazzpharma.com
Website: www.jazzpharma.com
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Email: jcsinfo@jouleinc.com
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KlinEra Global Services
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Contact: Char Marrazzo
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Website: www.KlinEra.com
Since 2005, KlinEra has partnered with the largest pharmaceutical, biotech and device companies to provide innovative and customized clinical trial and research services with a focus on clinical trials in India. To date, we’ve successfully completed over 50 large-scale Phase 1, 2 and 3 trials through full services offerings including: clinical trial management, medical monitoring, data management and site management services all utilizing high quality protocols and GCP's.

Knowledge
Booth: 2155
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Email: leslie.arturi@knowledgent.com
Website: www.knowledgent.com

Knowledgent is an industry information consultancy that improves lives & business through data. We integrate industry experience, data analyst & scientist capabilities, data architecture & engineering skills to uncover actionable insights. We not only have the technical knowledge to deliver game-changing solutions at all phases of development, but also the business acumen to evolve data initiatives from start to finish, ensuring that organizations realize the full value of their information.

KoNECT
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Contact: Hyejin Joo
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Email: hjoo@konekt.or.kr
Website: www.kcc.konekt.or.kr

KoNECT is a non-profit government agency affiliated to the Korean Ministry of Health and Welfare. We support all clinical trial sponsors who are interested in working with Korea's clinical trial sites, investigators and partners, providing various information and services (esp. disease/patient distribution data, match-up with right partners etc.). Please visit us at http://kcc.konekt.or.kr/ for more information.

Korea Institute of Toxicology
Booth: 2429
Contact: Yunlip Kim
Phone: 82-426-108-204
Email: ylkim@kitox.re.kr
Website: www.kitox.re.kr

Korea Institute of Toxicology (KIT) is a world-class prestigious nonclinical contract research organization located in South Korea. KIT’s GLP system has been certified by Korean and international regulatory authorities based on OECD and U.S.FDA GLP criteria. Also, KIT is the first organization in Asia accredited by AAALAC International for humane laboratory animal treatment. KIT offers a full range of nonclinical research with high scientific standards and competitive prices.

Kuantum CRO and Logistics
Booth: 1448
Contact: Mehtap Asenaoktar
Phone: 90-232-328-3530
Email: mehtap.asenaoktar@kuantum-cro.com
Website: www.kuantum-cro.com

Founded in 2003, Kuantum is a leading provider of CRO and Clinical Supplies Management Services for the life science industry in Turkey and in the region. We offer a comprehensive set of cGCP and cGDP compliant services including all clinical monitoring activities as well as IMP/ materials importation, storage, distribution, returns and destruction arrangements. Both of our facilities are inspected and approved by the Turkish Ministry of Health. We are your eye on clinical research in Turkey

LabConnect, LLC
Booth: 935
Contact: Dan Knabb
Phone: 206-322-4680
Email: dknabb@labconnectllc.com
Website: www.labconnectllc.com

Founded in 2002, LabConnect provides global central laboratory services, including routine and esoteric laboratory testing, kit building, sample management, biorepository and scientific support services for our clients. LabConnect’s unique combination of state-of-the-art technology, world-class laboratories, easy access to major and emerging markets and extensive specialized testing expertise means drug development companies can rely on one provider for all of their central laboratory needs.

Langland
Booth: 734
Contact: Kate Spencer, Managing Partner
Phone: +44-(0)1753-833348
Email: kate.spencer@langland.co.uk
Website: www.langlandpatientrecruitment.com

Langland is the world’s most creatively awarded healthcare advertising agency. But such accolades are just a healthy side effect of our patient-insight-driven approach – a method that has helped recruit 350,000+ patients across 75+ countries. Today, we are a creative flagship within Publicis Health (the largest health-oriented agency network in the world) and hold offices in both the UK and the USA – a breadth that allows us to develop effective strategies for any market.

Life Science Connect
Booth: 642
Contact: Sean Hoffman
Phone: 724-940-7555
Email: shoffman@vertmarkets.com
Website: www.lifescienceleader.com

Life Science Connect strives to be an essential business tool for Life Science executives. The editorial is designed to provide readers with content pertaining to the life cycle of Life Science products and services. Our goal is to provide information that helps high-level industry personnel improve profits and overcome hurdles within the industry.

Lionbridge Technologies
Booth: 849
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Website: www.lifesciences.lionbridge.com

Lionbridge Technologies is the leading provider of language and globalization services to pharmaceutical and biotechnology companies, CROs, and medical device manufacturers. We specialize in high-quality translation, linguistic validation, and interpretation services in 250+ languages. As a Forbes Most Trustworthy Company, our clients benefit from our highly specialized network of medically trained linguists, operating in over 40 full-service solution centers across 27 countries.

LMK Clinical Research Consulting
Booth: 527
Contact: Sholeh Ehdaivand
Phone: 919-464-3291
Email: info@lmkclinicalresearch.com
Website: www.lmkclinicalresearch.com

At LMK we believe the TMF is the foundation of every study, and a strong foundation is key to the overall health of your trial. That is why LMK makes the TMF a top priority. If you currently use a paper or an electronic TMF, successful TMF management depends on the compliance of people following standardized processes. Although technology helps, technology alone it is not enough. We offer our clients a combination of TMF expertise and extensive knowledge of the clinical drug development process.
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**LORENZ Life Sciences Group**  
Contact: Yapprak Eisinger, Maria DeRose  
Email: mderose@lorenz.cc  
Website: www.lorenz.cc  
Booth: 1730  
Phone: 866-956-7369  

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**LSK Global PS**  
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Website: www.lsglobal.com  
Booth: 535  
Phone: 82-2-546-1008  

LSK Global Pharma Services, established in March 2000, is a full service Korean CRO in Seoul, Korea, currently staffed with 250 employees. LSK Global PS provides clinical development consulting services to a number of global CROs, pharmaceutical companies, and other organizations. LSK Global PS has participated in over a hundred multinational clinical studies, both past and ongoing. Data from LSK Global PS have been submitted to the PMDA, US FDA and EMEA.

**LUZ, Inc.**  
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Email: marketing@luz.com  
Website: www.luz.com  
Booth: 1453  
Phone: 415-981-5890  

The Life Science Translation Partner That Delivers Peace of Mind™ Founded in 1994, LUZ is the world’s leading language translation company for life sciences. We simplify and speed up entry into global markets by delivering accurate and compliant translations of product and regulatory documentation. Our cloud-based AURORA translation management platform minimizes risk through real-time project management, predictive analytics, and centralized translation memory management.

**Lyophilization Technology, Inc.**  
Contact: Edward Trappler  
Email: inquiry@lyo-t.com  
Website: www.lyotechnology.com  
Booth: 1856  
Phone: 215-396-8373  

Lyophilization Technology, Inc. is a Contract Development and Manufacturing Organization providing development and technical services focused on lyophilized products. The comprehensive range of services includes product design, formulation development, process engineering, clinical supplies manufacturing for freeze dried pharmaceuticals, biologics, diagnostics, biopharmaceuticals and fine chemicals. Technical services encompass consulting, compliance support and training.

**Machaon Diagnostics, Inc.**  
Contact: Bjorn Stromness  
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Website: www.machaoniagnostics.com  
Booth: 1203  
Phone: 510-839-5600  

Machaon Diagnostics offers laboratory testing in a Good Lab Practices environment with expertise in coagulation, next generation sequencing and assay development. We are a CLIA laboratory with 13 years of experience.

**MakroCare**  
Contact: Ashok Ghone  
Email: ashok.ghone@makrocare.com  
Website: www.makrocare.com  
Booth: 1644  
Phone: 973-900-2728  

MakroCare is a knowledge and technology-enabled drug development partner and functional provider to global Pharma, Biotech and Device companies. Our 15+ years experience and constant innovation solve customer’s challenges in Regulatory Affairs, Clinical Research and Medical Affairs. Leveraging global resources, program models are managed using FSP or FFS arrangements. With multiple awards and quality certifications achieved all these years, clients can benefit from our depth and breadth.

**Mapi**  
Contact: Elan Josielewski  
Email: webinquiry@mapigroup.com  
Website: www.mapigroup.com  
Booth: 1034  
Phone: 859-223-4334  

Mapi is the leading Patient-Centered Research Company serving academia, life science researchers, and the pharmaceutical industry for 40 years. Our commitment to patients is reflected through our wide range of services, including Real World Evidence, HEOR, Linguistic Validation, Strategic Market Access, and our Mapi Research Trust. Visit http://www.mapigroup.com/ for more information.

**Marketing Systems Group**  
Contact: Rick Eisenberg / Tim Antoniewicz  
Email: reisenberg@m-s-g.com  
Website: www.m-s-g.com  
Booth: 2432  
Phone: 215-653-7100  

Marketing Systems Group is a 26 year old software development company. We employ over 50 dedicated professionals and are a member of the AUS family of companies, providing exceptional consulting and market research products and services to clients throughout the world. ARCS (Automated Recruiting and Communications System) delivers efficiencies, cost & time savings to managing and growing your volunteer panel, surveys, screening, recruiting, scheduling, incentive and engagement management.

**MASIMO**  
Contact: Scott Baldwin  
Email: sbaldwin@masimo.com  
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Booth: 1038  
Phone: 949-297-7000  

Masimo is a global medical technology company that develops and manufactures innovative noninvasive technologies, medical devices and sensors that may enable earlier detection and treatment of potentially life-threatening conditions—offers numerous award-winning patient monitoring solutions, including Masimo SET®, Masimo rainbow SET® noninvasive and continuous hemoglobin (SpHb®), acoustic respiration rate (RRa™), Masimo SafetyNet™, and SEDLine® (EEG-based) Brain Function Monitors.

**MasterControl**  
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Website: www.mastercontrol.com  
Booth: 1103  
Phone: 801-942-4000  

MasterControl Inc. produces software solutions that enable pharmaceutical companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl solutions include clinical management, quality management, document management, audit management, training management, supplier management, submissions document management, and more. MasterControl provides our customers with a complete information management solution across the entire enterprise.
At MaxisIT®, we improve how pharmaceutical, life sciences companies, and academia leverage information and make decisions in support of clinical research and development. Our cloud-based, integrated technology platform optimizes the information flow across the entire clinical value stream ranging from the data capture technologies to external CROs, vendors, and partners.

Mayo Validation Support Services

Booth: 2524
Phone: 866-873-8963

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.

MD Connect

Booth: 2250
Phone: 781-235-0999

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

Booth: 1553
Phone: 844-361-9641

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

Booth: 1755
Phone: 888-654-0856

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

Booth: 1031
Phone: 703-556-1733

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
Phone: 513-401-1216

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

Booth: 2125
Phone: 212-918-1800

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

Booth: 848
Phone: 630-330-6445

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.

Booth: 1606
Phone: 763-258-2735

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.  
Contact: Mary Kuramoto  
Email: m.kuramoto@medpace.com  
Website: www.medpace.com

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.  
Contact: William Cooney  
Email: bill.cooney@medpt.com  
Website: www.medpt.com

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  
Contact: Megan Lomazzi  
Email: mlomazzi@medrio.com  
Website: www.medrio.com

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 mL application leads the way in early phase trials. Medrio costs up to 75% less than other EDC solutions.

MedSource  
Contact: Eric Lund  
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MedTrials  
Contact: Jamie Edwards  
Email: jedwards@medtrials.com  
Website: www.medtrials.com

MedTrials offers professional clinical development services to the pharmaceutical, biotech and medical device industries including clinical trial management, monitoring, data management, statistical analysis and reporting in all phases and types of clinical trials. MedTrials’ compliance experts conduct GxP audits at investigational sites, sponsors, manufacturers, IRBs and other third party vendors. MedTrials is a WBENC-certified, diverse supplier.

Medtronic  
Contact: Richard Clark  
Email: Richard.L.Clark@Medtronic.com  
Website: www.medtronicdiagnostics.com/us/cardiac-monitors/seeq-mct-system/index.htm

As a global leader in medical technology, services and solutions, Medtronic improves the lives and health of millions of people each year. Partner with our Cardiac Monitoring for Clinical Research team to experience world-class clinical trial service and support. Let’s take healthcare Further, Together. Join us at Booth 2415 to learn more.

Merck  
Contact: Elizabeth Haldeman  
Email: elizabeth.haldeman@merck.com  
Website: www.merck.com

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Merge Healthcare, an IBM Company  
Contact: Scotti McConnell  
Email: smcconne@us.ibm.com  
Website: www.eclinicalos.com

Merge eClinical offers eClinicalOS, a single, scalable cloud-based platform you configure to suit your precise needs. From building your study and managing randomization to endpoint adjudication and archiving results, you pay only for the options you use. Available worldwide in any language, eCOS can be ready to launch within days.

MESM Ltd  
Contact: Taj Dhaliwal  
Email: taj.dhaliwal@mesm.co.uk  
Website: www.mesmglobal.com

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.

Microsoft Corporation  
Contact: Daniel Carchedi  
Email: daniel.carchedi@microsoft.com  
Website: www.microsoft.com/genomics

Microsoft (Nasdaq “MSFT”) is the leading platform and productivity company for the mobile-first, cloud-first world, and its mission is to empower every person and every organization on the planet to achieve more. URL: http://www.microsoft.com/genomics

Microsystems  
Contact: Matt Grubich  
Email: mattrg@microsystems.com  
Website: www.microsystems.com

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MMG
Contact: Michael Rosenberg
Website: www.mmgct.com
MMG is a full-service global patient recruitment company. For more than 25 years, MMG has accelerated recruitment in hundreds of trials for pharmaceutical, biotech, and government clients, including the U.S. National Institutes of Health. As part of the Omnicom Group and Ketchum we reach more than 70 countries in over 700 locations.

MonitForHire.com
Contact: Scott Freedman
Website: www.monitorforhire.com
Clinical trial sponsors should be able to locate independent clinical trial monitors anywhere in the world, fast. MonitorForHire.com is a patented web based resourcing tool with nearly 5,000 registered and pre-qualified monitors in 60 countries including the US, Europe, Asia & MENA. For more information contact us at: +1 (610) 862 0909.

Montrium, Inc.
Contact: Oliver Pearce
Website: www.montrium.com
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
Contact: Ethan Perlson
Website: www.morningtrans.com
Morningside is a leading provider of translations to global pharma and biotech companies. We provide translation and linguistic validation for clinical trials and translate regulatory documents for submission to agencies worldwide. We also offer medical interpretation and medical writing services. We localize into 100+ languages, and our translations are fully ISO 9001:2008 certified.

Mortara Instrument, Inc.
Contact: Myra Wilson
Website: www.mortara.com
Mortara Instrument is a recognized technology leader in the world of ECG. Mortara’s global headquarters is located in Milwaukee, Wisconsin with operations in Australia, Germany, Italy, the Netherlands, and the United Kingdom. The complete line of ECG products includes electrocardiographs, stress exercise systems, Holter systems, data warehousing solutions, and cardiology monitoring systems. www.mortara.com.

myClin
Contact: James Denmark
Website: www.myclin.com
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NACS, Inc.
Contact: Robert Doty / Megan Bittner
Website: www.nacssinc.com
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
Contact: Hawk Tran
Website: www.navref.org
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
Contact: David McCrary
Website: www.ncgs.com
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
Contact: Mladen Cvijanovic
Website: www.nctlinguistics.com
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
Contact: Tina Souls
Website: www.neurotrialsaustralia.com
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.
Exhibitor Directory

New Orleans Center for Clinical Research  
Booth: 1408  
Contact: Dr. William Smith  
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Email: wbsmd@noccr.com  
Website: www.noccr.com

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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Next Trials, Inc.  
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Next Trials provides innovative software solutions for clinical research. Prism™, Next Trials' EDC system, offers integrated randomization, inventory management, laboratory data management, and ad hoc reporting. NextTrials 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. Nexttrials is now part of PRA Health Sciences, a global full-service CRO.

NNIT  
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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  
Contact: Dennis Dockery  
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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  
Contact: John Cheevers  
Phone: 781-405-7559  
Email: john.cheevers@novemberresearch.com  
Website: www.novemberresearch.com

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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Website: www.nuventra.com

The success of your drug development program relies on expertise in the analysis and communication of PK/PD outcomes and the ability to translate your findings into actionable insights and regulatory reports. With Nuventra, the industry’s go-to resource for PK/PD based drug development, you benefit from our collective experience to make better clinical and non-clinical decisions and avoid costly mistakes.

Ocala Research Institute  
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Website: www.ocalaresearchinstitute.com

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  
Contact: Maikelin Martinez  
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Website: www.ocasa.com

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  
Contact: Dennis Constantinou  
Phone: 954-473-1254  
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Website: www.omnicomm.com

OmniComm provides comprehensive solutions for clinical research with extensive global experience from over 4,000 clinical trials dedicated to helping life sciences organizations maximize the value of their clinical research investments. OmniComm drives efficiency in clinical development, manages risks, ensures compliance and improves clinical operations performance. Visit us at booth 2201 to see why 4 of the 5 top CROs and 7 of the 10 largest Phase I Clinics run OmniComm EDC technologies.
The content noted on this page was made available to DIA as of May 15, 2016.

### Online Business Applications

**Contact:** Reed McLaughlin  
**Email:** reed.mclaughlin@irmsonline.com  
**Website:** www.irmsonline.com

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.

**Contact:** Michael Celata  
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**Website:** www.orbisclinical.com

Orbis Clinical, a Maxim Healthcare Services Company, has been driving the success of our clients, consultants and employees with Life Science Staffing and Consulting Services since 2004. Our mission is to provide the world’s leading biopharmaceutical companies with expertise essential to treating devastating diseases.

### OpenClinica

**Contact:** Tia Tep  
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**Website:** www.openclinica.com

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.

### OpenText

**Contact:** Robert Ciuffreda  
**Email:** rciuffre@opentext.com  
**Website:** www.opentext.com

OpenText solutions for the Life Sciences industry support critical documents and processes where global regulatory compliance management and shortening product development cycles are essential. Organizations can consolidate their controlled documents and processes under one system of truth to minimize risk and to enable quick response during regulatory review. Our platform is ideal for any life science enterprise which takes a “Quality and Safety First” approach to its operations.

### Optum

**Contact:** Sheila Hetu  
**Email:** shetu@qualitymetric.com  
**Website:** www.optum.com

Optum is a leading information and technology-enabled health services business dedicated to helping make the health care system work better for everyone. With more than 35,000 people worldwide, Optum delivers intelligent, integrated solutions that work to modernize the health system and help to improve overall population health.

### Oracle Health Sciences

**Contact:** Catherine Ginzer  
**Email:** catherine.ginzer@gmail.com  
**Website:** www.oracle.com/healthsciences

Oracle Health Sciences is a leading strategic software solutions provider to Life Sciences & Healthcare. We are helping to transform clinical R&D from pipeline to patient through innovative cloud and mHealth solutions that improve patient outcomes and safety, increase pipeline performance, and optimize clinical development efficiency. Companies worldwide rely on us to develop and bring life-improving therapies to patients faster, while reducing the cost and risk of clinical research.

### Orlando Clinical Research Center

**Contact:** Thomas Marbury  
**Email:** tmarbury@ocrc.net  
**Website:** www.ocrc.net

OCRC is a cutting edge independent Phase I - IV custom-built 35,000 sq. ft. research site. Designed specifically for Phase 1 clinical trials, OCRC includes 110 in-house volunteer beds, dual lead digital telemetry, CCTV security system, and cardkey access. A special treatment/observation area has 12 hospital beds (6 used for onsite Hemodialysis studies). OCRC specializes in Phase I trials with an emphasis in PK, QTc, and SAD/MAD studies in healthy, hepatic, hemodialysis, renal, and diabetic.

### Otto Trading, Inc.

**Contact:** Adem Kutlug  
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Otto Trading, Inc.

### Palm Beach CRO

**Contact:** Arthur Simon  
**Email:** ASimon@PalmBeachCRO.com  
**Website:** www.palmbeachcro.com

Palm Beach CRO is a full-service Clinical Research Organization (CRO) providing clinical trial support to pharmaceutical (RX and OTC), biotechnology, nutraceutical and medical device companies. Our teams of seasoned professionals are proactive in the clinical processes, enabling timely completion of projects, helping to reduce costs and preventing overruns of budgets, without compromising on quality.

### Paragon Solutions

**Contact:** Che Dildy  
**Email:** cdildy@consultparagon.com  
**Website:** www.consultparagon.com

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.

### PAREXEL

**Contact:** Jo Sudore  
**Email:** info@PAREXEL.com  
**Website:** www.PAREXEL.com

For over 30 years, PAREXEL has helped clients get their new and innovative drug treatments into the hands that need them most by simplifying their journey to market. Our global regulatory expertise, Phase I-IV clinical research services, integrated eClinical technologies, and advanced commercialization services all work together to move you through the development journey more smoothly and cost-effectively from beginning to end. PAREXEL operates in 77 locations throughout 51 countries.

### Patient Advertising Guru

**Contact:** Jeffrey Litwin  
**Email:** jeffrey.litwin@patientgenesis.com  
**Website:** www.patientgenesis.com

Patient Advertising Guru is a leading advertising agency that creates, shares 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.
## Exhibitor Directory

### Pharma Start
- **Contact:** Sarah Callaghan
- **Phone:** 888-330-1726
- **Website:** [www.pharma-start.com](http://www.pharma-start.com)

Pharma Start is a functional outsourcing firm focusing on the pharmaceutical, biotechnology, and devices industries. We combine our functional outsourcing delivery model with in-house expertise in scientific and medical research to offer a single, reliable bridge into the drug development realm. Our services include clinical development, in-home clinical trial visits, clinical pharmacology and nonclinical assessment, library intelligence, medical writing, and regulatory lifecycle management.

### Pharmaceutical eConsulting
- **Contact:** Yolanda Hall
- **Phone:** 978-422-0227
- **Website:** [www.pec-services.com](http://www.pec-services.com)

Pharmaceutical eConsulting (PeC) is a leading provider in delivering electronic submissions services for the global life sciences industry. PeC has customers spanning from small to large pharmaceutical companies to developing bio-tech. Our core mission is to support marketing filing efforts (eCTD, Nees or Paper submission) to the Regulatory Authorities (FDA, EMA, Health Canada, Rest of World). PeC is headquartered in Copenhagen with offices in Boston and London.

### PCM TRIALS
- **Contact:** Julie Church-Thomas/Rick Heth
- **Phone:** 888-628-9707
- **Website:** [www.pcmtrials.com](http://www.pcmtrials.com)

PCM TRIALS has provided clinical trial home visits for over 100+ protocols for 50+ sponsors since 2008. PCM TRIALS recruits, screens, hires, trains, tests (does not contract with local home health care agencies) and manages their own unique Certified Mobile Research Nurses (CMRNs) who understand the critical requirements of mobile clinical research. All CMRNs are trained in GCP, Nurse Guidelines, IATA and trial specific protocols. Services available in the U.S., Canada and ROW.

### PDR, LLC
- **Contact:** Kim Marich
- **Phone:** 201-358-7200
- **Website:** [www.PDRNetwork.com](http://www.PDRNetwork.com)

PDR Network, LLC is the leading distributor of FDA-approved drug labeling, safety and REMS information, as well as medication adherence and product support programs, through Physicians’ Desk Reference® (“PDR®”) suite of print and digital services. PDR Network provides innovative products and services to deliver industry-leading content across channels, including PDR.net®, mobilePDR®, PDR®3D™ and directly through electronic health record platforms. For more information, visit [www.pdrenetwork.com](http://www.pdrenetwork.com).

### PerkinElmer Informatics
- **Contact:** Rob Rittberg
- **Phone:** 617-588-9100
- **Website:** [www.perkinelmer.com/clinical-development-analytics](http://www.perkinelmer.com/clinical-development-analytics)

PerkinElmer’s advanced analytics and services solutions for Clinical Development help the world’s leading biopharmaceutical, medical device and diagnostics manufactures discover new therapeutics faster by streamlining clinical operations, transforming risk into safety and enabling actionable decisions that can lead to better health outcomes.

### Pharmaceutical Packaging Professionals Pty Ltd.
- **Contact:** Craig Rogers
- **Phone:** 61-3-9673-1003
- **Website:** [www.pharmpackpro.com](http://www.pharmpackpro.com)

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.

### PeC Services
- **Contact:** Yolanda Hall
- **Phone:** 978-422-0227
- **Website:** [www.pec-services.com](http://www.pec-services.com)

PeC Services is a leading provider in delivering electronic submissions services for the global life sciences industry. PeC has customers spanning from small to large pharmaceutical companies to developing bio-tech. Our core mission is to support marketing filing efforts (eCTD, Nees or Paper submission) to the Regulatory Authorities (FDA, EMA, Health Canada, Rest of World). PeC is headquartered in Copenhagen with offices in Boston and London.

### Percel Limited
- **Contact:** Sarah Callaghan
- **Phone:** 888-330-1726
- **Website:** [www.pharma-start.com](http://www.pharma-start.com)

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](http://www.pharma-sys.com) or call (919) 468-2547.
PharmaVOICE Booth: 1500  Contact: Marah Walsh  Phone: 215-321-8656  Email: mwalsh@pharmavoice.com  Website: www.pharmavoice.com  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 Booth: 512  Contact: Matt Kiernan  Phone: 610-945-4364

Pharm-Olam International Ltd. Booth: 811  Contact: Mark Eberhardt  Phone: 713-559-7900  Email: info@pharm-olam.com  Website: www.pharm-olam.com  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. Booth: 1604  Contact: Karen Redding  Phone: 44-(0)-1494-720420  Email: kredding@phlexglobal.com  Website: www.phlexglobal.com  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 Booth: 2407  Contact: Sandy Carson  Phone: 813-915-1663  Email: sandy.carson@pilgrimquality.com  Website: www.pilgrimquality.com  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 Booth: 2403  Contact: Max Kanevsky  Phone: 888-507-2270  Email: mkanevsky@pinnacle21.net  Website: www.pinnacle21.net  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 Booth: 1353  Contact: Sarah Callaghan  Phone: 708-505-4350  Email: scallaghan@planet-pharma.com  Website: www.planet-pharma.com  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. Booth: 1130  Contact: Barry Lyne  Phone: 011-44-166-682-6540  Email: info@pleasetech.com  Website: www.pleasetech.com  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. Booth: 2138  Contact: Breanna Hatter  Phone: 877-493-2541  Email: breanna.hatter@vptag.com  Website: www.polarleasing.com  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 Booth: 1511  Contact: Laura Waite  Phone: 44-014-803-0030-0  Email: laura.waite@papwoodhead.com  Website: www.papwoodhead.com  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: • Benefit/risk management strategy, implementation & effectiveness • Real World Evidence strategy & implementation • Market Access Excellence & Strategy • Payer Engagement • Digital enablement & integration • Organisational Capability Building

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Email: account.development@ppdi.com
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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 Booth: 1250
Contact: Sarah Jost
Email: s.jost@pqe.eu
Website: www.pqe.eu
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 Booths: 1713 & 1811
Contact: Tami Klerr
Email: Klerrnaivartami@praintl.com
Website: www.clearlypra.com
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 Booth: 2005
Contact: Robert Loll
Email: rloll@gopraxis.com
Website: www.gopraxis.com
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 Booth: 1749
Contact: Melissa Malski
Email: melissa.malski@precisionformedicine.com
Website: www.precisionformedicine.com
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.
**Q2 Business Intelligence**  
Booth: 1640  
Contact: Gary Huang  
Phone: 908-392-2820  
Website: www.q2bi.com

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.

**QARA BioPharma Solutions**  
Booth: 853  
Contact: Sonia Wheat, MS  
Phone: 978-394-9722  
Email: sonia.wheat@qarapharmasolutions.com  
Website: www.qarapharmasolutions.com

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**  
Booth: 1200  
Contact: Bhavna Malhotra  
Phone: 302-690-4962  
Email: info@qps.com  
Website: www.qps.com

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.**  
Booth: 1506  
Contact: Jason Bertram  
Phone: 818-853-7090  
Website: www.qc2.com

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.**  
Booth: 1309  
Contact: Paul Swidersky  
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Email: pswidersky@qualityassociatesinc.com  
Website: www.qualityassociatesinc.com

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. QA1 has a staff of 8 auditors, all with various scientific experience. QA1 maintains a GLP archive for storage of documents and specimens.

**Quanticate, Inc.**  
Booth: 2424  
Contact: Shawn Strait  
Phone: 919-287-5830  
Email: Shawn.Strait@Quanticate.com  
Website: www.quanticate.com

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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Phone: 678-779-9935  
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Website: www.quantificare.com

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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Website: www.qctn.com.au

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.

**Quipment**  
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Website: www.quipment.fr/en/home.html

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

Contact: Michael Quinn
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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.

Booth: 835 Phone: 206-448-4082

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

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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, nutriceuticals and pharma.

Booth: 1241 Phone: 877-335-8212

Reed Technology

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Website: www.ReedTech.com

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.

Booth: 2313 Phone: 215-734-2115

Regxia Inc.

Contact: Cameron McGregor
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Website: www.regxia.com

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.

Booth: 2042 Phone: 416-278-1023

ReSolution Latin America

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Website: www.resolutioncrs.com

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/region idsyncreasies 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).

Booth: 1940 Phone: 54-11-4784-4710

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.

Booth: 815 Phone: 919-408-8000

Randstad Life Sciences

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For over 28 years, Richman Chemical Inc. (RCI) has provided contract R&D, custom synthesis of materials for pre-clinical and toxicology studies , and cGMP-compliant (API, drug product) clinical and commercial manufacture for emerging technology and life science markets, including pharmaceutical, biotech, and medical device customers. Fixed bid and FTE options.

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Ropack Inc.

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Website: www.ropack.com

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.

Booth: 2240 Phone: 513-846-0921

RQ 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.

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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.

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Contact: Vera Terekhina Phone: 188-888-1787-6

RURO, Inc. Booth: 1536
Phone: 188-888-1787-6

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.

Website: www.rundo-cro.com
Email: hui.li@rundo-cro.com
Contact: Hui Li Phone: 86-21-51080001

Rundo International Pharmaceutical Research and Development Co., Ltd Booth: 538

RTI International
Contact: Graham Dyck
Email: gdyck@rti.org
Website: www.rtihs.org

Website: www.rtihs.org
Email: gdyck@rti.org
Contact: Graham Dyck Phone: 919-316-3788

RTI International Booth: 2540
Phone: 919-316-3788

RTI Health Solutions (RTI-HS) provides consulting and research expertise to help pharmaceutical, biotechnology, diagnostics and medical device companies develop and commercialize their products.

Website: www.rtihs.org
Email: gdyck@rti.org
Contact: Graham Dyck Phone: 919-316-3788

RTI International Booth: 2540
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Exhibitor Directory

The content noted on this page was made available to DIA as of May 15, 2016.
DIA 2016

Sharp Clinical Services
Contact: Luke Beedle
Email: info@sharpclinical.com
Website: www.sharpservices.com

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
Contact: Kathryn Burn
Website: www.smartpatients.com

SNBL Clinical Pharmacology Center, Inc.
Contact: Chris Hickey
Email: chickey@snbl-cpc.com
Website: www.snbl-cpc.com

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, QT, 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
Contact: Christine Pierre
Email: allyson.small@myscrs.org
Website: www.myscrs.org

The Society for Clinical Research Sites (SCRS) 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
Contact: Paulette Azar-Tannous & Carolyn Cheer
Email: enquiries@sonicclinicaltrials.com
Website: www.sonicclinicaltrials.com.au

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
Contact: Eunhee Chung, PhD
Email: eunhee-chung@ita-med.com
Website: www.ita-med.com/SouseikaiGlobal

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
Contact: David Lloyd
Email: info@southernstarresearch.com
Website: www.SouthernStarResearch.com

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.
Contact: Cindy Monroe
Email: Cindy.Monroe@sparktx.com
Website: www.sparktx.com

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
Contact: Paullette Azar-Tannous & Phone: 617-685-5800

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.

Spaulding Clinical Research
Contact: Tyler Borst
Email: tyler.borst@spauldingclinical.com
Website: www.spauldingclinical.com

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.

Splash Clinical, LLC
Contact: Meagan Guse
Email: mguse@teuteberg.com
Website: www.splashclinical.com

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 you recruit patients effectively.

Spm2 - safety projects and more GmbH
Contact: Diana Witticke
Website: www.spm2-safety.de
**Springer Nature**  
Contact: Acasia Dalmau  
Email: exhibits-ny@springer.com  
Website: www.springernature.com  

Springer Nature is one of the world’s leading global research, educational and professional publishers, home to an array of respected and trusted brands providing quality content through a range of innovative products and services. Springer Nature is the world’s largest academic book publisher and numbers almost 13,000 staff in over 50 countries. www.springernature.com

**Statistics & Data Corporation (SDC)**  
Contact: Jim Townsend  
Email: data@sdcclinical.com  
Website: www.sdcclinical.com

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.

**Stefanini**  
Contact: Denis Reyners  
Email: Denis.Reyners@stefanini.com  
Website: www.stefanini.com

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

**Sterling IRB**  
Contact: Kathye Richards  
Email: kathye.richards@sterlingirb.com  
Website: www.sterlingirb.com

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.**  
Contact: Shari Burgess  
Email: sburgess@stirisresearch.com  
Website: www.stirisresearch.com

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.

**Suvoda**  
Contact: Marc Lisi  
Email: mlisi@suvoda.com  
Website: www.suvoda.com

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.

**Symbio, LLC**  
Contact: Betsey Zbyszynski  
Email: bzbyszynski@symbioreserach.com  
Website: www.symbioreserach.com

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.

**Symphony Clinical Research**  
Contact: Nicki Norris  
Email: nnorris@symphonyclinicalresearch.com  
Website: www.symphonyclinicalresearch.com

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.

**Synchrogenix Information Strategies, Inc.**  
Contact: Lauren Sobocinski  
Email: lauren.sobocinski@synchrogenic.com  
Website: www.synchrogenic.com

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.

**Synex Consulting Ltd**  
Contact: Jooyoung Ahn  
Email: jyahn@synex.co.kr  
Website: www.synex.co.kr/index/en

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.

**Synexus US Clinical Research**  
Contact: Kelly Walker  
Email: KWalker@raasites.com  
Website: www.synexus.com

Synexus US Clinical Research (formerly Research Across America) is an Independent Site Network-ISM (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 Pano 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.
Syntel, Inc.  
Contact: Nagnath Jadhav  
Email: nagnath_jadhav@syntelinc.com  
Website: www.syntelinc.com  
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.

SynteractHCR  
Contact: Trisha Vonder Reith  
Email: trisha.vonderreith@synteracthcr.com  
Website: www.synteracthcr.com  
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.  
Contact: Warren Pearson  
Email: wpearsone@targethealth.com  
Website: www.targethealth.com  
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)

Tarius A/S  
Contact: Eva L. Petersen  
Email: elp@tarius.com  
Website: www.tarius.com  
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.

Tata Consultancy Services  
Contact: Mark Sekula  
Email: mark.sekula@tcs.com  
Website: www.tcs.com/clinicalresearch  
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.

Technical Resources International, Inc.  
Contact: Anais Colin  
Email: acolin@tech-res.com  
Website: www.tech-res.com  
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.

Teva Pharmaceuticals USA  
Contact: Kyle Webster  
Website: www.tevapharm.com  
Teva 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.

The Clinical Resource Network  
Contact: David Iannucci  
Email: diannucci@crnspg.com  
Website: www.solomonpage.com/crn  
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  
Contact: Lance Nickens  
Email: lance@tprausa.com  
Website: www.patientrecruiting.com  
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 Cal pre-screening Text messaging RADIUS365™ online response, referral delivery and retention tracking, managing & reporting system

Therapak Corporation  
Contact: Arbi Harootoonian  
Email: info@therapak.com  
Website: www.therapak.com  
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.
Therapeutics Inc.  
Contact: Bryan Macy  
Email: bmacy@therapeuticsinc.com  
Website: www.therapeuticsinc.com

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 Phl-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.

Thomas Jefferson University  
Contact: Hannah Smith  
Website: www.thomasjefferson.edu

Thomas Jefferson University Booth: 2040  
Contact: Hannah Smith  
Phone: 215-503-7770

Thomson Reuters  
Email: jessica.corrado@thomsonreuters.com  
Website: www.science.thomsonreuters.com/pharma

Thomson Reuters Life Sciences supports R&D productivity across the Pharma lifecycle with respected and comprehensive intelligence solutions. Offering unbiased scientific, competitive, regulatory, and generics information, analytics, and expertise for your organization, Thomson Reuters Life Sciences empowers and enables effective, evidence-based decision-making at every stage from discovery to launch and beyond. science.thomsonreuters.com/pharma

ThoughtSphere Inc.  
Contact: David Lacagnina  
Email: david.lacagnina@thoughtsphere.com  
Website: www.thoughtsphere.com

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.  
Contact: Bruce Gould  
Email: bgould@threewire.com  
Website: www.threewire.com

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.  
Contact: Lee R. Schwartz  
Email: lschwartz@tklresearch.com  
Website: www.tklresearch.com

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  
Contact: Anthony Bianchini  
Email: anthony.bianchini@xerox.com  
Website: www.tmshealth.com

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 customer-centric 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  
Contact: Patrick Foster  
Email: pfoster@totalcro.com  
Website: www.totalcro.com

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.

TransCom Global Ltd.  
Contact: Matan Topper-Erez  
Website: tran-s.com

TransCom Global Ltd. Booth: 2442  
Contact: Matan Topper-Erez  
Phone: 97-235-443-293

TransPerfect  
Contact: Ryan Simper  
Email: rsimper@transperfect.com  
Website: www.transperfect.com

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.

TrialX Inc.  
Contact: Sharib Khan  
Email: sharib@trialx.com  
Website: www.trialx.com

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.

TRIEVR, Inc.  
Contact: Greg Brigham  
Email: greg.brigham@trievr.com  
Website: www.trievr.com

TRIEVR, Inc. Booth: 2345  
Contact: Greg Brigham  
Phone: 845-481-9173

Trifacta  
Contact: Dale Jackson  
Email: sales@trifactaclinical.com  
Website: www.trifactaclinical.com

Trifacta 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. Trifacta'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.
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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<th><strong>Validated Cloud Inc.</strong></th>
<th><strong>Booth: 634</strong></th>
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<tr>
<td><strong>Contact:</strong> Douglas Lantigua</td>
<td><strong>Phone:</strong> 617-849-8650</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:info01@ValidatedCloud.com">info01@ValidatedCloud.com</a></td>
<td><strong>Website:</strong> <a href="http://www.ValidatedCloud.com">www.ValidatedCloud.com</a></td>
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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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<th><strong>Veeva Systems, Inc.</strong></th>
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<td><strong>Contact:</strong> Brittany Machion</td>
<td><strong>Phone:</strong> 925-452-6500</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:contact@veeva.com">contact@veeva.com</a></td>
<td><strong>Website:</strong> <a href="http://www.veeva.com">www.veeva.com</a></td>
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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.

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<th><strong>Verified Clinical Trials</strong></th>
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<tr>
<td><strong>Contact:</strong> Mitchell Efros</td>
<td><strong>Phone:</strong> 516-998-7499</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:DrEfros@verifiedclinicaltrials.com">DrEfros@verifiedclinicaltrials.com</a></td>
<td><strong>Website:</strong> <a href="http://www.verifiedclinicaltrials.com">www.verifiedclinicaltrials.com</a></td>
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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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<th><strong>Veristat, Inc.</strong></th>
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<tr>
<td><strong>Contact:</strong> JoAnn Eckhoff</td>
<td><strong>Phone:</strong> 617-901-0408</td>
</tr>
<tr>
<td><strong>Email:</strong> <a href="mailto:inquiry@veristat.com">inquiry@veristat.com</a></td>
<td><strong>Website:</strong> <a href="http://www.veristat.com">www.veristat.com</a></td>
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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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<th><strong>Vigilare International</strong></th>
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<tr>
<td><strong>Contact:</strong> Luis Encarnacion</td>
<td><strong>Phone:</strong> 267-402-8414</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:luis.encarnacion@vigilareintl.com">luis.encarnacion@vigilareintl.com</a></td>
<td><strong>Website:</strong> <a href="http://www.vigilareintl.com">www.vigilareintl.com</a></td>
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Vigilare is 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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<th><strong>Vince &amp; Associates Clinical Research</strong></th>
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<tr>
<td><strong>Contact:</strong> Sheila Graham</td>
<td><strong>Phone:</strong> 913-696-1601</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:info@vinceandassociates.com">info@vinceandassociates.com</a></td>
<td><strong>Website:</strong> <a href="http://www.vinceandassociates.com">www.vinceandassociates.com</a></td>
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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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<th><strong>VirtualScopics</strong></th>
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<td><strong>Contact:</strong> Carolyn Carpenter</td>
<td><strong>Phone:</strong> 585-249-6231</td>
</tr>
<tr>
<td><strong>Email:</strong> <a href="mailto:Carolyn_Carpenter@virtualscopics.com">Carolyn_Carpenter@virtualscopics.com</a></td>
<td><strong>Website:</strong> <a href="http://www.virtualscopics.com">www.virtualscopics.com</a></td>
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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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<th><strong>Vitalograph, Inc.</strong></th>
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<td><strong>Contact:</strong> John Buchholz</td>
<td><strong>Phone:</strong> 913-730-3212</td>
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<tr>
<td><strong>Email:</strong> <a href="mailto:john.buchholz@vitalograph.com">john.buchholz@vitalograph.com</a></td>
<td><strong>Website:</strong> <a href="http://www.vitalograph.com">www.vitalograph.com</a></td>
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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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<tr>
<th><strong>VitalTrax</strong></th>
<th><strong>Booth: 2435</strong></th>
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<tr>
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</tr>
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VitalTrax delivers cloud based eCOA solutions for today’s clinical trials. Patient data is captured from the source: devices used by the patient, caregiver or their clinician or transmitted directly from a certified medical device. Data is instantly available to all stakeholders to enable smart and timely decisions. Sophisticated design tools make study startup a breeze. Dashboards keep sponsors, sites and patients informed and engaged throughout the study. This is the eCOA system you imagined!

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<th><strong>Wake Research Associates</strong></th>
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<tr>
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Wake Research Associates is an independent multi-center clinical research group designed to work closely with and meet the needs of the pharmaceutical industry and CROs in the conduct of Phase I-IV trials. We are known for effectively combining strategic patient recruitment and retention with high quality clinical research procedures. Our approach is uncompromising - each study conducted at our site is carefully planned and executed according to regulations and guidelines with superior quality.
**WCCT Global**
Contact: Salvador Solis
Email: mgr@wcct.com
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**Zigzag Associates Ltd**  
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