Join the Conversation #DIA2019

DIA 2019

PROGRAM

San Diego Convention Center
June 23-27 | San Diego

DIAglobal.org/DIA2019

practical e-clinical solutions.

Built by clinical professionals, for clinical professionals.

SIMPLE: Quick implementation and user-friendly interface

COMPREHENSIVE: Full clinical research life cycle solutions and TMF services

MOBILE: Key eTMF processes at your fingertips

TRIAL INTERACTIVE

BY TRANSPERFECT

VISIT BOOTHS 1731 & 1838

lifesciences.transperfect.com | www.trialinteractive.com

Site Selection & Activation | eTMF & Clinical Content Management | E-Learning & Compliance Training

Message from DIA Global Chief Executive

Welcome to San Diego, and to the DIA 2019 Global Annual Meeting! We're thrilled you are here: Through your participation you've demonstrated your commitment to our collective quest to drive progress against the enormous challenges in advancing healthcare innovation and improved patient outcomes around the world. And we thank you for that.

We are all DIA, and DIA is far more than this meeting: From the Americas to Asia to Europe to Africa and to the Middle East, our shared global reach and thought leadership have been a critical force in therapeutic development. Through our neutral platform, diverse research perspectives, and guiding principle of fostering transparent, collaborative environments, we are advancing knowledge and expertise across disciplines and around the world, reaching regulators, industry and academic researchers, policy makers, payers, and—most importantly—patients.

Here in San Diego, you'll have an opportunity to be part of this ongoing revolution. Engage with the terrific speakers and panelists, check out the exhibitors, connect with old colleagues and meet new ones. Most of all, open your minds to the new world of healthcare that is being transformed by our understanding of genetics, Big Data, Artificial Intelligence and myriad innovations. And share your experience via Twitter using the hashtag #DIA2019.

But San Diego should be just one stop on your journey. DIA is global – and it is also digital. Every day on the DIA website, on mobile, in our online communities, our eLearning offerings, social media, and other digital platforms you'll find new ideas, new opportunities for career growth, and new companions to share your quest. We welcome you to continue your participation – and commitment to being a force for driving change – in these digital arenas all year round.

Each day, somewhere around the world, members of your DIA community are taking the next step, creating new knowledge, and joining together to collectively move forward in our mission to advance the health and well-being of the patients who inspire us. Your presence, and commitment, make this extraordinary progress possible.

Sincerely Yours,

Barbara Lopez Kunz
Global Chief Executive
DIA

DIA 2019 Honorary Co-Chairs

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

Professor Guido Rasi began his second term as Executive Director of the European Medicines Agency (EMA) on November 16, 2015. From November 2014 to mid-November 2015, Professor Rasi served as EMA's Principal Adviser in Charge of Strategy. From November 2011 to November 2014 he was the Executive Director of EMA and a member of its Management Board in the three years prior to this.

Professor Rasi holds a degree in medicine and surgery, with specializations in internal medicine, allergology, and clinical immunology, from the University of Rome. He is also an author of more than 100 scientific publications.

Joanne Waldstreicher, MD
Chief Medical Officer
Johnson & Johnson

In Joanne's current role with Johnson & Johnson, she has oversight across pharmaceuticals, devices, and consumer products for safety, epidemiology, clinical and regulatory operations transformation, collaborations on ethical science, and technology and R&D policies, including those related to clinical trial transparency and compassionate access. She chairs the R&D Development Pipeline Review Committee for The Janssen Pharmaceutical Companies of Johnson & Johnson, and supports the Medical Devices and Consumer Development Committees. Joanne is also a faculty affiliate of the Division of Medical Ethics, Department of Population Health, New York University School of Medicine.

Joanne received both the Jonas Salk and Belle Zeller scholarships from the City University of New York, and graduated summa cum laude from Brooklyn College. She graduated cum laude from Harvard Medical School, completed her internship and residency at Beth Israel Hospital and her endocrinology fellowship at Massachusetts General Hospital.

DIA 2019

Follow **#DIA2019** for real-time updates

TABLE OF CONTENTS

Get to know DIA!
Booth #1531

DIAmond SESSIONS
Page 12

Global Regulatory Sessions
Page 13

DIA 2019
GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

Schedule At-A-Glance
DIAglobal.org/DIA2019

SATURDAY, JUNE 22

Registration Hours

8:00AM–5:00PM	Exhibitor Registration

SUNDAY, JUNE 23

Registration Hours

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

Schedule

9:00AM–12:30PM	Half Day Morning Preconference Short Courses*
9:00AM–5:00PM	Full Day Preconference Short Courses*
11:00AM–12:30PM	Student and Emerging Professional Forum
1:30–5:00PM	Half Day Afternoon Preconference Short Courses*
2:30–5:00PM	Professional Development Sessions

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

MONDAY, JUNE 24

Registration Hours

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

Schedule

6:30–7:30AM	CISCRP Medical Heroes Appreciation 5K
7:00–8:00AM	Coffee and Light Refreshments
7:00–7:45AM	Annual Meeting Orientation
8:00–10:00AM	Opening Plenary, Keynote Address, and DIAmond Session
10:00AM–6:00PM	Exhibit Hall Open Student Posters Open (Exhibit Hall)
10:00–11:00AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub (Sails Pavilion) Student Poster Session and Oral Presentations (Exhibit Hall)
11:00AM–12:00PM	Educational Tracks
12:00–2:00PM	Luncheon Service
12:15–2:15PM	Student Poster Session and Oral Presentations (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Sessions (Exhibit Hall) Content Hub and Community Rounds (Sails Pavilion)
2:15–3:15PM	Educational Tracks
3:30–4:30PM	Educational Tracks
4:30–6:00PM	Opening Reception (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Student Poster Session and Oral Presentations (Exhibit Hall) Engage and Exchange (Exhibit Hall)
5:30PM	2019 Life Science Leader CRO Leadership Awards (The Prado at Balboa Park)

TUESDAY, JUNE 25

Registration Hours

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

Schedule

7:00–8:00AM	Coffee and Light Refreshments
8:00–9:15AM	Educational Tracks
9:00AM–5:00PM	Exhibit Hall Open
9:00AM–4:00PM	Professional Posters Open (Exhibit Hall)
9:15–10:30AM	Coffee Break (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (Sails Pavilion) Innovation Theater Presentations (Exhibit Hall)
10:30–11:30AM	Educational Tracks
11:30AM–1:30PM	Luncheon Service
11:45AM–2:00PM	Innovation Theater Presentations (Exhibit Hall) Content Hub (Sails Pavilion) Engage and Exchange Sessions (Exhibit Hall) Professional Poster Session and Oral Presentations (Exhibit Hall)
2:00–3:15PM	Educational Tracks Community Rounds (Sails Pavilion) Engage and Exchange Session (Exhibit Hall)
3:15–4:15PM	Refreshment Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (Sails Pavilion) Professional Poster Session (Exhibit Hall)
3:30–4:00PM	Annual Meeting of the Members (DIA Booth #1531)
4:15–5:30PM	Educational Tracks Community Rounds (Sails Pavilion)

WEDNESDAY, JUNE 26

Registration Hours

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

Schedule

7:00–8:00AM	Coffee and Light Refreshments
8:00–9:15AM	Educational Tracks Community Rounds (Sails Pavilion)
9:00AM–4:00PM	Exhibit Hall Open Professional Posters Open (Exhibit Hall)
9:15–10:30AM	Coffee Break (Exhibit Hall) Content Hub and Community Rounds (Sails Pavilion) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session (Exhibit Hall)
10:30–11:30AM	Educational Tracks
11:30AM–1:30PM	Luncheon Service
11:45AM–2:00PM	Content Hub and Community Rounds (Sails Pavilion) Innovation Theater Presentations (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Professional Poster Session and Oral Presentations (Exhibit Hall)
2:00–3:15PM	Educational Tracks Engage and Exchange Sessions (Exhibit Hall) Content Hub (Sails Pavilion)
3:15–4:00PM	Refreshment Break (Exhibit Hall) Engage and Exchange Session (Exhibit Hall) Content Hub and Community Rounds (Sails Pavilion) Professional Poster Session (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall)
4:15–5:30PM	Educational Tracks

THURSDAY, JUNE 27

Registration Hours

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

Schedule

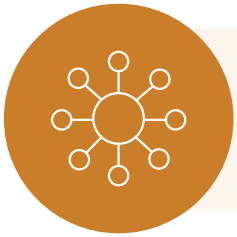
8:00–9:00AM	Coffee and Light Refreshments Content Hub and Community Rounds (Sails Pavilion)
9:00–10:15AM	Educational Tracks
10:15–10:45AM	Coffee Break
10:45AM–12:00PM	FDA Town Hall

Learning Formats at DIA 2019

DIAmond Sessions

- Thought-provoking, worldwide issues will be deconstructed by acclaimed global panelists
- Rare opportunities to listen to open conversations on controversial topics

Content Hubs



- Led by DIA Community Members
- High-interaction between audience and speaker
- 30 attendees, 30 minutes
- Relaxed, casual learning environment

Poster Sessions

- View research and new best practices from a diverse group of students and professionals
- Student Posters on Monday and Professional Posters on Tuesday and Wednesday

Engage and Exchange

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

Community Round Tables

- Led by DIA Community Members
- Open to all, 60 minutes
- Topics discussed are based off concurrent educational sessions

Innovation Theaters

- Exhibitor-led and sponsored
- Held in the Exhibit Hall
- Limited seating, 30-45 minutes
- Round out your onsite experience by taking in new products and services

Concurrent Educational Sessions

- Traditional workshops or interactive educational format
- Panel discussions or didactic presentations
- 60-75 minutes
- 175+ sessions spanning 13 educational tracks

DIA 2019

MORE THAN A MEETING: FOCUSED ON THE FUTURE OF HEALTH

Get Social with DIA and be Part of Our Social Wall!

SNAP
A picture with your phone

TAG
#DIA2019 and #MoreThanAMeeting

SHARE
On Instagram and Twitter

PRINT
Post your picture on the Social Wall!

WIN PRIZES!

Social Wall Located in the Sails Pavilion Lobby

To Learn More, Visit the DIA Booth #1531

Plenary Session and Keynote Address

Monday, June 24 | 8:00-10:00AM | Ballroom 20

Advancing Discovery Science for Public Health Impact

Gary H. Gibbons, MD
Director, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

About the Keynote

Through the keynote speech, Advancing Discovery Science for Public Health Impact, Dr. Gibbons will address the value of implementation science that turns discovery science into improved population health, as well as the innovation of evidence-based initiatives in the treatment of chronic disease, to balance the scales of health equity in all populations.

About NHLBI

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, blood, and sleep disorders and enhance the health of all individuals.

For decades, the NHLBI has been turning discovery into health and contributing to dramatic improvements in longevity and quality of life for citizens of the United States and abroad. Despite substantial reductions in morbidity and mortality from decades of improvements in prevention and treatment, chronic heart and lung diseases remain amongst the leading causes of death and significant challenges in disease burden and outcomes persist.

About the Speaker

Gary H. Gibbons, M.D., is Director of the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), where he oversees the third largest institute at the NIH, with an annual budget of approximately $3 billion and a staff of nearly 2,100 federal employees, contractors, and volunteers. NHLBI provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Since being named Director of the NHLBI, Dr. Gibbons has enhanced the NHLBI investment in fundamental discovery science, steadily increasing the payline and number of awards for established and early stage investigators. His commitment to nurturing the next generation of scientists is manifest in expanded funding for career development and loan repayment awards as well as initiatives to facilitate the transition to independent research awards.

Innovation Theater Schedule

Monday, June 24

Advanced Clinical | Theater 1 | 10:15AM
Raising the Bar on Clinical Oversight to Reduce Risk and Ensure Inspection Readiness

ArisGlobal | Theater 2 | 10:15AM
Can Blockchain Technology Change Life Sciences?

IQVIA | Theater 1 | 12:15PM
When Context is Hard to Come By – The Emerging Value of External Comparators

Parexel | Theater 2 | 12:15PM
Transforming the Drug Development Journey Through the Patient's Eyes

Veeva Systems | Theater 1 | 1:00PM
Annual Industry Report: Trends, Insights, and Strategies to Improve Study Execution

WCG | Theater 2 | 1:00PM
Getting the Most Out of Your Site Selection Strategy

Cognizant | Theater 1 | 1:45PM
Shared Investigator Platform: Innovating Clinical Trials Feasibility and Study Start Up

SAS | Theater 2 | 1:45PM
Smarter Clinical Trial Enrollment with Real World Data and Simulation Analytics

Appian | Theater 1 | 4:45PM
Accelerating the Regulatory Information Management Journey with Intelligent Automation

Deloitte Consulting | Theater 2 | 4:45PM
Reimagining Patient Safety

SDC | Theater 1 | 5:30PM
Artificial Intelligence and Machine Learning: Innovations in Clinical Trial Data Automation

Syneos Health | Theater 2 | 5:30PM
Coloring in the Full Spectrum of FSP Offerings

Tuesday, June 25

DiagnoSearch Life Sciences | Theater 1 | 9:45AM
Disruptive Innovation: 'Wide-Angle-Data' – Fully Integrated Platform with Advanced Analytics and Customized Algorithms for Real-Time Safety and Risk Management

Covance | Theater 2 | 9:45AM
Fixing the Patient Recruitment "Leaky Funnel"

Veeva Systems | Theater 1 | 11:40AM
Shortening Database Builds by 40-60%

ArisGlobal | Theater 2 | 11:40AM
Getting More Value From Your Date Through a Unified Regulatory Platform

AMPLEXOR | Theater 1 | 12:40PM

Bioclinica | Theater 2 | 12:40PM
When EDC is not enough: Automating Multi-Country Data Collection and Complex Workflows

UBC | Theater 1 | 1:40PM
Standardizing and Enhancing Registry Data to Improve Evidence Generation

IBM Watson Health | Theater 2 | 1:40PM
Real World Insights and Collaboration in Protocol Development

PPD | Theater 1 | 3:30PM
Have You Considered Market Access in Your Trial Design?

Parexel and Microsoft | Theater 2 | 3:30PM
Change the Way You Work: Transforming Regulatory Processes with Parexel and Microsoft

Wednesday, June 26

Salesforce | Theater 1 | 9:45AM
Digital R&D: Accelerating Intelligent Innovation with IQVIA's Orchestrated Clinical Trials Platform, powered by Salesforce Health Cloud

SAS Institute, JMP Division | Theater 2 | 9:45AM
Semi-Automation of the Narrative Section of the Clinical Study Report for Oncology Studies

IQVIA | Theater 1 | 11:40AM
From Research-Ready Data to Future-Ready Data

ZS | Theater 2 | 11:40AM
Designing with Confidence

IQVIA | Theater 1 | 12:40PM
The Digital Patient Experience

Tata Consulting Services | Theater 1 | 1:40PM
Enabling Perpetual Digital Transformation in Research & Development

PRA Health Sciences | Theater 2 | 1:40PM
The Importance and Impact of Age-Specific Content in Pediatric Studies

Thank You to our Media Partners

CLINICAL LEADER
CenterWatch
digital biomarkers
Pharmaceutical Outsourcing
Outsourcing-Pharma.com
International CLINICAL TRIALS
PharmaVOICE
GaBi Generics and Biosimilars Initiative
Life Science Leader
pharmaLEADERS
Applied Clinical Trials
PM360
Pharmaceutical Executive
pharma TECH OUTLOOK
cell & gene
MM&M
CLSA

The content noted on this page was made available to DIA as of April 29, 2019

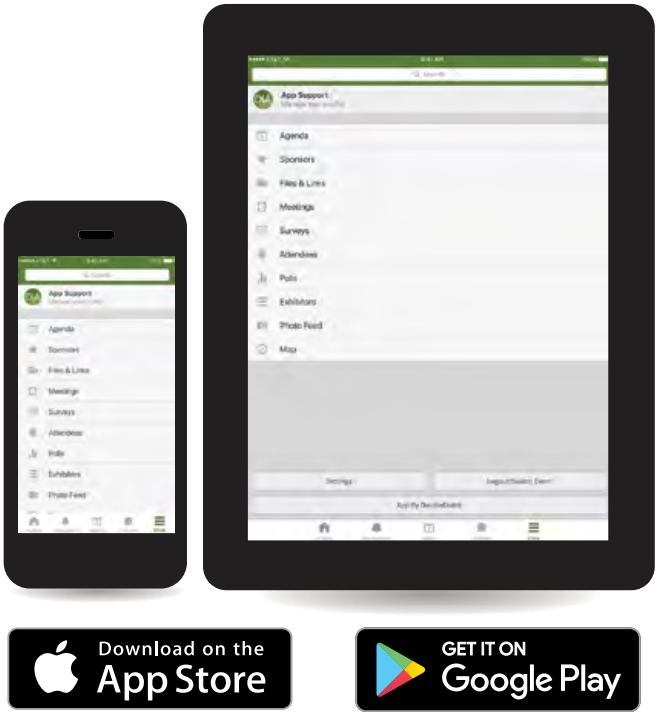
Stay Connected

Navigate DIA 2019 from Your Mobile Device with DIA's Global App

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

Benefits of the App:

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



Download on the App Store

GET IT ON Google Play

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

Win Prizes and Make Connections

Get Social!

Stay connected with your colleagues from around the world and all the innovation happening in San Diego by following #DIA2019 on your social media channels. Connect by:

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

Search **DrugInfoAssn** to follow DIA.

FOLLOW US
#DIA2019

Play Games and Win Prizes

Exhibitor Passport
Scavenger Hunt
DIA Global App Leaderboard

For more details, see the flyer in your registration bag or visit us at DIA Booth #1531.

Get Social with DIA and be Part of Our Social Wall!

Tag your photo **#DIA2019** and **#MoreThanAMeeting**

Social Wall located in Sails Pavilion Lobby

Program Commitee

Jonathan Andrus, MS, Chief Business Officer, Clinical Ink, Inc.

Matt Baldwin, MS, Senior Biostatistician, Advance Research Associates, Inc (ARA)

David Bowers, PharmD, Director, Medical Communications, PPD

Philip (P.J.) Brooks, PhD, Program Director, Office of Rare Diseases Research, National Center for Advancing Translational Sciences (NCATS), NIH

Jennifer Burgess, MBA, MPH, Executive Director of Engagement, TransCelerate BioPharma Inc.

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

Susan Callery-D'Amico, BSN, Vice President, R&D Quality Assurance, AbbVie, Inc.

Dannis Chang, PharmD, Senior Director, Global Medical Information and Scientific Communications, Halozyme Therapeutics Inc.

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

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

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

Sonya Eremenco, MA, Associate Director, PRO Consortium, Critical Path Institute

Ron Fitzmartin, PhD, MBA, Senior Project Manager, Office of the Director, CBER, FDA

David Fryrear, MS, Senior Director, R&D Quality Assurance, AbbVie, Inc.

Barbara Gladson, PhD, MS, Director of Biopharma Initiative; Interim Chair, Health Informatics, Rutgers School of Health Professions

Richard Gliklich, MD, Chief Executive Officer, OM1

William Gregory, PhD, Safety and Risk Management, Pfizer Inc

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

Sabine Haubenreisser, PhD, MSc, Principal Scientific Administrator, Stakeholders and Communication Division, European Medicines Agency (EMA), The Netherlands

Jennifer Helfer, PhD, Patient Advocacy, bluebird bio, Inc.

Nita Ichhpurani, PMP, Consultant, Phase One Forward

Jeremy Jokinen, PhD, MS, Senior Director, Decision Sciences, AbbVie, Inc.

Nadina Jose, MD, Assistant Professor, Clinical Trial Sciences, BioPharma Educational Initiative, Rutgers, The State University of New Jersey

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

Sean D. Kennedy, MPH, Clinical Operations Lead, NRDG Clinical Trial Strategy and Operations, GCO Bristol Myers Squibb

Agnes Klein, MD, Senior Medical Advisor, Health Canada

Darryl L'Heureux, Global Strategic and Regulatory Documentation, Bristol-Myers Squibb

Erik Laughner, Project Manager, Business Operations Staff, Office of the Director, CBER, FDA

Rebecca Lipsitz, PhD, Associate Director, Janssen

Chris Matheus, MBA, President, Matheus BD Connections

K. Kimberly McCleary, Founder and Chief Executive Officer, The Kith Collective, LLC

Ann Meeker-O'Connell, MS, Vice President, Global Head, Quality Assurance, IQVIA

Christine Moore, PhD, Global Head and Executive Director, GRACS CMC – Policy, Merck Research Laboratories

The content noted on this page was made available to DIA as of April 29, 2019

Program Commitee

Jean Mulinde, MD, Medical Officer, Senior Policy Advisor, Office of Scientific Investigations, Office of Compliance, FDA

Amanda Roache, MS, Operations Research Analyst, Office of the Center Director, CDER, FDA

Jeffrey Stuart, PhD, Executive Director, Global Regulatory Affairs, Merck & Co., Inc.

Nobumasa Nakashima, PhD, Senior Director for International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

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

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

Khyati Roberts, PharmD, RPh, Head US/Canada, Regulatory Policy and Intelligence, AbbVie, Inc.

Rachel Turow, JD, MPH, Executive Counsel, Regulatory Law, Teva Pharmaceutical Industries Ltd.

David Olaleye, PhD, Senior Manager and Principal Research Statistician, SAS Institute Inc.

Khushboo Sharma, MBA, Chief of Staff, Office of New Drugs, CDER, FDA

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

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

Leigh Shultz, PhD, PMP, Associate Vice President, Project Management, Merck & Co., Inc.

Robin Whitsell, President, Whitsell Innovations, Inc.

Sissi Pham, PharmD, Chief Executive Officer, AESARA

Nancy Slater, MBA, PMP, Senior Director, Portfolio Program Management Therapeutic Area Head, AbbVie, Inc.

Amy Xia, PhD, Vice President, Biostatistics, Design and Innovation, Amgen Inc.

Kim Quaintance-Lunn, Vice President and Head, Regulatory Policy, North American Regulatory Affairs, Bayer

Nancy Smerkanich, DrSc, Assistant Professor, Department of Regulatory and Quality Sciences, USC School of Regulatory Science, University of Southern California

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

Giuseppe Randazzo, MS, Director, Office of New Drug Products, Office of Pharmaceutical Quality, CDER, FDA

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

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

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

General Information

Access Presentations

Full-conference and one-day registrants can access speaker presentations (PDF version only) by visiting DIAglobal.org/DIA2019Presentations, and entering your User ID and Password. If you do not have a User ID and Password, click "Forgot User ID?", and enter the email address you provided at registration.

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

Baggage Check

There is an area in the Exhibit Hall C Lobby (near Starbucks) where you can check your belongings Monday-Thursday. The San Diego Convention Center's cost of checking a bag is $5 per item. Baggage Check will be available on the following days and times:

Monday: 7:00AM–6:30PM

Tuesday: 7:00AM–6:00PM

Wednesday: 7:00AM–7:00PM

Thursday: 8:00AM–12:30PM

Business Center

The FedEx Office, located in the Exhibit Hall D Lobby of the San Diego Convention Center, offers an array of exhibitor services and products tailored to meet your needs. FedEx Office hours are:

Sunday: 8:30AM–5:00PM

Monday: 8:00AM–5:00PM

Tuesday: 8:00AM–5:00PM

Wednesday: 8:00AM–6:00PM

Thursday: 8:30AM–5:00PM

For more information, call 619.525.5450 or email usa1324@fedex.com.

DIA Mobile App

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

- View schedules, room locations, speakers, and explore sessions (build your agenda!)
- Play the DIA Exhibitor Scavenger Hunt and win prizes
- Interact 1:1 with other attendees (private message others)
- Comment on your DIA 2019 experience and complete session evaluations
- Get notified of premier events to attend and receive important reminders

DIA Career Development

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

The DIA Career Center offers employers targeted access to quality industry professionals, quick and easy job posting, online job activity reports, and access to the National Healthcare Career Network of more than 60 top healthcare associations and professional organizations.

For additional information, visit the DIA Booth #1531, located in the Exhibit Hall.

Free DIA WiFi

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

First Aid Center

First Aid is available for routine health problems and emergency care. The First Aid Center is located on the ground floor of the Convention Center, near the Starbucks that is located at the Exhibit Hall C entrance. To report an emergency, please call extension 5490 from any Convention Center house phone, or 619.525.5490 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**. For a life-threatening emergency, dial 5911 from any Convention Center house phone or 619.525.5911 from your cell phone. We also urge you to complete the emergency contact information card, available at Attendee, Speaker, and Exhibitor Registration, and keep it in your badge holder at all times.

Ask Me Stations

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

Lost and Found

Misplaced items will be stored at Onsite Attendee Registration, located in the Sails Pavilion of the San Diego Convention Center, until the end of the meeting. Items remaining at the close of the meeting will be turned over to San Diego Convention Center security. After the meeting, please call 619.525.5407 or email lost.found@visitsandiego.com regarding any misplaced items.

The content noted on this page was made available to DIA as of April 29, 2019

General Information

DIA Luncheon Service

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

Meeting Name Badge

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

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

Private Social Functions Policy

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

Saturday: All times are acceptable

Sunday: All times are acceptable

Monday: Before 8:00AM and after 6:00PM

Tuesday: Before 8:00AM and after 5:30PM

Wednesday: Before 8:00AM and after 5:30PM

Thursday: Before 9:00AM and after 12:15PM

Selection of Offerings

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

Getting Around San Diego

By Taxi: Several taxi providers offer service to/from the airport. Follow the signs leading to the Transportation Plazas on the Arrivals/Baggage Claim level adjacent to each terminal. Taxi fares from the airport to the Convention Center and downtown hotels are based on trip distance and may vary. The average fare is approximately $20.

By Public Transit: Metropolitan Transit System (MTS), San Diego's commuter trolley and bus system, is available for transportation to/from the airport and throughout San Diego. San Diego is a very walkable city, however, there is a trolley station at the Convention Center and within a short walk from most major downtown hotels. Visit SDMTS.com/home for additional information.

By FRED San Diego: There is a new way to get around downtown San Diego: the free electric, open-air, Free Ride Everywhere Downtown (FRED). Download the app via thefreeride.com/san-diego.php and request a driver. FRED seats five passengers. Check the website for hours of operation.

Show Your Badge Discounts

Select restaurants, shops, and vendors throughout San Diego are extending exclusive discounts to DIA 2019 Attendees who show their name badge. Visit meetmeinsandiego.com/dia2019 for a list of participants.

Visitor Services Desk

Visit the San Diego Convention Center's Concierge Desk, located in Lobby B, for dining referrals, reservations, destination information, maps, directions, coupons, and tickets for attractions and tours. Call 619.525.5609 or 619.525.5610 for any assistance you may need or access meetmeinsandiego.com/dia2019. The hours for the Visitor Service Desk are:

Sunday: 9:00AM–6:00PM

Monday: 9:00AM–7:00PM

Tuesday: 9:00AM–6:00PM

Wednesday: 9:00AM–6:00PM

Thursday: 9:00AM–2:00PM

DIA Courtesy Shuttle to/from the San Diego Convention Center

Complimentary shuttle service will be provided between the Convention Center and all official DIA hotels Monday-Thursday, with the exception of the Grand Hyatt, Hard Rock, Hilton Bayfront, Hilton Gaslamp, Hotel Solamar, Omni, Pendry, Marriott Gaslamp, and the Marriott Marquis. The shuttle will be available in the morning and at the conclusion of DIA events each day.

Shuttles will arrive and depart from Harbor Drive. Please note that you must be staying at an official DIA hotel to utilize the complimentary shuttle. A shuttle pass and shuttle schedule will be provided to all participants when checking into their hotel.

Use of the shuttle pass will be strictly enforced.

The content noted on this page was made available to DIA as of April 29, 2019

Meeting Highlights: DIAmond Sessions

DIAmond SESSIONS *Conversations on Today's Priorities!*

Thought-provoking, worldwide issues deconstructed by acclaimed panelists representing multiple stakeholders from around the world in this growing ecosystem of life sciences. DIAmonds represent rare opportunities to listen to open conversations on controversial topics.

Monday, June 24 | 8:00–10:00AM | Ballroom 20

Part of the Opening Plenary and Keynote

#100 Who Owns My Health Data: Patients, Data, and the Future of R&D

Consumers today are increasingly sensitive to how their data is used and monetized, largely in the wake of Facebook/ Cambridge Analytica and other high-profile scandals. Use of personal health data is not immune from these concerns, from GDPR and California Consumer Privacy Act to the rise of state bills challenging ownership over personal health data even if de-identified. These consumer and policy trends are raising new questions for patients and medical providers and are challenging comfortable norms.

During this session, we will discuss the evolving relationship of patients and health data, from access and sharing to privacy and ownership. As well as the consumer and policy trends that may reshape expectations when personal health data is monetized. We will conclude our discussion with a conversation around the data dependence of drug development today and the implications for medical research tomorrow.

Thursday, June 27 | 9:00–10:15AM | Room 6B

#412 Keeping Up with FDA and EMA Collaborations: Question Time

How do large regulatory agencies collaborate? What are the challenges they face, in organizations with different structures and working under different legislative frameworks, in finding ways to align to facilitate and enhance global medicines development? This forum brings together pairs of experts from FDA and EMA to launch discussion in such context, with focus on several themes that will provide a foundation for discussing challenges and successes in communication and collaboration covering four areas.

Thursday, June 27 | 10:45AM–12:00PM | Room 6B

#413 FDA Town Hall

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

DIA 2019 Evaluations

We Want To Hear From You!

Your feedback about DIA 2019 and the educational sessions is extremely important to us, and helps to shape our content for 2020 and beyond. We have implemented a new and streamlined evaluation system this year to make it easier than ever to tell us what you think of our meeting.

1. Download the DIA Global App. (Please find download instructions on pg 10)
2. Under "Agenda", select the session that you wish to evaluate.
3. Select "Take Survey" to fill out the 4 question evaluation. The evaluation should take no more than 30 seconds to complete.
4. You may also select any speaker in that session and rate them on a 1 to 5 star scale in the "Rate and Review" section.

The content noted on this page was made available to DIA as of April 29, 2019

Regulatory Affairs Around the World: Map Your Sessions at DIA 2019

Monday, June 24 | 11:00AM–12:00PM | Room 6B

#117 International Regulatory Convergence
This forum will include leadership from international regulatory agencies.

Monday, June 24 | 2:15–3:15PM | Room 6F

#147 Update from Health Canada: The Health Protection Branch
While we generally speak of Health Canada abroad, there is a need to understand that responsibilities for health-related matters are split between the Federal and Provincial and Territorial Governments. This session aims to provide a broad and comprehensive picture of the activities within our mandates.

Monday, June 24 | 2:15–3:15PM | Room 14B

#150 TFDA Town Hall: Focus on Regenerative Medicine
Regenerative medicine is a potential treatment that can help repair or replace damaged or diseased human cells or tissues to restore normal function. This forum will discuss the regulatory aspects and experience with regenerative medicine.

Monday, June 24 | 3:30–4:30PM | Room 6E

#166 National Medical Products Administration (NMPA) Town Hall
This forum will present and discuss updates in several key areas in NMAP's efforts and progress: drug review and approval, GMP/GCP inspection and enforcement, and development of standards and pharmacopeia.

Monday, June 24 | 3:30–4:30PM | Room 6B

#167 Strategic Priorities of the International Coalition of Medicines Regulatory Authorities in an Increasingly Globalized Industry
The International Coalition of Medicines Regulatory Authorities (ICMRA) will explore its strategic priorities in the context of a globalized world. To overcome these challenges ICMRA can champion greater harmonization and convergence. The session will be delivered by members of ICMRA and conclude with a panel discussion of questions raised by the audience.

Tuesday, June 25 | 8:00–9:15AM | Room 6F

#214 Global Pediatric Policy Update: Are You Ready to Implement FDARA Section 504?
The new requirements in FDARA Section 504 represent a significant paradigm shift in pediatric oncology development. This session will review these requirements and their likely global impacts as well as possible mitigation strategies.

Tuesday, June 25 | 10:30–11:30AM | Room 6F

#240 Harmonizing Regulatory Science through the International Council for Harmonization (ICH)
This session will provide an overview of the ICH Association and offer insight into strategic, long-term views on advancing global convergence of regulatory science through ICH.

Tuesday, June 25 | 10:30–11:30AM | Room 6E

#241 PMDA Town Hall
In this forum, PMDA will share the latest details regarding its policies and initiatives and other related strategic directives. Three senior level representatives from PMDA and MHLW will introduce the latest situations regarding scientific review systems, regulatory capacity building activities, and the current international collaboration.

Tuesday, June 25 | 10:30–11:30AM | Room 16AB

#243 The Future of Combination Products in the EU
This forum will focus on the applicability of the new European Medical Device Regulation (EU-MDR) on March 26, 2020. Implications and challenges of the new legal requirements and technical provisions for drug-device combination products will be discussed from the perspective of regulators, industry, and patients. The discussions will include a global approach and a comparison with the current status for these products in the US.

Wednesday, June 26 | 8:00–9:15AM | Room 6F

#314 Medical Devices: EU Medical Device Regulation, PMDA Updates, and US MDUFA IV – Where Are We Now?
Since 2017, we have analyzed the new EU Medical Devices Regulations, the enabling acts (still to come!), and MDUFA IV. Now one more year on, we examine what has improved, where action is still required and what to do now to keep products on the market and review new initiatives in Japan.

Meeting Highlights: Global Regulatory Sessions cont'd

Wednesday, June 26 | 10:30–11:30AM | Room 6D

#342 When is Real World Evidence Ready for Prime Time?
We see growing interest in the value of using real world data (RWD) to support label expansions and approvals of drugs for rare conditions and oncology products. The FDA released its Framework for Real World Evidence Program in December 2018, following the release of its MyStudies App designed to incorporate patient-originated data with other RWD for research purposes. In Europe, the Heads of Medicines Agencies and the European Medicines Agency released a joint report in February, 2019 on their big data taskforce summarizing many areas of interest to better understand RWD and its possible uses. This session will distill key lessons from demonstration projects and other experiences to understand what is being done to evaluate data sets to give confidence in a RW study design, and its findings, including the challenges encountered when comparing data from clinical trials with a medicine's performance in routine clinical practice, as actually prescribed by physicians and taken by patients.

Wednesday, June 26 | 10:30–11:30AM | Room 6E

#341 The Evolving Gene Therapy Regulatory Framework: A Brave New World
This forum will bring together panelists with regulatory expertise in gene therapy to present an update on recent changes to the regulatory framework and discuss its impact on the development of gene therapy products.

Wednesday, June 26 | 2:00–3:15PM | Room 6F

#368 Global Rare Disease Town Hall
FDA and international regulators will address unique regulatory complexities and challenges specific to orphan product development. It will provide key information and updates about programs available to expedite orphan drug development and include audience Q&A.

Wednesday, June 26 | 4:15–5:30PM | Room 6D

#392 Breakthrough Therapy and PRIME Expedited Regulatory Pathways: Experience, Analysis, and Reflections from EMA, FDA, and Industry
This session will compare recent hands-on experience with expedited regulatory pathways in EU and US (PRIME and Breakthrough Designation) both from the regulators' and sponsors' viewpoint. It will also include analysis of data comparing each program's utilization and scope. A panel debate will be structured around statements that both panelists and the audience will be able to vote upon with the aim of inspiring honest discussion on the real benefits, drawbacks and future opportunities of these regulatory tools in the EU, US, and globally.

Thursday, June 27 | 9:00–10:15AM | Room 6B

#412 Keeping Up with FDA and EMA Collaborations: Question Time
How do large regulatory agencies collaborate? What are the challenges they face, in organizations with different structures and working under different legislative frameworks, in finding ways to align to facilitate and enhance global medicines development? This forum brings together pairs of experts from FDA and EMA to launch discussion in such context, with focus on several themes that will provide a foundation for discussing challenges and successes in communication and collaboration.

Thursday, June 27 | 10:45AM-12:00PM | Room 6B

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

The content noted on this page was made available to DIA as of April 29, 2019

Meeting Highlights: Professional Development

Sunday, June 23 | 11:00AM–12:30PM | Marriott Marquis San Diego Marina

Forum for Students and Emerging Professionals (Complimentary)
This forum is a unique opportunity for students and young/emerging professionals to meet, network, share, and learn about career opportunities and participate in small group discussions and activities.

Sunday, June 23 | 2:30–3:30PM | Room 15AB

#001 Self-Branding for Social Media
How you are seen by others is important. You are your own brand. If one doesn't manage one's brand, it will be created for them by others.

Sunday, June 23 | 3:45–5:00PM | Room 14B

#002 Student and Young Professional Resume Workshop
This interactive session will introduce students and young/new/emerging professionals to the fundamentals of resume/CV writing skills.

Sunday, June 23 | 3:45–5:00PM | Room 15AB

#003 Effective Networking: Know Yourself
Being effective in a clinical research career requires working well and networking with others. The myths of how each personality type networks will be explored, and the differences will be explained.

Monday, June 24 | 11:00AM–12:00PM | Room 14A

#121 Emerging Professionals: Making the Most of Your Networking Experience at the DIA 2019 Global Annual Meeting
This workshop will help emerging professionals prepare to connect and grow their networks during DIA 2019, as well as develop a networking strategy and learn tactics to build and maintain professional relationships.

Monday, June 24 | 2:15–3:15PM | Room 14A

#153 How Storytelling, Images, and Engagement Can Wow Your Audience: Presentations with a Punch!
This session will focus on strategies to create a more memorable presentation. We will explore the use of streamlined slides, images, and storytelling as well as specific presenting techniques to grab and hold the attention of an audience.

Monday, June 24 | 3:30–4:30PM | Room 14A

#171 The Courage of Career Transitions
This session will present examples of career transition considerations to advance growth and development.

Tuesday, June 25 | 8:00–9:15AM | Room 14A

#220 DISC and RISK: How DISC Profile in Clinical Trial Teams Impact Implementation of Risk-Based Approaches
An interactive workshop that shows how to best implement and operationalize risk-based approaches to clinical operations and quality management by recognizing their DISC (Dominance, Influence, Steadiness, and Compliant) profile.

Tuesday, June 25 | 10:30–11:30AM | Room 14A

#247 Pregnancy, Breastfeeding, Childcare, Oh My! Finding a Balance for New Moms
A panel will discuss how to navigate the period after maternity leave when working with a new baby at home and trying to find balance with wanting to succeed in the workplace. This forum will also be useful for managers who want to create policies to accommodate working moms when they return to work as well as colleagues who want to support women during this time.

Tuesday, June 25 | 2:00–3:15PM | Room 14A

#273 Presentations as Listeners Like Them: How to Tailor Messaging
Good data is not always enough. Providing context, clear graphics, etc. is important – but one overlooked aspect of presenting data is analyzing the audience. Best practices will be discussed.

Wednesday, June 26 | 10:30–11:30AM | Room 14A

#345 Achieving High-Performance Through Emotional Intelligence
Participants will learn practical tips and tools for self-management. Elements will include effective listening, challenging assumptions, and breaking disruptive patterns.

Wednesday, June 26 | 4:15–5:30PM | Room 14A

#397 PowerUp: Stories of Career Transforming Moments
Speakers will share stories of twists, detours, and turns in their careers in the hopes of inspiring the audience to define and embrace Plan B or go find a Plan C.

Meeting Highlights: Professional Development cont'd

Engage and Exchange Sessions | Exhibit Hall

A full Engage and Exchange schedule will be posted in the Exhibit Hall next to the Engage and Exchange session space as well as within the DIA Global App.

Tuesday, June 25 | 9:30–10:15AM

#222EE The Negotiation Game: Learn What You Never Knew About Negotiation in a Fun, Interactive, Collaborative Game

Content Hub Sessions | Community Zone | Sails Pavilion, Main Level

The full Content Hub schedule will be posted in the Community Zone as well as within the DIA Global App.

Monday, June 24 | 12:15–12:45PM

#122CH Leveraging Extra Value from an Intern Program: Non-Traditional Majors Add Unexpected Value

Wednesday, June 26 | 9:15–9:45AM

#320CH Considering Consulting? The Good, the Bad, the Ugly, and the Profitable!

Wednesday, June 26 | 2:00–3:15PM

#373CH Success in the Workplace: What Does that Mean and How Can You Achieve It?

Learn what differentiates successful people in the workplace and what you can do to emulate them. We'll learn and practice timeless principles that lead to success with an aim to help you create an immediate impact.

Community Round Table Discussions | Community Zone | Sails Pavilion, Main Level

DIA Community members will host round table discussions inspired by sessions from within the DIA 2019 agenda in the DIA Community Zone. These are open to all meeting attendees. A full schedule will be posted in the Community Zone as well as within the DIA Global App.

Student Poster Session and Oral Presentations Poster Area | Exhibit Hall

Monday, June 24 | 10:00AM-6:00PM

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

10:30–10:50AM | 12:30–2:10PM | 5:10–5:30PM

Student Oral Presentations

Tuesday, June 26 | 12:15–1:45PM

Student Poster Awards Ceremony

Student Poster Awards to be held during the DIA Community Luncheon.

Professional Poster Sessions and Oral Presentations Poster Area | Exhibit Hall

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

Tuesday, June 25, and Wednesday, June 26 | 9:00AM–4:00PM

Poster Presentations

Tuesday, June 25, and Wednesday, June 26 | 12:00–1:40PM

Oral Presentations

Monday, June 24 | 7:00–7:45AM | Room 14A

Annual Meeting Orientation

Are you new to the DIA Global Annual Meeting? Join us for breakfast and learn how to navigate this incredible learning and networking experience from members of the Annual Meeting Program Steering Committee and Program Development Team. Let us help you with maximizing the value of your time at DIA 2019!

DIA Members: Get Engaged
Booth #1531 | Exhibit Hall

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

Stop by the DIA Booth #1531, to learn how to take advantage of volunteer opportunities to raise your visibility and enjoy a tour of the Community platform. Becoming a DIA member is the first step to joining a global network where you can play an important role advancing healthcare product development through global collaboration, communication, and education.

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

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

Join at DIAglobal.org/Communities. Stop by Booth #1531 in the Exhibit Hall so we can show you how!

Community Zone | Sails Pavilion

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

DIA Community Luncheon

June 25 | 12:15–1:45PM | Ballroom 20 Lobby

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

Tuesday, June 25 | 3:30–4:00PM | Booth #1531
Annual Meeting for Members

DIA 2019 Patient Scholars

Each year, the DIA Patient Scholars program provides full support for a number of patients and patient partners to participate in the Global Annual Meeting. We are pleased to introduce the 2019 awardees:

Melinda Bachini, *Advocacy Coordinator, Cholangiocarcinoma Foundation*

Kathleen Higgins, *Director of Community Outreach, Li Fraumeni Syndrome Association*

Rachael Jones, *Executive Director, The XLH Network, Inc*

Maureen Smith, *Secretary, Board of Directors, Canadian Organization for Rare Disorders*

Celeste Graham, *Research and Education Committee, Association for Creatine Deficiencies*

Bethany Firem, *Director of Development and Strategic Partnerships, The Genesis Foundation for Children*

Eileen Sullivan, *Parent Liaison, INFORM (International Network for Fatty Acid Oxidation Research and Management)*

To learn more about this year's Patient Scholars, their patient communities, and the work of their organizations, visit the DIA Patient Scholars Booth.

CONTINUING EDUCATION

The DIA 2019 Global Annual Meeting brings together key thought leaders and innovators from industry, academia, regulatory and government agencies, health, patient, and philanthropic organizations from around the globe, across all disciplines involved in the discovery, development, and lifecycle management of healthcare products. DIA 2019 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 the DIA 2019 Global Annual Meeting, participants should be able to:

- Discuss the role of Real World Evidence in medical product development and throughout the product lifecycle
- Identify challenges and emerging standards and methodologies to ensure the appropriate use of real world data in developing evidence for regulatory decision-making and lifecycle applications
- Discuss the role of big data and analytics, approaches and methodologies for their application throughout the product lifecycle, and legal, privacy, and security implications for their use
- Apply principles of risk assessment and management to development and post-market phases of new healthcare products
- Summarize issues in clinical safety data collection, analysis, and reporting
- Distinguish regional approaches to integration of evidence-based medicine and comparative effectiveness research into healthcare decision-making
- Describe current issues and approaches 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
- 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
- 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
- Articulate the challenges facing regulatory agencies and industry in research study design and statistical methodology in preclinical and clinical development
- Examine ways to provide appropriate support to the clinical trial process that will ultimately impact patient outcomes
- Describe meaningful engagement of patients with sponsors, regulators, and other stakeholders throughout the medical product lifecycle
- Identify policies, practices, and resources to ensure integration of the patient voice in decision-making throughout the lifecycle
- Identify relevant data, document and systems standards, and integration approaches for medical product development and explain their impact on quality and end-to-end efficiency in data collection, management, submission, and approval processes
- Identify legal, advertising, and marketing issues related to providing product information
- Discuss the evolving role of medical affairs and scientific communications in the medical product development landscape
- Examine the challenges and opportunities in assessing medical product value and access to medicines
- Interpret and apply quality standards, regulations, and guidelines for medical product development and lifecycle management to ensure that products are safe, efficacious, and available to patients who need them most
- Improve professional development and workplace dynamics by identifying best practices for increasing productivity, enhancing interpersonal relationships, valuing diversity, and keeping abreast of current hiring practices, leadership opportunities, and new technology trends

Specific learning objectives for each offering are found on the DIA 2019 website under the program description details and will be shown in all meeting rooms.

Select program offerings (including sessions, forums, and workshops) may be approved for *AMA PRA Category 1 Credits™*, pharmacy or nursing contact hours, Project Management Institute (PMI) professional development units (PDUs), or International Association for Continuing Education (IACET) and Training continuing education units (CEUs). Continuing education (CE) credit information will be clearly identified in the final program and on the DIA 2019 website with the statement CME, Pharmacy, Nursing, or PMI PDUs. IACET CEUs are offered for most program offerings. CE credits are **NOT AVAILABLE** for Engage and Exchange sessions, Innovation Theater presentations, Content Hubs, or Community Round Tables.

ACCREDITATION AND CREDIT DESIGNATION STATEMENTS — *Monday, June 24–Thursday, June 27*

Joint Accreditation Statement

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

Physician Continuing Medical Education

The Postgraduate Institute for Medicine designates this live activity for a maximum of 17.75 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CONTINUING NURSING EDUCATION

The maximum number of hours awarded for this Continuing Nursing Education activity is 17.75 contact hours.

Provider approved by the California Board of Registered Nursing, Provider Number 13485, for 17.75 contact hours.

Accreditation Council for Pharmacy Education (ACPE)

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Participants can earn up to 17.75 contact hours or 1.775 continuing education units (CEUs) for participating in the Annual Meeting program offerings.

ACPE Credit Requests MUST BE SUBMITTED BY FRIDAY, AUGUST 9, 2019

Select program offerings (including sessions, forums, and workshops) may be approved for AMA PRA Category 1 Credits™, pharmacy or nursing contact hours, or Project Management Institute (PMI) professional development units (PDUs), or International Association for Continuing Education and Training (IACET) continuing education units (CEUs). Continuing education credit information will be clearly identified in the final program and on the DIA 2019 website with the statement CME, Pharmacy, Nursing, or PMI PDUs. IACET CEUs are offered for majority of the program offerings. Continuing education credits are NOT AVAILABLE for the Engage and Exchange sessions, the Innovation Theater presentations, Content Hubs, or Community Rounds.

The content noted on this page was made available to DIA as of May 11, 2019.

DIA is required by the ACPE to report pharmacy-requested CEUs through the CPE Monitor. If ACPE credit requests are not submitted within the 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 2019 Global Annual Meeting website at DIAglobal.org/DIA2019CE and in the final program.

Project Management Institute (PMI)

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

Participants may receive up to 12.5 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 2019 Global Annual Meeting website at DIAglobal.org/DIA2019CE and on each designated offering description.

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

International Association for Continuing Education and Training (IACET)

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

As an IACET accredited provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.7 CEUs for this program.

CONTINUING LEGAL EDUCATION

For attorneys who would like to receive continuing legal education credits for attending DIA 2019, please complete your state's application for credit and submit accordingly. If you require additional information, please contact CE@DIAglobal.org.

CE CREDIT ALLOCATION

Annual Meeting Program Offerings, Sunday–Thursday, June 23–27

Credit amounts range based upon the length of time for each offering. This program offers up to 24.25 *AMA PRA Category 1 Credits™*; 2.4 IACET CEUs (.2 IACET CEUs are offered for a 1.5 hour program offering and .1 IACET CEU is offered for a 1.25 hour program offering); 24.25 Nursing contact hours; 24.25 Pharmacy contact hours or 2.425 CEUs; and 15.75 PMI PDUs.

DIA CERTIFICATE PROGRAMS

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

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

In addition, DIA's Certificate Program units will be available for DIA 2019 short courses. See specific units that are available for each offering noted on the DIA 2019 website. For more information on DIA's Certificate Program, visit DIAglobal.org/CertificatePrograms.

STATEMENTS OF CREDIT

Participants who would like to receive continuing education credit for DIA 2019 must scan their DIA name badge at each offering to record their attendance. Participants must scan their badges within 45 minutes for the 1.5 hour offerings, and 30 minutes for the 1–1.25 hour offerings. Participants who do not scan their badges within the allotted time will not be eligible to request the available continuing education credits for that offering. If a participant attends multiple offerings within the same timeframe, only the last scanned entry will be recorded.

My Transcript Opens Tuesday, July 2, 2019

To access My Transcript:

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

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

EVALUATION

DIA 2019 online evaluations can be found at DIAglobal.org/DIA2019evals. All participant scanned data will be uploaded into the evaluation portal so only the offerings you attended will appear in your record. Attendees will sign into the evaluation portal using their email address and Badge ID.

The evaluation portal opens on Sunday, June 23 and closes on Friday, July 26, 2019.

Evaluation feedback is very important to DIA. To thank you for your feedback, DIA will conduct a drawing with a chance for one attendee to win a free registration to the DIA 2020 Global Annual Meeting. Eligible attendees must complete an evaluation from each program offering attended, as well as the overall evaluation. The winner of the drawing will be contacted by DIA the week of August 5, 2019.

DISCLAIMER

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

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

Disclosure of Conflicts of Interest

The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers, and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations. Disclosure statements will be included on a slide in the meeting room, as well as on the DIA 2019 website.

DIA 2019 TRACKS AND FEATURED TOPICS

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

Featured Topics	
1.	Real World Evidence
2.	Artificial Intelligence
3.	Precision Medicine
4.	Regulator Thinking
5.	Patient-Focused
6.	Advanced Therapies
7.	Rare Diseases
8.	Innovative Trial Design
9.	Generics
10.	What's Next
11.	Student Programming

CONTENT LEVEL GUIDE

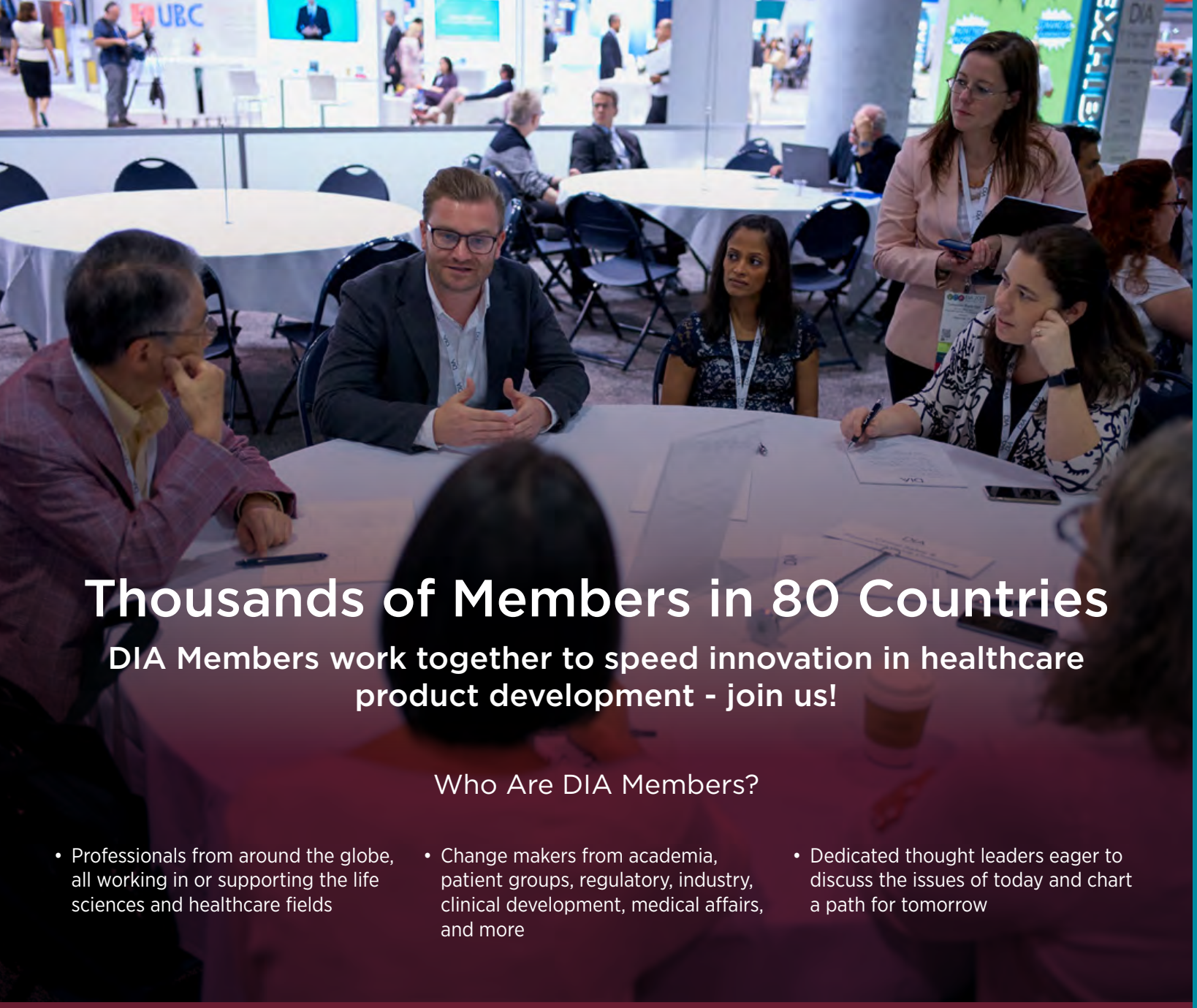
The difficulty level of each offering has been determined by the program offering chair and is indicated by one of the following symbols. This provides a guide for registrants in their selection of program offerings to attend.

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

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

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

The content noted on this page was made available to DIA as of April 4, 2019.



Thousands of Members in 80 Countries

DIA Members work together to speed innovation in healthcare product development - join us!

Who Are DIA Members?

- Professionals from around the globe, all working in or supporting the life sciences and healthcare fields
- Change makers from academia, patient groups, regulatory, industry, clinical development, medical affairs, and more
- Dedicated thought leaders eager to discuss the issues of today and chart a path for tomorrow

Relationship Building Opportunities

Knowledge and Insights

Collaborative Connections

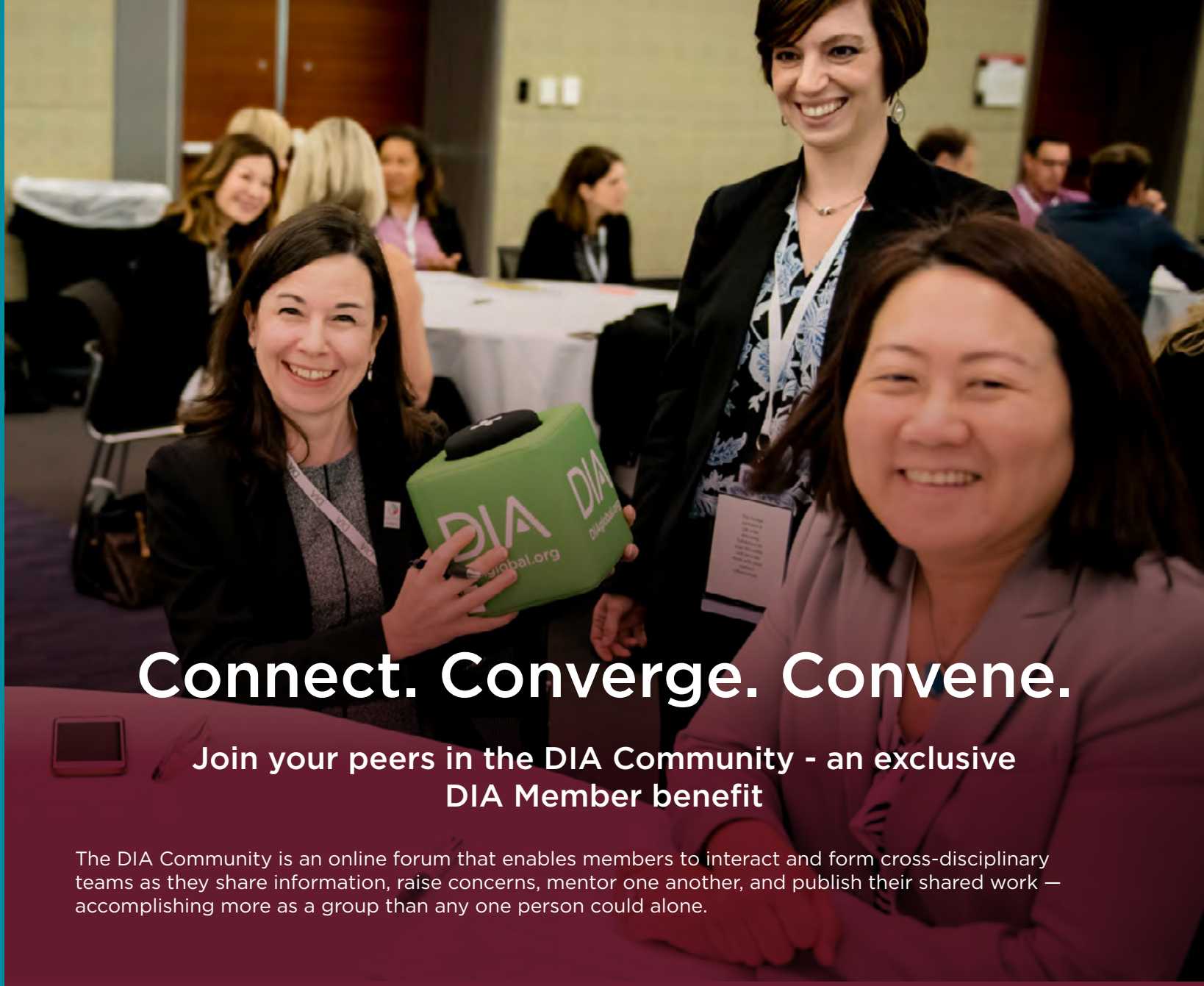
Skills Development

Leadership Growth

Stop by DIA Booth #1531 to learn more and explore all the benefits DIA Membership has to offer!

DIA

SCHEDULE



Connect. Converge. Convene.

Join your peers in the DIA Community - an exclusive DIA Member benefit

The DIA Community is an online forum that enables members to interact and form cross-disciplinary teams as they share information, raise concerns, mentor one another, and publish their shared work — accomplishing more as a group than any one person could alone.

Benefits of Joining DIA Communities:

- Network and collaborate with peers across the globe
- Use the Community Directory to find new connections
- Sign up for multiple volunteer opportunities
- Receive exclusive invitations and first-look access to face-to-face Community Events and live Community-curated webinars
- Access insightful resources such as blog posts and archived library documents uploaded by fellow Community Members

Stop by the DIA Booth #1531 in the Exhibit Hall to learn how to take advantage of volunteer opportunities to raise your visibility and tour the new Community platform.

Join us at the DIA Community Luncheon on Tuesday, June 25, 12:15-1:45PM, or check out the Community Zone in the Sails Pavilion throughout the meeting to engage with Community Members, participate in round table discussions and attend sessions within the content hubs.

DIA Communities

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
SUNDAY, JUNE 23							
2:30–3:30PM							
#001	13	Self-Branding for Social Media	Room 15AB	WORKSHOP	60	Level: ●	
3:45–5:00PM							
#002	13	Student and Young Professional Resume Workshop	Room 14B	WORKSHOP	75	Level: ●	
#003	13	Effective Networking: Know Yourself	Room 15AB	WORKSHOP	75	Level: ●	
MONDAY, JUNE 24							
7:00–7:45AM							
		Annual Meeting Orientation	Room 14B	SESSION	45	Level: ●	
8:00–10:00AM							
#100		**OPENING PLENARY, KEYNOTE, AND DIAMOND SESSION | BALLROOM 20** Join us for the DIA 2019 Global Annual Meeting Keynote Address and Opening DIAmond Session! Beginner Level | CE Credits: ACPE, CME, IACET, RN					

Chair
Barbara Lopez Kunz, MSc
Global Chief Executive, DIA

Keynote Address
Gary Gibbons, MD
Director, National Heart, Lung, and Blood Institute, NIH

Honorary Chair Welcome
Guido Rasi, MD
Executive Director, European Medicines Agency (EMA)

Panelist
Harlan Krumholz, MD, MPH
Harold H. Himes, Jr. Professor of Medicine and Director CORE, Yale University

Honorary Chair Welcome
Joanne Waldstreicher, MD
Chief Medical Officer, Johnson & Johnson

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

DIAmond Session: Who Owns My Health Data - Patients, Data, and the Future of R&D
Craig Lipset, MPH
Former Head of Clinical Innovation, Pfizer

Panelist
Deven McGraw, JD
General Counsel and Chief Regulatory Officer, Ciitizen

Panelist
Donna R. Cryer
Interim Executive Director, People-Centered Research Foundation

10:00–11:00AM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS OPEN | EXHIBIT HALL**					
10:10–10:40AM							
#101 CH	16	Modernizing Data Review in Drug Development with R Shiny	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
10:10–10:55AM							
#102 EE	15	The Female Perspective on the Clinical Trial Patient Experience: A Live Focus Group	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ●	
10:15–10:45AM							
#103 IT	18	Advanced Clinical Innovation Theater: Raising the Bar on Clinical Oversight to Reduce Risk and Ensure Inspection Readiness	Theater 1 Exhibit Hall	SESSION	30		
#104 IT	18	ArisGlobal Innovation Theater: Can Blockchain Technology Change Life Sciences?	Theater 2 Exhibit Hall	SESSION	30		

MONDAY, JUNE 24, CONTINUED

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
11:00AM–12:00PM							
#105	01	Addressing Heterogeneity of Real World Evidence in Drug Safety	Room 6D	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#106	01	Moving Forward in EU Pharmacovigilance	Room 6C	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#107	02	Emerging Technologies in Clinical Research	Room 11A	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#108	02	Innovation in Enrollment, Recruitment, and Retention	Room 9	SESSION	60	Level: ■	ACPE, CME, AICET, RN
#109	02	When Disaster Strikes: Developing a Proactive Plan to Address Challenges Brought on by Large Scale Natural Disasters	Room 10	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#110	03	Automation with Intelligence: Transformation From Human Resource to Artificial Intelligence in Risk Management	Room 1AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#111	04	PhactMI Benchmarking Survey Highlights: How are the Twenty Seven Member Companies Executing on Medical Information Initiatives	Room 4	FORUM	60	Level: ◆	ACPE, CME, IACET, RN
#112	05	Collecting Better Patient Experience Data: Lessons Learned from Patient Organizations	Room 5AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#113	06	Artificial Intelligence in Drug Discovery and Development: Emerging Technologies and Applications	Room 2	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#114	07	Patient Perspective Diversity: Taking Cultural Differences in Patient Views Into Consideration in US, EU, and Japan	Room 15AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN, PMI
#115	08	Quality Management Post-Quality Management System Implementation In The Wake of ICH E6 (R2)	Room 17AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#116	09	Harnessing Power of Advanced Technologies for Digital Transformation in Regulatory Affairs	Room 6F	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#117	09	International Regulatory Convergence	Room 6B	FORUM	60	Level: ■	
#118	11	Statistical Considerations for Trials Using Surrogate Endpoints for Accelerated Approval	Room 3	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#119	12	Making Value-Based Contracting Stick	Room 11B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#120	12	FDA Payer Communication Guidance, Twenty Years in the Making: Now What?	Room 14B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#121	13	Emerging Professionals: Making the Most of Your Networking Experience at the DIA Global Annual Meeting	Room 14A	WORKSHOP	60	Level: ●	
12:15–12:45PM							
#122 CH	16	Leveraging Extra Value from an Intern Program: Non- Traditional Majors Add Unexpected Value	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
#123 IT	18	IQVIA Innovation Theater: When Context is Hard to Come By – The Emerging Value of External Comparators	Theater 1 Exhibit Hall	SESSION	30		
#124 IT	18	Parexel Innovation Theater: Transforming the Drug Development Journey Through the Patient's Eyes	Theater 2 Exhibit Hall	SESSION	30		
12:15–1:00PM							
#125 EE	15	ICH E2B IND Safety Reporting to FDA Adverse Event Reporting System (FAERS)	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ■	
12:15–2:15PM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS OPEN | EXHIBIT HALL**					
1:00–1:30PM							
#126 CH	16	Separating the Hype from Reality in Pharmacovigilance Automation	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
#127 IT	18	Veeva Systems Innovation Theater: Annual Industry Report: Trends, Insights, and Strategies to Improve Study Execution	Theater 1 Exhibit Hall	SESSION	30		
#128 IT	18	WIRB-Copernicus Group Innovation Theater: Getting the Most Out of Your Site Selection Strategy	Theater 2 Exhibit Hall	SESSION	30		

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
1:15–2:00PM							
#129 EE	15	The Potential Value of Shared Decision Making (SDM) in Clinical Trial Consideration and Participation	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ■	
#130 RT	17	Round Table Discussion: Emerging Technologies in Clinical Research	Community Zone Sails Pavilion	SESSION	60	Level: ●	
1:30–2:15PM							
#131 SB	06	On the Soapbox: Designing Babies - Medical, Ethical, and Social Questions	Room 16AB	FORUM	45	Level: ■	ACPE, CME, IACET, RN
1:45–2:15PM							
#132 CH	16	Advancing Trailblazing Research and Development: When to Speed Up, When to Slow Down	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
#133 IT	18	Cognizant Technology Solutions Corporation Innovation Theater: Shared Investigator Platform: Innovating Clinical Trials Feasibility and Study Start Up	Theater 1 Exhibit Hall	SESSION	30		
#134 IT	18	SAS Institute Inc Innovation Theater: Smarter Clinical Trial Enrollment with Real World Data and Simulation Analytics	Theater 2 Exhibit Hall	SESSION	30		
2:15–3:15PM							
#135	01	Using Real World Data to Develop a Safety Monitoring Program and Pre- and Post-Market Continuity	Room 6D	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#136	01	Interpretation of New Pharmacovigilance Regulations: Key Insights	Room 6C	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#137	02	Emerging Technology to Improve Sponsor-Site Interactions	Room 11A	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#138	02	Blockchain in Clinical Trials Demo: Truth or Dare	Room 9	WORKSHOP	60	Level: ■	ACPE, CME, IACET, RN
#139	02	Developing Standard Core Clinical Outcome Assessments and Endpoints: FDA Perspective and Plans	Room 10	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#140	03	Use of Real World Data in Clinical Trials: Abstracting Endpoints from Encounters	Room 1AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#141	04	Knowledge Management and Information Sharing to Support Business Continuity	Room 4	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#142	05	Show Me the Money! Patient and Caregiver Roles and Compensation in Research, Development, and Innovation	Room 5AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#143	06	Opportunities and Challenges with First-In-Human Multiple Expansion Cohort Designs in Oncology	Room 2	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#144	07	Ready or Not: Business Continuity Planning	Room 15AB	FORUM	60	Level: ◆	ACPE, CME, IACET, PMI, RN
#145	08	Examining Essential Elements of Vendor Governance and Comparing Perspectives of Large and Emerging Biopharma	Room 17AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#146	09	Communications with Regulators Beyond Formal Meetings	Room 6B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#147	09	Update from Health Canada: The Health Protection Branch	Room 6F	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#148	09	Hot Topics in Digital Health: How is FDA's Approach Evolving, and What Do Industry and Patients Need to Know?	Room 6E	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#149	09	Hype Versus Reality: Artificial Intelligence and Real World Evidence	Room 11B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#150	09	TFDA Town Hall: Focus on Regenerative Medicine	Room 14B	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#151	10	Update on ICH Quality Topics	Room 8	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#152	11	Making Data Meaningful: Using Data Visualization to Drive Efficiency in Safety Analysis	Room 3	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#153	13	How Storytelling, Images, and Engagement Can Wow Your Audience: Presentations with Punch!	Room 14A	WORKSHOP	60	Level: ●	

MONDAY, JUNE 24, CONTINUED

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
3:30–4:30PM							
#154	01	Current Initiatives on Patient Involvement in the Medicinal Product Lifecycle: CIOMS XI	Room 6C	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#155	01	Incorporating Systems-Theory and Human Factors into the Investigations of Serious Harm in Clinical Research	Room 6D	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#156	02	Clinical Research in Emerging Regions	Room 9	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#157	02	A Large Academic Medical Center's Perspective on Using Precision Medicine to Find Patient Disease Subgroups at Scale	Room 11A	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#158	02	Enhancing Patient-Focused Outcome Assessment in Medical Product Development	Room 10	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#159	03	Understanding the Data Journey In Virtual Trials	Room 1AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#160	04	New Communication Channels for Medical Information	Room 4	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#161	05	Making Trials Work for Special Populations	Room 5AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#162	06	Precision Medicines in Clinical Trials: Understanding and Overcoming Barriers to Adoption	Room 2	FORUM	60	Level: ◆	ACPE, CME, IACET, RN
#163	07	Strategic Integration: Is Anyone Getting it Right?	Room 15AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN, PMI
#164	08	Compliance: The Importance of Periodic Screenings to Ensure Good Inspection Health	Room 17AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#165	09	Drug Development Tools in a Digital Era	Room 6F	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#166	09	National Medical Products Administration (NMPA) Town Hall	Room 6E	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#167	09	Strategic Priorities of the International Coalition of Medicines Regulatory Authorities in an Increasingly Globalized Industry	Room 6B	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#168	10	Regulating Innovation in Chemistry, Manufacturing, and Controls: Challenges and Opportunities	Room 8	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#169	11	How Statistics Can Help Improve Data Quality: ICH E6 R2	Room 3	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#170	12	Making Early Access for Patients Happen	Room 14B	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#171	13	The Courage of Career Transitions	Room 14A	SESSION	60	Level: ■	
#172 CH	16	Paving the Path for Family-Centered Design: Caregiver Roles in Medical Product Development	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
4:30–6:00PM		**STUDENT POSTER SESSION AND ORAL PRESENTATIONS OPEN |EXHIBIT HALL**					
4:45–5:15PM							
#173 IT	18	Appian Innovation Theater: Accelerating the Regulatory Information Management Journey with Intelligent Automation	Theater 1 Exhibit Hall	SESSION	30		
#174 IT	18	Deloitte Consulting Innovation Theater: Reimagining Patient Safety	Theater 2 Exhibit Hall	SESSION	30		
5:15–6:00PM							
#175 EE	15	Data Analytics Use in Quality Processes	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ◆	
5:30–6:30PM							
#176 IT	18	Statistics & Data Corporation Innovation Theater: Artificial Intelligence and Machine Learning: Innovations in Clinical Trial Data Automation	Theater 1 Exhibit Hall	SESSION	30		
#177 IT	18	Syneos Health Innovation Theater: Coloring in the Full Spectrum of FSP Offerings	Theater 2 Exhibit Hall	SESSION	30		

TUESDAY, JUNE 25

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
8:00–9:15AM							
#201	01	To Err is Human: Progress and Challenges in the Prevention of Medication Errors	Room 6C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#202	01	Updates and Lessons Learned from Novel Approaches to Pharmacovigilance Collaboration	Room 6D	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#203	02	eConsent Done Right	Room 11A	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#204	02	Protocol Developments of the Future	Room 9	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#205	02	Driving Enrollment with a Patient-Centric Focus to Artificial Intelligence	Room 10	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#206	03	Single Source of Truth, Integrations, or IoT (Internet of Things): Exploring Ways to Improve Connectedness of Clinical Data	Room 1AB	FORUM	75	Level: ◆	ACPE, CME, IACET, RN
#207	04	Leveraging Artificial Intelligence and Natural Language Processing in Medical Writing	Room 4	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#208	05	Patient Focus as Part of the Regulatory Affairs DNA: Opportunities and Challenges	Room 5AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#209	06	Emerging Issues in CRISPR and Gene Editing Symposium	Room 2	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#210	07	Increasing Personal Resilience To Manage Change	Room 15AB	WORKSHOP	75	Level: ●	ACPE, CME, IACET, RN, PMI
#211	08	Pharmacovigilance Reporting and Quality	Room 17AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#212	08	Translating Academic Research into Product Development: Integrating GXPs into the Process (Part 1 of 4)	Room 16AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#213	09	Facilitating Access: Patient Perspectives on a Streamlined Development Approach for Treatments for Severely-Debilitating or Life-Threatening Diseases	Room 6B	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#214	09	Global Pediatric Policy Update: Are You Ready to Implement FDARA Section 504?	Room 6F	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#215	09	Conducting Clinical Trials with GMOs: Strategies to Overcome Regulatory, Operational, and Patient Enrollment Challenges	Room 6E	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#216	09	Identifying the Reference Listed Drug for ANDA Submission, Overview of FDA's Orange Book, and Exclusivities for NDAs and ANDAs	Room 11B	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#217	10	Quality Considerations for Complex Generics	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#218	11	Real World Data to Real World Evidence	Room 3	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#219	12	Personalized Healthcare and Clinical Outcomes: How Real World Endpoints Can Improve Approval and Access to Medicine?	Room 14B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#220	13	DISC and RISK: How DISC Profile in Clinical Trial Teams Impact Implementation of Risk-Based Approaches	Room 14A	WORKSHOP	75	Level: ●	IACET
9:15–9:45AM							
#221 CH	16	Getting the Question Right (GTQR) with Interdisciplinary Collaboration	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
9:30–10:15AM							
#222 EE	15	The Negotiation Game: Learn What you Never Knew About Negotiation in a Fun, Interactive, Collaborative Game	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ●	
9:30–10:30AM							
#223 RT	17	Round Table Discussion: Interpretation of New Pharmacovigilance Regulations: Key Insights	Community Zone Sails Pavilion	SESSION	60	Level: ●	

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
TUESDAY, JUNE 25, CONTINUED							
#224 RT	17	Round Table Discussion: Enhancing Patient-Focused Outcome Assessment in Medical Product Development	Community Zone Sails Pavilion	SESSION	60	Level: ●	
9:45–10:15AM							
#225 IT	18	DiagnoSearch Life Sciences Innovation Theater: Disruptive Innovation: 'Wide-Angle-Data' – Fully Integrated Platform with Advanced Analytics and Customized Algorithms for Real Time Safety and Risk Management	Theater 1 Exhibit Hall	SESSION	30		
#226 IT	18	Covance Innovation Theater: Fixing the Patient Recruitment "Leaky Funnel"	Theater 2 Exhibit Hall	SESSION	30		
10:00–10:30AM							
#227 CH	16	GCP for Contributing Investigator Versus Conducting Investigator-Initiated Trials in Emerging Regions	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
10:30–11:30AM							
#228	01	Emerging Safety Challenges in New Oncology Treatments	Room 6D	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#229	01	An Industry Collaboration on Pharmacovigilance Analytics	Room 6C	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#230	02	Assessing Opportunities to Improve Outsourcing Oversight and the Vendor Qualification Assessment Process	Room 10	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#231	02	Outcomes, Endpoints, and Methods Supporting Oncology and Alzheimer Therapies	Room 9	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#232	02	Retooling Risk Assessment to Align with ICH-E6(R2) and Connect to Centralized Monitoring and Risk-Based Monitoring	Room 11A	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#233	03	Creating Clarity: Changes at CDISC to Make Standards Implementation Easier for all Stakeholders	Room 1AB	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#234	04	Quality and Compliance Management in Medical Information/ Medical Affairs	Room 4	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#235	05	Walking the Talk: Using Home Nursing as a Patient-Centric Service in Clinical Trials - From Multiple Perspectives	Room 11B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#236	05	Our Doors are Open! Pathways and Programs for Patient Stakeholders to Engage with FDA	Room 5AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#237	06	The Rare Disease Experience in Clinical Trials	Room 2	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#238	07	Build and Leverage Your Networks to Influence Stakeholders	Room 15AB	FORUM	60	Level: ●	ACPE, CME, IACET, RN, PMI
#239	08	Improving Clinical Trial Risk Management: How To Leverage the IRB's Designed Purpose	Room 17AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#240	09	Harmonizing Regulatory Science Through the International Council for Harmonization (ICH)	Room 6F	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#241	09	PMDA Town Hall	Room 6E	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#242	09	Use of Real World Evidence to Support Regulatory Decision-Making: First-Year Findings From the RCT-DUPLICATE Project	Room 6B	SESSION	60	Level: ●	ACPE, CME, IACET, RN
#243	09	The Future of Combination Products in the EU	Room 16AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#244	10	Where Quality Meets Safety and Efficacy: A Conversation with CMC Experts	Room 8	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#245	11	Artificial Intelligence Enhanced Data Analytics for Clinical Trials	Room 3	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#246	12	How Employers are Reinventing Healthcare and What it Means for Research Participation and Evidence	Room 14B	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#247	13	Pregnancy, Breastfeeding, Childcare, Oh My! Finding a Balance for New Moms	Room 14A	FORUM	60	Level: ■	

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
11:40AM–12:25PM							
#248 IT	18	Veeva Systems Innovation Theater: Shortening Database Builds by 40–60%	Theater 1 Exhibit Hall	SESSION	45		
#249 IT	18	ArisGlobal Innovation Theater: Getting More Value From Your Data Through A Unified Regulatory Platform	Theater 2 Exhibit Hall	SESSION	45		
11:45AM–12:15PM							
#250 CH	16	How to Efficiently Implement a Healthcare Compliance Program in Preparation for Your First Product Launch	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
11:45AM–2:00PM		**PROFESSIONAL POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
12:40–1:25PM							
#251 IT	18	AMPLEXOR Innovation Theater	Theater 1 Exhibit Hall	SESSION	45		
#252 IT	18	Bioclinica Innovation Theater: When EDC is not Enough: Automating Multi-Country Data Collection and Complex Workflows	Theater 2 Exhibit Hall	SESSION	45		
1:40–2:00PM							
#253 IT	18	UBC Innovation Theater: Standardizing and Enhancing Registry Data to Improve Evidence Generation	Theater 1 Exhibit Hall	SESSION	20		
#254 IT	18	IBM Watson Health Innovation Theater: Real World Insights and Collaboration in Protocol Development	Theater 2 Exhibit Hall	SESSION	20		
2:00–3:00PM							
#254.1 RT	17	Round Table Discussion: Current Initiatives on Patient Involvement in the Medicinal Product Lifecycle: CIOMS XI	Community Zone Sails Pavilion	SESSION	60	Level: ●	
2:00–3:15PM							
#255	01	Pharma and Regulatory Perspectives on Machine Learning Applications in Pharmacovigilance	Room 6C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#256	02	Wearables and Patient Technologies Utilized in Clinical Trials	Room 10	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#257	02	Clinical Trial Diversity: Moving from Admiring the Problem to Solving it	Room 11A	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#258	02	Build-a-Bot Workshop: Design and Build a Conversational Agent that Speaks for You	Room 9	WORKSHOP	75	Level: ●	ACPE, CME, IACET, RN
#259	03	FDA Data Standards Update	Room 1AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#260	04	Clinical Trial Disclosure and Transparency: Intersection of Regulators, Industry, and Patients	Room 4	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#261	05	Patient Experience Data: How Could this Data Enhance Decision-Making at Different Stages of Medical Product Development?	Room 5AB	FORUM	75	Level: ●	ACPE, CME, IACET, RN
#262	05	Measuring the Impact of Patient Engagement Activities in Medicines R&D: A Way to Sustain the Cultural Change?	Room 16AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#263	06	Drug Development for Ocular Disease, New Therapies, Regulations, and Patient Perspectives	Room 6D	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#264	06	Immuno-Oncology Product Development: Overcoming Scientific and Regulatory Challenges	Room 2	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#265	07	Decision Leadership: How Using a Structured Approach to Decision Making Can Help You Lead Teams Better	Room 15AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN, PMI
#266	08	Electronic Systems: Are Yours Fit for Purpose?	Room 17AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#267	08	Translating Academic Research Into Product Development: The What and Why of cGMP in Translational Science (Part 2 of 4)	Room 11B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#268	09	Current Status of FDA Framework for the Evaluation of Real World Evidence	Room 6B	SESSION	75	Level: ●	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
TUESDAY, JUNE 25, CONTINUED							
#269	09	Driving Complex Generics to Approval: What are the Keys to Success	Room 6F	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#270	10	Where Quality Meets Safety and Efficacy: An Interactive Experience	Room 8	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#271	11	Master Protocols: Applications in Oncology	Room 3	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#272	12	Aligning Facilitated Regulatory and Access Pathways: Observations from the North American Experience	Room 14B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#273	13	Presentations as Listeners Like Them: How to Tailor Messaging	Room 14A	SESSION	75	Level: ■	IACET
#274 EE	15	Pharma Powered by the Digital	Engage and Exchange Area Exhibit Hall	WORKSHOP	60	Level: ●	
3:15–4:15PM		**PROFESSIONAL POSTER SESSION | EXHIBIT HALL**					
3:15–4:15PM							
#275 EE	15	Access to Investigational Drugs Outside of Clinical Trials: What's Fair?	Engage and Exchange Area Exhibit Hall	WORKSHOP	60	Level: ●	
#276 RT	17	Round Table Discussion: Updates and Lessons Learned from Novel Approaches to Pharmacovigilance Collaboration	Community Zone Sails Pavilion	SESSION	60	Level: ●	
#277 RT	17	Round Table Discussion: Clinical Research in Emerging Regions	Community Zone Sails Pavilion	SESSION	60	Level: ●	
3:30–4:00PM							
#278 CH	16	How to Write a Compelling Poster Abstract	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
#279 IT	18	PPD Innovation Theater: Have you Considered Market Access in Your Trial Design	Theater 1 Exhibit Hall	SESSION	30		
#280 IT	18	Parexel and Microsoft Innovation Theater: Change The Way You Work: Transforming Regulatory Processes with PAREXEL and Microsoft	Theater 2 Exhibit Hall	SESSION	30		
4:15–5:30PM							
#281	01	Structured Evidence Planning, Production, and Evaluation (SEPPE): A "Quality-Based" Framework for Drug Development	Room 6C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#282	01	The Elephant in the Room: Meaningful Communication of Near Synonyms as Suspected Adverse Reactions	Room 6D	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#283	02	Let's Talk Risk-Based Monitoring	Room 9	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#284	02	Virtual Clinical Trials	Room 10	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#285	02	Using Mobile Sensors in Clinical Trials and Evidentiary Considerations for Electronic Submissions	Room 11A	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#286	03	The Machines are Here! Learn About Real Uses of Machine Learning and Artificial Intelligence in Pharma	Room 1AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#287	04	A Case Study in Structuring Clinical Content and Structured Content Management (SCM)	Room 4	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#288	04	The Changing Landscape of Medical Affairs: Are We Prepared For 2020?	Room 11B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#289	05	Impact of Patient Engagement on the Biopharmaceutical Industry's Business and Organization	Room 5AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#290	06	The Responsibility Industry, Agencies, and Early Education own in Cure-Model Based Therapeutics	Room 16AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#291	06	Transgenic Products: A DNA Construct Goes Regulatory-A Coming of Age Story	Room 2	SESSION	75	Level: ■	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#292	07	Conversations with the Participant: Layperson Summaries and Return of Results	Room 15AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN, PMI
#293	08	Real World Evidence: How Does its Use Challenge Quality and Compliance Programs?	Room 17AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#294	09	Update From the US FDA on Progress and Topics of Current Interest in US Biosimilar Policy, Regulation, and Outreach/ Education	Room 6F	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#295	09	Prescription Drug Labeling: New Guidances from the US FDA	Room 6B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#296	09	Informing Development and Authorizations Using Real World Evidence/Artificial Intelligence	Room 6E	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#297	10	Integration of Manufacturing Quality Assessment and Pre-Approval Inspections	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#298	11	Clinical Safety Assessment: What's a Statistician Got to Do with It?	Room 3	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#299	12	Public and Regulatory Response To Drug Pricing Concerns	Room 14B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#299.1 CH	16	Challenge of Regulatory Starting Material Designation and Its Implication on the Global Markets for the Post Approval Process	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	

WEDNESDAY, JUNE 26

8:00–9:15AM

#301	01	So Much Data, So Little Time: Hot Topics in Benefit-Risk Assessment	Room 6C	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#302	01	Triple-s (3S) Smart Safety Surveillance	Room 6D	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#303	02	Disruptive Technology Transforming Clinical Trials: The Case for Artificial Intelligence, Blockchain, and Mobile Tech/Wearables	Room 11A	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#304	02	Operationalizing Master Protocols	Room 10	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#305	02	Demystifying Technology Selection in Mobile Clinical Trials	Room 9	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#306	03	Methods for Integrating EHR Data into EDC and eSource Databases	Room 1AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#307	04	Can Topic-Based Approaches to Document Authoring Help Meet the Demands of Accelerated Marketing Application Timelines?	Room 4	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#308	05	Identifying High-Value Patient Engagement Opportunities: A Collaborative Three-Step Process for Sponsors and Patient Groups	Room 5AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#309	06	Neoantigen-Based Cancer Therapies: Regulatory Challenges and Opportunities	Room 2	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#310	07	Project Planning 101: Turning Strategy into Execution	Room 15AB	WORKSHOP	75	Level: ●	ACPE, CME, IACET, RN, PMI
#311	08	Improving Trial Quality by Better Preparing Site Teams	Room 17AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#312	08	Translating Academic Research into Product Development: The Importance of Understanding GLPs at an Early Stage (Part 3 of 4)	Room 14A	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#313	09	Model Integrated Evidence as Pivotal Information for Drug Regulatory Decision Making: When, Where, and Why	Room 6E	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#314	09	Medical Devices: EU Medical Device Regulation, PMDA Updates, and US MDUFA IV – Where Are We Now?	Room 6F	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#315	10	Measuring and Assessing Product Manufacturing Quality	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#316	11	Implementation of Innovative and Adaptive Designs in Clinical Trials	Room 3	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#317	11	Designing Clinical Trials with the Right Endpoints: Applying ICH-E9(R1) - Getting the Questions Right (GTQR),Estimands and Handling Missing Data	Room 11B	FORUM	75	Level: ■	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
WEDNESDAY, JUNE 26, CONTINUED							
#318	12	Opportunities and Challenges of Collecting Data in a Pre-Approval Access Setting: A Multi-Stakeholder Perspective	Room 14B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#319	12	How to Solve the Problem of Access for Rare Diseases	Room 16AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
9:15–9:45AM							
#320 CH	16	Considering Consulting? The Good, the Bad, the Ugly, and the Profitable!	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
9:30–10:15AM							
#321 EE	15	One Size Does NOT Fit All: Know How to Adapt your Communication Style to be Effective Communicating Up, Down and Peer-to-Peer	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ●	
#322 RT	17	Round Table Discussion: Real World Data to Real World Evidence	Community Zone Sails Pavilion	SESSION	60	Level: ●	
#323 RT	17	Round Table Discussion: Personalized Healthcare and Clinical Outcomes: How Real World Endpoints Can Improve Approval and Access to Medicine?	Community Zone Sails Pavilion	SESSION	60	Level: ●	
9:45–10:15AM							
#324 IT	18	Salesforce Innovation Theater: Digital R&D: Accelerating Intelligent Innovation With IQVIA's Orchestrated Clinical Trials Platform, Powered by Salesforce Health Cloud	Theater 1 Exhibit Hall	SESSION	30		
#325 IT	18	SAS Institute Inc JMP Innovation Theater: Semi-automation of the Narrative Section of the Clinical Study Report for Oncology Studies	Theater 2 Exhibit Hall	SESSION	30		
10:00–10:30AM							
#326 CH	16	2020 and Beyond, Data Capture Across Systems, Functions, and Modalities	Content Hub Sails Pavilion	WORKSHOP	30	Level: ◆	
10:30–11:30AM							
#327	01	Digital Risk Minimization: The "Next Generation" Risk Management Tools	Room 6C	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#328	02	Risk-Based Monitoring: Best Practice Today and Technology for Tomorrow	Room 9	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#329	02	Global Clinical Trials: Make Them Really Global and Involve Africa	Room 10	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#330	02	The Analytics Revolution: Opportunities and Threats for Disrupting Clinical Development Operations	Room 11A	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#331	02	A Pharma/CRO Partnership in the Design and Execution of Paperless Clinical Trials from eICF to Database Lock	Room 11B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#332	03	eSource Adoption: Where We Are - Our Experiences from eSource Implementation	Room 1AB	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#333	04	Pediatric Plans: The Challenges Between Regulations and Reality	Room 4	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#334	05	Understanding and Exploring Elements of a Patient-Focused Product Launch	Room 5AB	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#335	05	Highlights of the Patient Engagement Preparedness, Capabilities, Experience, and Impact (PEPCEI) Study	Room 14B	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#336	06	Exploring the Evolving Requirements for the Clinical Assessment of Abuse and Dependence Potential of CNS-Active Drugs	Room 2	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#337	07	Application of Project Management Methodologies and Tools in NonProfit Institutions	Room 15AB	SESSION	60	Level: ●	ACPE, CME, IACET, RN, PMI
#338	08	Expanding Use of Interactive Response Technologies in Clinical Trials: Maintaining Data Quality and Reliability	Room 17AB	SESSION	60	Level: ◆	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#339	09	Hot Topics in Quality and Regulatory Affairs for Combination Products	Room 6B	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#340	09	Digital Technology Advances Labeling Management and Patient Access	Room 6F	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#341	09	The Evolving Gene Therapy Regulatory Framework: A Brave New World	Room 6E	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#342	09	When is Real World Evidence Ready for Prime Time?	Room 6D	FORUM	60	Level: ●	ACPE, CME, IACET, RN
#343	10	Efficient Preparation of Global CMC Dossiers	Room 8	SESSION	60	Level: ■	ACPE, CME, IACET, RN
#344	11	Meaningful Patient-Focused Drug Development for Rare Disease and Personalized Medicine	Room 3	FORUM	60	Level: ■	ACPE, CME, IACET, RN
#345	13	Achieving High Performance Through Emotional Intelligence	Room 14A	WORKSHOP	60	Level: ■	CME, IACET, RN, PMI
11:40AM–12:25PM							
#346 IT	18	IQVIA Innovation Theater: From Research-Ready Data to Future-Ready Data	Theater 1 Exhibit Hall	SESSION	45		
#347 IT	18	ZS Innovation Theater: Designing With Confidence	Theater 2 Exhibit Hall	SESSION	45		
11:45AM–2:00PM		**PROFESSIONAL POSTER SESSION AND ORAL PRESENTATIONS | EXHIBIT HALL**					
12:30–1:00PM							
#348 CH	16	Project Managing Your Own Leadership Journey	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	
12:30–1:30PM							
#349 EE	15	Regulatory Affairs Governance: Benchmarking and Sharing of Best Practices	Engage and Exchange Area Exhibit Hall	WORKSHOP	60	Level: ■	
12:40–1:25PM							
#350 IT	18	IQVIA Innovation Theater: The Digital Patient Experience	Theater 1 Exhibit Hall	SESSION	45		
#350.1 IT	18	Oracle Health Sciences Innovation Theater: The AI Revolution in Multivigilance	Theater 2 Exhibit Hall	SESSION	45		
12:45–1:45PM							
#351 RT	17	Round Table Discussion: An Industry Collaboration on Pharmacovigilance Analytics	Community Zone Sails Pavilion	SESSION	60	Level: ●	
#352 RT	17	Round Table Discussion: Clinical Trial Disclosure and Transparency: Intersection of Regulators, Industry, and Patients	Community Zone Sails Pavilion	SESSION	60	Level: ●	
1:15–1:45PM							
#353 CH	16	The Current and Future State of RIM	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
1:40–2:00PM							
#353.1	18	Tata Consultancy Services: Enabling Perpetual Digital Transformation in Research & Development	Theater 1 Exhibit Hall	SESSION	20		
#354 IT	18	PRA Health Sciences Innovation Theater: The Importance and Impact of Age Specific Content in Pediatric Studies	Theater 2 Exhibit Hall	SESSION	20		
2:00–3:15PM							
#355	01	History of Risk Evaluation and Mitigation Strategies (REMS): What Have We Learned?	Room 6C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#356	01	Involving Patients in Medicinal Product Benefit-Risk Communication: How're We Doing?	Room 6D	SESSION	75	Level: ■	ACPE, CME, IACET, RN

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
#357	02	Accelerating Drug Development via Structured Content Reuse: Introducing the TransCelerate Clinical Template eSuite	Room 11A	SESSION	75	Level: ■	ACPE, CME, IACET, RN
		WEDNESDAY, JUNE 26, CONTINUED					
#358	02	Improving the Trial Experience for Rare Disease Patients: Identifying and Overcoming Obstacles	Room 9	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#359	02	Training for the Electronic Capture of PRO Data in Clinical Trials: Views from ePRO Vendors, Sponsors, Sites, and Patients	Room 10	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#360	03	Identification of Medicinal Products: FDA's Perspective and Approach	Room 1AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#361	04	Returning Plain Language Summaries to Research Participants: Best Practices and the Role of the IRB	Room 4	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#362	05	Patient Engagement Quality Guidance: Results and Learnings from Global Multistakeholder Pilots	Room 5AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#363	06	Neurodegenerative Diseases: Early-Stage Challenges and Optimal Models in Drug Development	Room 2	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#364	07	Effective Portfolio Management of Assets Across an Organization	Room 15AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN, PMI
#365	08	Leveraging Data Analytics to Drive Compliance and Quality in a Risk-Based Monitoring Environment	Room 17AB	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#366	08	Translating Academic Research into Product Development: Integrating GCP Training into the Process (Part 4 of 4)	Room 16AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#367	09	Model-Informed Drug Development (MIDD) and Complex Innovative Designs (CID) Programs: Where are We and What Have We Learned?	Room 6B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#368	09	Global Rare Disease Town Hall	Room 6F	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#369	09	User-Fee Programs Myth Busting: General Financial Principles Explained	Room 6E	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#370	10	Challenges and Opportunities in Product Quality: Lifecycle Management	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#371	11	Efficient Pediatric Drug Development: Incorporating Innovative Techniques Using Extrapolation and Historical Information	Room 3	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#372	12	Advancing Value and Access With Technology	Room 14B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#373 CH	16	Success in the Workplace: What Does That Mean and How Can You Achieve it?	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
#374 EE	15	Enabling Patient-Centric Clinical Studies: TransCelerate's Patient Engagement Tools	Engage and Exchange Area Exhibit Hall	WORKSHOP	60	Level: ■	
#375 RT	17	Round Table Discussion: Can Topic-Based Approaches to Document Authoring Help Meet the Demands of Accelerated Marketing Application Timelines?	Community Zone Sails Pavilion	SESSION	60	Level: ●	
#375.1 RT	17	Round Table Discussion: The Elephant in the Room: Meaningful Communication of Near Synonyms as Suspected Adverse Reactions	Community Zone Sails Pavilion	SESSION	60	Level: ●	
3:15–4:00PM							
#376 EE	15	Assessing Medical Adherence in a Clinical Trial Setting: Challenges and Solutions	Engage and Exchange Area Exhibit Hall	WORKSHOP	45	Level: ■	
#376.1 RT	17	Round Table Discussion: Master Protocols: Applications in Oncology	Community Area Sails Pavilion	SESSION	60	Level: ●	
#377 RT	17	Round Table Discussion: Pharma and Regulatory Perspectives on Machine Learning Applications in Pharmacovigilance	Community Zone Sails Pavilion	SESSION	60	Level: ●	

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
3:15–4:00PM		**PROFESSIONAL POSTER SESSION | EXHIBIT HALL**					
3:30–4:00PM							
#378 CH	16	Measuring "Value" in Value-Based Healthcare: A Health Economics Perspective	Content Hub Sails Pavilion	WORKSHOP	30	Level: ●	
#378.1 SB	05	On the Soapbox: Good for People and Good for Research - Individuals as Research Partners	Room 16AB	FORUM	30	Level: ●	ACPE, CME, IACET, RN
4:15–5:30PM							
#379	01	From Trials to Real World: How Safety Protocols Impact REMS	Room 6C	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#380	02	Incorporating Patient Input into the Design and Conduct of Clinical Trials	Room 9	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#381	02	A New Path Forward for Using Decentralized Clinical Trials	Room 10	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#382	03	Real World Data Quality for Regulatory Decision-Making	Room 1AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#383	04	Next-Generation Approaches for Developing Narratives	Room 4	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#384	05	Patient Preferences in Decision Making and the PREFER Project: Past, Present, and Future	Room 5AB	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#385	06	The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety	Room 2	SESSION	75	Level: ◆	ACPE, CME, IACET, RN
#386	07	Setting the Stage for Effective Stakeholder Collaboration	Room 15AB	WORKSHOP	75	Level: ●	ACPE, CME, IACET, RN, PMI
#387	08	Global Perspective on ICH E8(R1): General Considerations for Clinical Trials	Room 17AB	FORUM	75	Level: ◆	ACPE, CME, IACET, RN
#388	09	Convergence of the Regulatory Pathways for Advanced Therapy Medicinal Products	Room 6F	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#389	09	Transparency, Expanded Access Navigator, Right to Try: Helping Patients Get Access to Investigational Medicines?	Room 6B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#390	09	Clinical Trial Innovation: Pathways for Selecting and Developing Novel, Fit-for-Purpose, Technology-Derived Study Endpoints	Room 6E	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#391	09	Real World Evidence and Artificial Intelligence to Inform Post-Authorization Studies	Room 16AB	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#392	09	Breakthrough Therapy and PRIME Expedited Regulatory Pathways: Experience, Analysis, and Reflections from EMA, FDA, and Industry	Room 6D	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#393	10	Case Studies in Resolving Quality Issues	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#394	11	Demystifying Basic Statistical Concepts for Anyone Involved with Clinical Trials	Room 11B	WORKSHOP	75	Level: ●	ACPE, CME, IACET, RN
#395	11	Utilization and Evaluation of Innovative Approaches for Efficient Drug Development	Room 3	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#396	12	Challenges to Access: Bringing Payers to the Table	Room 14B	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#397	13	PowerUp: Stories of Career Transforming Moments	Room 14A	FORUM	75	Level: ●	IACET
		THURSDAY, JUNE 27					
8:00–9:00AM							
#401 RT	17	Round Table Discussion: Digital Risk Minimization: The "Next Generation" Risk Management Tools	Community Zone Sails Pavilion	SESSION	60	Level: ●	
8:30–9:00AM							
#402 CH	16	Manage Risks and Enhance Engagement Through Digital Approaches	Content Hub Sails Pavilion	WORKSHOP	30	Level: ■	

THURSDAY, JUNE 27, CONTINUED

Offering Number	Track Number	Title of Offering	Room Number	Type of Format	Length (Minutes)	Level of Difficulty	Continuing Education Credits
9:00–10:15AM							
#403	01	Successes and Challenges in Pharmacovigilance for Biologics and Biosimilars	Room 6D	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#404	02	Investigational Medicinal Products: eLabeling Initiative, Supply Forecasting Strategies, and Patient-Centric Technology for Medicine Adherence	Room 11A	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#405	02	eSource and the Sites: Have They Bonded?	Room 10	FORUM	75	Level: ■	ACPE, CME, IACET, RN
#406	03	Electronic Submissions Update	Room 1AB	SESSION	75	Level: ●	ACPE, CME, IACET, RN
#407	05	A Patient Engagement Wrap Up: Lessons Learned from DIA 2019 and Where Do We Go from Here	Room 5AB	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#408	06	FDA Botanicals	Room 2	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#409	08	Case Studies From FDA and MHRA: Good Clinical Practices	Room 6C	WORKSHOP	75	Level: ■	ACPE, CME, IACET, RN
#410	09	Advancing Benefit-Risk Assessment to Support FDA's Regulatory Review of Human Drugs and Biologics	Room 6F	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#411	10	Recent CMC Changes in Emerging Regulatory Agencies	Room 8	SESSION	75	Level: ■	ACPE, CME, IACET, RN
#412	14	Keeping Up with FDA and EMA Collaborations: Question Time	Room 6B	FORUM	75	Level: ■	ACPE, CME, IACET, RN
10:45AM–12:00PM							
#413	14	FDA Town Hall	Room 6B	FORUM	75	Level: ■	ACPE, CME, IACET, RN

NOTES

Student Poster Session

Monday, June 24 | 10:00AM–6:00PM | Posters will be displayed in the Exhibit Hall

This year's Student Poster Program features students from various academic institutions from all over the world who will showcase their latest research. Student Poster presenters will be judged for their poster and onsite presentation on Monday and recognized at the Student Poster Award Ceremony held on Tuesday, June 25, 2019.

Track 1 Clinical Safety and Pharmacovigilance

M-01 Efficacy and Safety of Tyrosine-Kinase Inhibitors as First-Line Treatment in Advanced NSCLC Patients: A Network Meta-Analysis
Ismaeel Yunusa, PharmD
Massachusetts College of Pharmacy and Health Sciences
ORAL PRESENTATION: 10:30AM

M-02 Impact of Patient Support Programs on the Performance of Adverse Drug Event (ADE) Signal Detection
Inyoung Lee, MS
University of Illinois at Chicago
ORAL PRESENTATION: 10:40AM

Track 2 Clinical Trials and Clinical Operations

M-03 Systematic Evaluation of Randomized Controlled Trials on Nutraceuticals Containing Chinese Medicines for Diabetes Management
Junnan Shi, MSc
University of Macau, China
ORAL PRESENTATION: 12:40PM

M-04 A Review on Methodological Quality of Traditional Chinese Medicine's Clinical Trials' Design in 2016
Zhi Cui, MSc
University of Macau, China

Track 3 Data and Data Standards

M-05 Data-Driven Impact of Depression, Anxiety and Antidepressant Treatment on Clinical Outcomes for Type 2 Diabetes Mellitus
Elham Heidari, PharmD, MS
University of Texas
ORAL PRESENTATION: 12:50PM

Track 6 Preclinical Development and Early-Phase Clinical Development

M-06 Evaluation of the Effect of Aegle Marmelos in a Murine Model of Trinitrobenzene Sulfonic acid (TNBS) Induced Coliti
Abhishek Mane, MD
Seth GS Medical College & KEM Hospital, India

M-07 Evaluation of the Anti-Anxiety Effect of Minocycline on Resident Intruder Model of PTSD in Golden Syrian Hamsters
Panini Patankar, MD
Seth GS Medical College & KEM Hospital, India
ORAL PRESENTATION: 1:00PM

M-08 Improvement of Intestinal Dysbiosis With Exogenous Prebiotic Metabolites Reduces Intestinal Bowel Inflammation
Millicent Yeboah-Awudzi, MSc
Louisiana State University
ORAL PRESENTATION: 1:10PM

Track 8 R&D Quality and Compliance

M-09 Disseminating Regulatory Self-Study Tools: A Study of the Efficacy and Promulgation of USC's Clinical Trial Quality Training
Advaita Chandramohan
University of Southern California

M-10 Study on Reducing Errors in Data Input to a Case Report Form
Hikari Ishii
Waseda University, Japan
ORAL PRESENTATION: 1:20PM

Track 9 Regulatory

M-11 Barriers and Facilitators to Using Current and Revised Australian Product Information: Perceptions of Healthcare Professionals
Hsiu-Chun Tony Yuan, PhD, MSc
The University of Sydney, Australia

M-12 Pharmacogenomics in Drug Labeling and Guidelines: An International Perspective
Christina Salama
Saint John's University
ORAL PRESENTATION: 1:30PM

M-13 Orphan Drug Demand Analysis in China: Empirical Forecasting Study of National Market from 2019 to 2028
Jiaqi Xu, MHA
University of Macau, China

M-14 Biopharmaceutical Innovation: An Evaluation of Clinical Phase and Market Entry Period in Novel Drug Products
Ruoying Sheng, MS
University of Southern California

Track 10 Regulatory CMC and Product Quality

M-15 Global Supply Chain Issues Affecting Biopharmaceutical Manufacturers: An Analysis of FDA Warning Letters from 2013–2018
Sean Kerns
University of Southern California
ORAL PRESENTATION: 1:40PM

Track 11 Statistics

M-16 Impact of Different Randomization Techniques on The Statistical Efficiency in Clinical Trials
Jackline Kemboi, MSc
African Institute for Mathematical Science (AIMS)
ORAL PRESENTATION: 1:50PM

M-17 Sample Size Planning in Bioequivalence Trials: A Systematic Review of Methodology
Junior Sinclair Awounvo
University of Bremen, Germany
ORAL PRESENTATION: 2:00PM

Track 12 Value and Access

M-18 Generic Medications: A Comparison on Drug Prices and a Cross Sectional Survey on Knowledge, Perception, and Use
Cezar Manansala, RPh
Centro Escolar University, Kenya, Philippines
ORAL PRESENTATION: 5:10PM

M-19 An Evaluation of Comments to the CMS Proposed Drug Price Transparency in Direct-to-Consumer Television Advertising Rule
Achint Raince
Ernest Mario School of Pharmacy
ORAL PRESENTATION: 5:20PM

Professional Poster Session 1

Tuesday, June 25 | 9:00AM–4:00PM | Posters will be displayed in the Exhibit Hall

Life Sciences Professionals from all fields related to the mission of DIA will participate in this year's Professional Poster Program. There will also be oral presentations where select poster authors will deliver an overview of their work. Presentations will be held in the Poster Area located in the Exhibit Hall.

Track 1 Clinical Safety and Pharmacovigilance

T-01 Use of Adverse Event Data to Develop an Artificial Intelligence Application for Assessing Seriousness
Niki Tetarenko
Celgene Corporation
ORAL PRESENTATION: 12:00PM

T-02 Using Innovative Automation to Author Development Safety Update Reports and Enhance Cost Effectiveness
Nipa Parikh, PharmD
Otsuka Pharmaceutical Development and Commercialization Inc.
ORAL PRESENTATION: 12:10PM

T-03 Development of an AI Approach for Identifying Adverse Events
Sujan Perera
IBM Watson Health

T-04 Effect of Drug Safety Communications on Adverse Event Reporting in Multiple Sclerosis DMTs Using the FAERS Database 2000–2017
Hunter Davis, PharmD
Rutgers University

T-05 Opioids Misuse and Abuse: Safety Communications Across Regulatory Agencies
Nidhi Patel, MD
APCER Life Sciences

T-06 Febuxostat Versus Allopurinol in Patients with Gout: A Real World Comparison
Manfred Stapff, DrMed
Trinetx

T-07 FDA Developed Tool for Adverse Event Data Signal Detection in Clinical Safety Analysis
Xin (Joy) Li, MS, MSc
FDA

T-08 Pan American Countries: Harmonization of Drug Safety Risk Management Planning and Communication
Harshil Patel, MPharm
APCER Lifesciences

T-09 Structure and Target Based Statistical Tools for Safety Analysis
Samir Lababidi, PhD
FDA

Track 2 Clinical Trials and Clinical Operations

T-10 A Seamless Phase 2/3 Adaptive Design for Clinical Trials with a Continuous Endpoint in Asia
Lien-Cheng Chang, PhD
TFDA, Chinese Taipei
ORAL PRESENTATION: 12:20PM

T-11 Subject Training is Needed For Key Terminology in Gastrointestinal Clinical Trials
Elisa Conrad, MA
ERT
ORAL PRESENTATION: 12:30PM

T-12 Design and Analysis of Biosimilarity Based on Interval Estimations
Chin-Fu Hsiao, PhD
National Health Research Institutes, Chinese Taipei

T-13 Academia's Challenges for Implementing an Investigator-initiated Clinical Trial Aimed at Developing A New Biological Drug
Tetsuya Kusakabe, PhD, MPH
Osaka City University, Graduate School of Medicine, Japan

T-14 Quality Management Using Six Sigma Tools For Clinical Research Sites
Toshiko Ishibashi, PhD, RN
Ono Pharmaceutical Co., Ltd., Japan

T-15 Natural History Studies: An Assessment of Current Trends in Design and Disease Research
Juliane Mills, MPH, MSc, MT
PRA Health Sciences

T-16 Generating Synthetic Control Patients Using Machine Learning for Alzheimer's Disease Clinical Trials
Yannick Pouliot
Unlearn.AI

T-17 Streamlining Clinical Trials and Patient Experience Using Blockchain and Data Science Technologies
Mohit Juneja
Lyfescience

T-18 Effectiveness of Patient Portals in Clinical Trial Recruitment
Lauren Holmes, PharmD, MBA, MPH
Rutgers University/Ernest Mario School of Pharmacy

Track 3 Data and Data Standards

T-19 Metadata Framework for Sharing and Developing Code Repository for Standard Analyses
Hanming Tu, MSc
Frontage Laboratories, Inc.

T-20 Understanding Heterogeneity in Rheumatoid Arthritis Disease Progression by Using Word Embedding: An Electronic Health Record
Ye Jin Eun, PhD
Janssen

Track 4 Medical Affairs and Scientific Communication

T-21 Characteristics of Expanded Access Programs Inclusive of Children in the United States
Jit Sheth, PharmD
Alnylam Pharmaceuticals and Northeastern University
ORAL PRESENTATION: 12:40PM

T-22 Writing a Platform Master Protocol Using the Common Protocol Template
Anthony Davidson
Eli Lilly and Company

T-23 Adherence to Standardized INCI Labeling Practices in Twenty One Natural or Organic Global Consumer Baby Products
Christopher Varghese
Rutgers University

Track 5 Patient Engagement

T-24 Should I Stay or Should I Go? A Comparison of Primary and Secondary Research on Clinical Trial Retention
Christina Curry, MSc
Genentech

T-25 ClinLine.ru: The New Integrated Infomedia Russian Platform for all Parties Involved in Clinical Trials
Oksana Karavaeva, MD
IPHARMA LLC, Russian Federation

T-26 Demystifying the Patient's Experience: Use of Patient Journey Studies to Gather Valuable Qualitative Insight into the Patient
Caroline Seo
Pharmerit International

T-27 Measuring the Patient Experience: Learnings from Real World Implementation to Improve Data Collection and Patient Engagement
Renee Willmon, MSc
Self Care Catalysts

Track 6 Preclinical Development and Early-Phase Clinical Development

T-28 The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety
Andre Ghetti
AnaBios

Track 7 Project Management and Strategic Planning

T-29 Python Optimization Tools for Remote Server Work
Masaki Mihaila, MS
Pfizer

Track 8 R&D Quality and Compliance

T-30 An FDA Analysis of Inspected Entities After Receiving Official Action Indicated Letters for GCP Violations
Miah Jung, PharmD, MS, RAC
FDA
ORAL PRESENTATION: 12:50pm

Track 9 Regulatory

T-31 Characterizing the Clinical Impact of Immunogenicity in Prescription Drug Labeling
Daphne Guinn, PhD
FDA
ORAL PRESENTATION: 1:00PM

T-32 Baseline Adjustment in Concentration-QTc Modeling: Impact on Assay Sensitivity
Dalong Huang, PhD
FDA

T-33 Compliance with FDA's Postmarketing Adverse Drug Experience Laws and Regulations
Namita Kothary, PharmD, RAC
FDA

T-34 Otsuka's Experience on eSubmission of Promotional Labeling and Advertising Materials via the eCTD FDA Gateway
Joanne Hathaway
Otsuka Pharmaceutical Commercialization & Development

T-35 Considerations in Using Biomarkers as Efficacy Endpoints: The Review of Clinical Trials of Orphan Drugs Approved in Japan
Tomoko Nakai
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

T-36 The South African Regulatory Environment: Challenges and Opportunities for a Reformed Regulatory Review Process
Andrea Keyter, MS
South African Health Products Regulatory Authority, South Africa

T-37 Regulatory Review Reliance Models: What are the Barriers and Enablers to the Successful use of These Models for Medicines?
Neil McAuslane, PhD, MSc
Centre For Innovation In Regulatory Science (CIRS), United Kingdom

T-38 Agencies Strategies to Enhance the Review Efficiency of IND for Human Cell Therapy Products in Taiwan
Meng Ting Tsai
Center For Drug Evaluation (CDE), Chinese Taipei

Track 10 Regulatory CMC and Product Quality

T-39 Use of Social Media in Clinical Trials: A Survey of IRB Chairs
Susan Pusek, MHS, MS
University of North Carolina Chapel Hill
ORAL PRESENTATION: 1:10PM

T-40 Comprehensive QOS and Established Conditions: Creating a Path for Flexible Regulatory Approaches to Post Approval CMC Changes
Connie Langer, MSc
Pfizer Inc.

Track 11 Statistics

T-41 Using Causal Inference Modelling to Predict Unbiased Treatment Response for Managed Care Organizations and Drug Manufacturers
Denise Meade
IBM Watson Health
ORAL PRESENTATION: 1:20PM

T-42 Sample Size Re-Estimation in Action: Design Consideration, Charter Development, and Implementation of Analyses in a Trial with Adaptive Components
Adam Hamm, PhD
Cytel

T-43 Combining Tabular Data with Visual Display to Enhance Interpretation of Clinical Trial Data
Teresa Curto, MPH
Cytel

Track 12 Value and Access

T-44 A Real World Budget Impact Analysis of Apremilast or Biologic Treatment in Biologic-Naive Patients With Psoriasis
Brian Ung
Celgene Corporate
ORAL PRESENTATION: 1:30PM

T-45 A Decision Analytic Benefit-Risk Assessment Framework to Support Portfolio Prioritization Decisions
George Quartey, PhD, MSc
Genentech, A Member of the Roche Group

T-46 An Analysis of Healthcare Plan CART Cell Coverage Criteria for Medicaid Beneficiaries
Landon Shupe
Rutgers University/Ernest Mario School of Pharmacy

T-47 Assessment of the Quality of Pharmacoeconomic Reports in Taiwan
Shu-Mei Hsu, MHS
Center For Drug Evaluation, Chinese Taipei

Professional Poster Session 2

Wednesday, June 26 | 9:00AM–4:00PM | Posters will be displayed in the Exhibit Hall

Track 1 Clinical Safety and Pharmacovigilance

W-01 A Real World Investigation of Finasteride and the Risk of Prostate Cancer
Stephan Palm
Trinetx
ORAL PRESENTATION: 12:00PM

W-02 Improving Cost Effectiveness by Automating the Aggregate Report Scheduling & Distribution
Jennifer Cichone, MS
Otsuka Pharmaceutical Development and Commercialization Inc.

W-03 Development and Operationalization of a Method for Determining Adverse Drug Reactions from a Clinical Study Safety Data Set
Fred Jerva, PharmD, PhD, RPh
AstraZeneca

W-04 Reducing the Cost of Systematic Risk Assessments of Medical Products by Using a Modular Learning Risk Repository System
Stephen Sun, MD, MPH
Syneos Health

W-05 Design Thinking in Pharmacovigilance
Ruta Mockute, MS
Celgene Corporation

W-06 Healthcare Professionals' Knowledge and Adherence to the National Guidelines for Management of Pediatric Asthma
Hamad Alyami, PharmD
Najran University, Saudia Arabia

Track 2 Clinical Trials and Clinical Operations

W-07 A General Framework for Utilizing Real World Data with Clinical Trials
Xiaoyun (Nicole) Li, PhD
Merck & Co., Inc.
ORAL PRESENTATION: 12:10PM

W-08 Using a Continuous Learning Risk Repository System to Drive Efficiencies in Identification of Clinical Protocol Risk Patterns
Thaddeus Urban
Syneos Health
ORAL PRESENTATION: 12:20PM

W-09 Exploring Accuracy of Abdominal Pain Reporting with and Without Specific Instruction
Alyssa Peechatka, PhD, MA
ERT
ORAL PRESENTATION: 12:30PM

W-10 The Rise of Electronic Patient-Recorded Outcomes in Oncology (ePRO)
Bhavish Lekh, MS
Synteract

W-11 Advantages of a Peer Mentoring Program in Clinical Operations
Wen Liu, MPH
Merck & Co., Inc.

W-12 Relationship Between Efficacy and Discontinuation Rates in Clinical Trials of Moderate to Severe Crohn's Disease
Austin Marrazza
Pennsylvania State University

W-13 Best Practices for the Electronic Migration and Implementation of Clinician-Reported Outcomes Assessments in Clinical Trials
Heather Romero, PhD
MedAvante-ProPhase

W-14 Common Symptom Terminology is Frequently Misunderstood
Rinah Yamamoto, PhD
ERT

W-15 Patients are Uncomfortable and Unable to be as Honest When Discussing Depression Symptoms During Recorded Interviews
Nadeeka Dias, PhD
ERT

W-16 Patient Understanding of Rescue Medication: Value of Patient Training on Reporting Rescue Medication Use
Kelly Dumais, PhD
ERT

W-17 Subject Training Substantially Improves Understanding of Key Terminology in Gastrointestinal Clinical Trials
Michael Sadler, PhD
ERT

Track 4 Medical Affairs and Scientific Communication

W-18 Putting the Patient at the Center of Medical Information: A Patient-Centric Standard Response Letter Initiative
Chelsea Aiudi, PharmD
TESARO

W-19 Defining Excellence and Best Practices in Medical Information for AMCP Dossier Creation and Compendia Review
Sally Stansbury, PharmD
Takeda

Track 5 Patient Engagement

W-20 Building Patient Trust: Our Journey to "Radical" Transparency in Compassionate Use
Christine Maccracken, BSN, MEd
Janssen

W-21 Meaningful Patient Engagement: From Vision to Reality in the Rare Disease Space
Linda Brennan, MPH
Cystic Fibrosis Foundation

W-22 Tell Me More: Exploring Patient Perspective on the Benefits and Disadvantages of Drugs During Clinical Trials
Alexis Miller, JD
Sanofi

W-23 Evaluation of Publicly Available Patient Medical Education Videos on Breast Cancer
Min Kyung (Amy) Kim, PharmD
Rutgers University/Ernest Mario School of Pharmacy

W-24 Awareness of Polycystic Ovarian Syndrome in Pakistan Through Patient Engagement
Sabahat Arif, PharmD
Kellyocg, Pakistan

W-25 Bring your own Wearable (BYOW): Considerations for Clinical Research
Marie McCarthy, MSc
ICON plc

Track 7 Project Management and Strategic Planning

W-26 Educational, Gender, and Age Diversity in the Corporate Leadership of Fortune 500 Pharmaceutical Companies
Michael Severo, PharmD
Rutgers University/Ernest Mario School of Pharmacy
ORAL PRESENTATION: 12:40PM

W-27 Identifying Gaps in Competitive Intelligence and Business Development Strategy: Opportunities in the PD-1/PD-L1 Landscape
Matthew Eberle, MLIS
BizInt Solutions, Inc.

Track 8 R&D Quality and Compliance

W-28 Main Difference Between Quality Tolerance Limits and Key Risk Indicators
Artem Andrianov, PhD, MBA
Cyntegrity Germany GmbH

Track 9 Regulatory

W-29 Single Pivotal Trial Characteristics Supporting Regulatory Approval of Non-Orphan, Non-Oncology Drugs in EU and US, 2012–16
Vivien Jagalski, PhD
Lundbeck
ORAL PRESENTATION: 12:50PM

W-30 Analysis of Products Awarded the Rare Pediatric Disease Priority Review Voucher and the Impact of Advancing Hope Act
Caitlin Skenyon, PharmD
Northeastern University
ORAL PRESENTATION: 1:00PM

W-31 A Retrospective Analysis of Bridging Study Evaluation in Taiwan During 2011-2018: Focus on Multi-Regional Clinical Trials
Hui-Chun Hong, MPharm
TFDA/Center for Drug Evaluation, Chinese Taipei

W-32 Evaluation of Branded Prescription Drug Facebook Messenger Responses to Consumer Requests for Product Information
Alexandra Didonato, PharmD
St. John's University/Allergan

W-33 An Analysis of Regulatory Promotion Material Enforcement Actions for 2018
Amandeep Kaur, PharmD
Rutgers University/Ernest Mario School of Pharmacy

W-34 FDA Advisory Committee Meetings: A Five Year Retrospective Analysis
Lauren Aronin, PharmD
St. John's University

W-35 Regulatory Flexibility in the Review of Biologics for Rare Diseases
Julienne Vaillancourt, MPH, RPh
FDA

W-36 Prescribers' Perception of the PLLR when Making Clinical Decisions for Patients with Chronic Respiratory Conditions
Victoria Quang, PharmD
Rutgers University/Ernest Mario School of Pharmacy

Track 10 Regulatory CMC and Product Quality

W-37 Evaluation of ICH Q12 Implementation Readiness
Lois Castellano
Merck & Co., Inc.

Track 11 Statistics

W-38 Defining the Methodology for Interim Analysis and Data Peek for Power in Late-Phase Research and Pragmatic Clinical Trials
John Uebersax
Kelly OCG
ORAL PRESENTATION: 1:10PM

W-39 Using Synthetic Control Databases to Accelerate Indication-Specific Safety and Efficacy Evidence
Colin Neate, MSc
Roche
ORAL PRESENTATION: 1:20PM

W-40 Practice of Interactive Visual Analysis of Clinical Trials for Different Roles
Gaoyang Li, MS
Bayer

W-41 Targeted Review of Adverse Events of Special Interest (AESI)
Wei Wang, MD, MPH
Eli Lilly and Company

W-42 Performance of Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies
Kun Nie, PhD
Clindata Insight Inc

Track 12 Value and Access

W-43 Calcitonin Gene Receptor Peptide (CGR) Antibodies: Real World Evidence on Acute Migraine Treatment
Ria Westergaard, PharmD
Express Scripts
ORAL PRESENTATION: 1:30PM

W-44 New Methods for Analyzing Clinical and Cost Outcomes in Regulatory Affairs With Interactive Visual Analytics
Sharon Hensley Alford, PhD, MPH
IBM Watson Health

W-45 The impact of US FDA Breakthrough Designation (BTD) on Global Access to Innovative Medicines
Magdalena Bujar, PhD, MSc
Centre For Innovation In Regulatory Science (CIRS), United Kingdom

AWARD WINNERS

DIA Inspire Awards recognize significant individuals or group accomplishments in the discovery, development, or lifecycle management of biopharmaceutical, device, or related therapeutic healthcare products, and/or exceptional volunteer contributions to advancing DIA's mission and vision.

GLOBAL INSPIRE AWARDS

These are awarded to an individual, group, or organization for significant and innovative contribution to advancing global health, evaluated and selected by the DIA Fellows, and approved by DIA Board of Directors.

President's Award for Outstanding Contribution to Global Health
The Global Fund

The Global Fund is a 21st-century partnership organization designed to accelerate the end of AIDS, tuberculosis, and malaria as epidemics. Founded in 2002, the Global Fund is a partnership between governments, civil society, the private sector, and people affected by the diseases. The Global Fund raises and invests nearly four billion dollars a year to support programs run by local experts in countries and communities most in need. Working together, they have saved millions of lives and provided prevention, treatment, and care services to hundreds of millions of people, helping to revitalize entire communities, strengthen local health systems, and improve economies.

Global Connector
Deborah Chee, MD, PhD
President
Korea National Enterprise for Clinical Trials, Korea

Excellence in Service
Jingsong Wang, MD, PhD
Founder, Chairman & CEO
Harbour BioMed

Community Engagement
Robert Paarlberg, MS
Principal
Paarlberg & Associates, LLC

Community Engagement
Francine Lane, MBA
Vice President, Global Transparency
TrialScope

DIA AUTHOR(S) OF THE YEAR AWARD

The DIA Author(s) of the Year Award is an annual award presented to the author(s) of an article published in *Therapeutic Innovation & Regulatory Science* (TIRS), DIA's official peer-reviewed scientific journal, that has made a significant contribution to advancing healthcare product development. The article and its author(s) are chosen based on two criteria: the total number of web accesses for the article on the journal (now indexed in PubMed) website, and the total number of full-text downloads the article has had during the past year.

Advancing a Framework for Regulatory Use of Real World Evidence: When Real is Reliable
Author: Nancy A. Dreyer, PhD, MPH, Chief Scientific Officer, Real World and Analytic Solutions, IQVIA
Volume 52, Issue 3: 362–368

INSPIRE AWARDS: AMERICAS

President's Award for Outstanding Contribution to Global Health
TransCelerate

TransCelerate aspires for a future state where research and development is faster, more efficient, and harnesses all the available information. They create pragmatic solutions such as templates, guidance, model frameworks, and systems that address barriers and issues that are negatively impacting the ability of the biopharmaceutical industry to bring medicines to patients that need them. These solutions are developed collaboratively and can be voluntarily adopted by stakeholders in the clinical research ecosystem.

Excellence in Service
Kim Quaintance-Lunn
Vice President and Head, Regulatory Policy, North American Regulatory Affairs
Bayer

Excellence in Service
Jonathan Andrus, MS
Chief Business Officer
Clinical Ink, Inc.

Excellence in Service
Linda Bowen, MS
RAC (US, EU, CAN), FRAPS
Head of Regulatory Policy and Intelligence
Seattle Genetics

FELLOWS OF DIA CLASS OF 2019

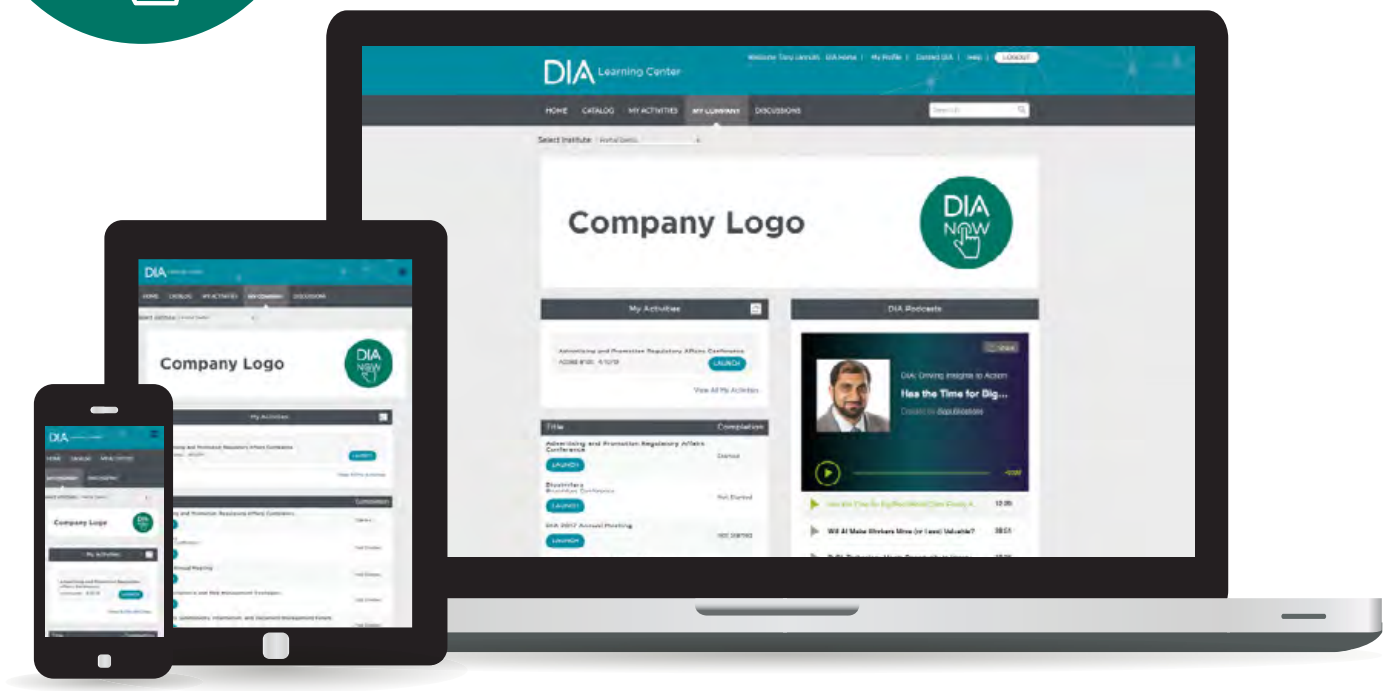
Fellow Chair of DIA
John A. Roberts, MBA
President and CEO
Cancer Genetics, Inc

Fellow of DIA
Gerald Dal Pan, MD
Director, Office of Surveillance and Epidemiology, CDER
FDA

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

Fellow of DIA
Birka Lehmann, MD
Senior Expert Drug Regulatory Affairs
Germany

Always-On Insights



- On-demand access to global DIA content
- Latest trends and newest developments from every event
- Strategic intelligence at your fingertips
- Accessible anytime, anywhere, on any device
- Upgrade your team performance with curated content

Enhance Team Competency

Shorten Approval Timelines

Accelerate Patient Access

Optimize Revenues

Ask to see a demo and get a special giveaway at DIA Booth #1531

DIAglobal.org

DIA

SPEAKERS

SPEAKERS

SPEAKER INDEX BY NAME

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

The content noted on this page was made available to DIA as of April 29, 2019.

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

Refer to the Meeting Schedule beginning on page 21 for more detailed Session information.

The content noted on this page was made available to DIA as of April 29, 2019.

UNIVERSAL ACTIVITY NUMBERS

Below are the pharmacy designated Universal Activity Numbers (UANs) and type of activity that is applicable for each of the following program offerings:

MONDAY, JUNE 24

Number	Session Title	Assigned UAN	Type of Activity
100	DIA 2019 Global Annual Meeting Keynote Address and Opening DIAmond Session: Who Owns My Health Data: Patients, Data, and the Future of R&D	0286-0000-19-730-L04-P	Knowledge
105	Addressing Heterogeneity of Real World Evidence in Drug Safety	0286-0000-19-522-L04-P	Knowledge
106	Moving Forward in EU Pharmacovigilance	0286-0000-19-523-L04-P	Knowledge
107	Emerging Technologies in Clinical Research	0286-0000-19-534-L04-P	Knowledge
108	Innovation in Enrollment, Recruitment, and Retention	0286-0000-19-535-L04-P	Knowledge
109	When Disaster Strikes: Developing a Proactive Plan to Address Challenges Brought on by Large Scale Natural Disasters	0286-0000-19-536-L04-P	Knowledge
110	Automation with Intelligence: Transformation From Human Resource to Artificial Intelligence in Risk Management	0286-0000-19-524-L04-P	Knowledge
111	PhactMI Benchmarking Survey Highlights: How are the Twenty Seven Member Companies Executing on Medical Information Initiatives	0286-0000-19-525-L04-P	Knowledge
112	Collecting Better Patient Experience Data: Lessons Learned from Patient Organizations	0286-0000-19-526-L04-P	Knowledge
113	Artificial Intelligence in Drug Discovery and Development: Emerging Technologies and Applications	0286-0000-19-527-L04-P	Knowledge
114	Patient Perspective Diversity: Taking Cultural Differences in Patient Views Into Drug Development in US, EU, and Japan	0286-0000-19-528-L04-P	Knowledge
115	Quality Management Post-Quality Management System Implementation In The Wake of ICH E6 (R2)	0286-0000-19-529-L04-P	Knowledge
116	Harnessing Power of Advanced Technologies for Digital Transformation in Regulatory Affairs	0286-0000-19-530-L04-P	Knowledge
117	International Regulatory Convergence	0286-0000-19-537-L04-P	Knowledge
118	Statistical Considerations for Trials Using Surrogate Endpoints for Accelerated Approval	0286-0000-19-531-L04-P	Application
119	Making Value-Based Contracting Stick	0286-0000-19-532-L04-P	Knowledge
120	FDA Payer Communication Guidance, Twenty Years in the Making: Now What?	0286-0000-19-533-L04-P	Knowledge
131	On the Soapbox: Designing Babies - Medical, Ethical, and Social Questions	0286-0000-19-733-L04-P	Knowledge
135	Using Real World Data to Develop a Safety Monitoring Program and Ensure Pre- and Post-Market Continuity	0286-0000-19-538-L04-P	Knowledge
136	Interpretation of New Pharmacovigilance Regulations: Key Insights	0286-0000-19-539-L04-P	Knowledge
137	Emerging Technology to Improve Sponsor-Site Interactions	0286-0000-19-547-L04-P	Knowledge
138	Blockchain in Clinical Trials Demo: Truth or Dare	0286-0000-19-548-L04-P	Knowledge
139	Developing Standard Core Clinical Outcome Assessments and Endpoints: FDA Perspective and Plans	0286-0000-19-549-L04-P	Knowledge
140	Use of Real World Data in Clinical Trials: Abstracting Endpoints from Encounters	0286-0000-19-540-L04-P	Knowledge
141	Knowledge Management and Information Sharing to Support Business Continuity	0286-0000-19-541-L04-P	Knowledge
142	Show Me the Money! Patient and Caregiver Roles and Compensation in Research, Development, and Innovation	0286-0000-19-542-L04-P	Knowledge
143	Opportunities and Challenges with First-In-Human Multiple Expansion Cohort Designs in Oncology	0286-0000-19-543-L04-P	Knowledge
144	Ready or Not: Business Continuity Planning	0286-0000-19-544-L04-P	Knowledge
145	Examining Essential Elements of Vendor Governance and Comparing Perspectives of Large and Emerging Biopharma	0286-0000-19-545-L04-P	Knowledge
146	Communications with Regulators Beyond Formal Meetings	0286-0000-19-546-L04-P	Knowledge
147	Update from Health Canada: The Health Protection Branch	0286-0000-19-552-L04-P	Knowledge
148	Hot Topics in Digital Health: How is FDA's Approach Evolving, and What Do Industry and Patients Need to Know?	0286-0000-19-553-L04-P	Knowledge
149	Hype Versus Reality: Artificial Intelligence and Real World Evidence	0286-0000-19-554-L04-P	Knowledge
150	TFDA Town Hall: Focus on Regenerative Medicine	0286-0000-19-734-L04-P	Knowledge
151	Update on ICH Quality Topics	0286-0000-19-551-L04-P	Knowledge
152	Making Data Meaningful: Using Data Visualization to Drive Efficiency in Safety Analysis	0286-0000-19-550-L04-P	Knowledge
154	Current Initiatives on Patient Involvement in the Medicinal Product Lifecycle: CIOMS XI	0286-0000-19-555-L04-P	Knowledge

MONDAY, JUNE 24

Number	Session Title	Assigned UAN	Type of Activity
155	Incorporating Systems-Theory and Human Factors into the Investigations of Serious Harm in Clinical Research	0286-0000-19-570-L04-P	Knowledge
156	Clinical Research in Emerging Regions	0286-0000-19-566-L04-P	Knowledge
157	A Large Academic Medical Center's Perspective on Using Precision Medicine to Find Patient Disease Subgroups at Scale	0286-0000-19-567-L04-P	Knowledge
158	Enhancing Patient-Focused Outcome Assessment in Medical Product Development	0286-0000-19-568-L04-P	Knowledge
159	Understanding the Data Journey In Virtual Trials	0286-0000-19-556-L04-P	Knowledge
160	New Communication Channels for Medical Information	0286-0000-19-557-L04-P	Application
161	Making Trials Work for Special Populations	0286-0000-19-558-L04-P	Knowledge
162	Precision Medicines in Clinical Trials: Understanding and Overcoming Barriers to Adoption	0286-0000-19-559-L04-P	Knowledge
163	Strategic Integration: Is Anyone Getting it Right?	0286-0000-19-560-L04-P	Knowledge
164	Compliance: The Importance of Periodic Screenings to Ensure Good Inspection Health	0286-0000-19-561-L04-P	Application
165	Drug Development Tools in a Digital Era	0286-0000-19-562-L04-P	Knowledge
166	National Medical Products Administration (NMPA) Town Hall	0286-0000-19-563-L04-P	Knowledge
167	Strategic Priorities of the International Coalition of Medicines Regulatory Authorities in an Increasingly Globalized Industry	0286-0000-19-571-L04-P	Knowledge
168	Regulating Innovation in Chemistry, Manufacturing, and Controls: Challenges and Opportunities	0286-0000-19-569-L04-P	Knowledge
169	How Statistics Can Help Improve Data Quality: ICH E6 R2	0286-0000-19-564-L04-P	Knowledge
170	Making Early Access for Patients Happen	0286-0000-19-565-L04-P	Application

TUESDAY, JUNE 25

Number	Session Title	Assigned UAN	Type of Activity
201	To Err is Human: Progress and Challenges in the Prevention of Medication Errors	0286-0000-19-572-L04-P	Knowledge
202	Updates and Lessons Learned from Novel Approaches to Pharmacovigilance Collaboration	0286-0000-19-573-L04-P	Knowledge
203	eConsent Done Right	0286-0000-19-585-L04-P	Knowledge
204	Protocol Developments of the Future	0286-0000-19-586-L04-P	Knowledge
205	Driving Enrollment with a Patient-Centric Focus to Artificial Intelligence	0286-0000-19-587-L04-P	Knowledge
206	Single Source of Truth, Integrations, or IoT (Internet of Things): Exploring Ways to Improve Connectedness of Clinical Data	0286-0000-19-574-L04-P	Knowledge
207	Leveraging Artificial Intelligence and Natural Language Processing in Medical Writing	0286-0000-19-575-L04-P	Knowledge
208	Patient Focus as Part of the Regulatory Affairs DNA: Opportunities and Challenges	0286-0000-19-576-L04-P	Knowledge
209	Emerging Issues in CRISPR and Gene Editing Symposium	0286-0000-19-577-L04-P	Knowledge
210	Increasing Personal Resilience To Manage Change	0286-0000-19-578-L04-P	Application
211	Pharmacovigilance Reporting and Quality	0286-0000-19-579-L04-P	Knowledge
212	Translating Academic Research into Product Development: Integrating GXPs into the Process (Part 1 of 4)	0286-0000-19-580-L04-P	Knowledge
213	Facilitating Access: Patient Perspectives on a Streamlined Development Approach for Treatments for Severely-Debilitating or Life-Threatening Diseases	0286-0000-19-581-L04-P	Knowledge
214	Global Pediatric Policy Update: Are You Ready to Implement FDARA Section 504?	0286-0000-19-582-L04-P	Knowledge
215	Conducting Clinical Trials with GMOs: Strategies to Overcome Regulatory, Operational, and Patient Enrollment Challenges	0286-0000-19-589-L04-P	Application
216	Identifying the Reference Listed Drug for ANDA Submission, Overview of FDA's Orange Book, and Exclusivities for NDAs and ANDAs	0286-0000-19-590-L04-P	Knowledge
217	Quality Considerations for Complex Generics	0286-0000-19-588-L04-P	Knowledge
218	Real World Data to Real World Evidence	0286-0000-19-583-L04-P	Knowledge
219	Personalized Healthcare and Clinical Outcomes: How Real World Endpoints Can Improve Approval and Access to Medicine?	0286-0000-19-584-L04-P	Knowledge
228	Emerging Safety Challenges in New Oncology Treatments	0286-0000-19-591-L04-P	Knowledge
229	An Industry Collaboration on Pharmacovigilance Analytics	0286-0000-19-592-L04-P	Knowledge

The content noted on this page was made available to DIA as of April 29, 2019.

TUESDAY, JUNE 25

Number	Session Title	Assigned UAN	Type of Activity
230	Assessing Opportunities to Improve Outsourcing Oversight and the Vendor Qualification Assessment Process	0286-0000-19-604-L04-P	Knowledge
231	Outcomes, Endpoints, and Methods Supporting Oncology and Alzheimer Therapies	0286-0000-19-605-L04-P	Knowledge
232	Retooling Risk Assessment to Align with ICH-E6(R2) and Connect to Centralized Monitoring and Risk-Based Monitoring	0286-0000-19-606-L04-P	Knowledge
233	Creating Clarity: Changes at CDISC to Make Standards Implementation Easier for all Stakeholders	0286-0000-19-593-L04-P	Knowledge
234	Quality and Compliance Management in Medical Information/Medical Affairs	0286-0000-19-594-L04-P	Knowledge
235	Walking the Talk: Using Home Nursing as a Patient-Centric Service in Clinical Trials - From Multiple Perspectives	0286-0000-19-595-L04-P	Knowledge
236	Our Doors are Open! Pathways and Programs for Patient Stakeholders to Engage with FDA	0286-0000-19-608-L04-P	Knowledge
237	The Rare Disease Experience in Clinical Trials	0286-0000-19-596-L04-P	Knowledge
238	Build and Leverage Your Networks to Influence Stakeholders	0286-0000-19-597-L04-P	Application
239	Improving Clinical Trial Risk Management: How To Leverage the IRB's Designed Purpose	0286-0000-19-598-L04-P	Application
240	Harmonizing Regulatory Science Through the International Council for Harmonization (ICH)	0286-0000-19-599-L04-P	Knowledge
241	PMDA Town Hall	0286-0000-19-600-L04-P	Knowledge
242	Use of Real World Evidence to Support Regulatory Decision-Making: First-Year Findings From the RCT-DUPLICATE Project	0286-0000-19-601-L04-P	Knowledge
243	The Future of Combination Products in the EU	0286-0000-19-609-L04-P	Knowledge
244	Where Quality Meets Safety and Efficacy: A Conversation with CMC Experts	0286-0000-19-607-L04-P	Knowledge
245	Artificial Intelligence Enhanced Data Analytics for Clinical Trials	0286-0000-19-602-L04-P	Knowledge
246	How Employers are Reinventing Healthcare and What it Means for Research Participation and Evidence	0286-0000-19-603-L04-P	Knowledge
255	Pharma and Regulatory Perspectives on Machine Learning Applications in Pharmacovigilance	0286-0000-19-610-L04-P	Knowledge
256	Wearables and Patient Technologies Utilized in Clinical Trials	0286-0000-19-623-L04-P	Knowledge
257	Clinical Trial Diversity: Moving from Admiring the Problem to Solving it	0286-0000-19-624-L04-P	Knowledge
258	Build-a-Bot Workshop: Design and Build a Conversational Agent that Speaks for You	0286-0000-19-625-L04-P	Application
259	FDA Data Standards Update	0286-0000-19-611-L04-P	Knowledge
260	Clinical Trial Disclosure and Transparency: Intersection of Regulators, Industry, and Patients	0286-0000-19-612-L04-P	Knowledge
261	Patient Experience Data: How Could this Data Enhance Decision-Making at Different Stages of Medical Product Development?	0286-0000-19-613-L04-P	Knowledge
262	Measuring the Impact of Patient Engagement Activities in Medicines R&D: A Way to Sustain the Cultural Change?	0286-0000-19-731-L04-P	Knowledge
263	Drug Development for Ocular Disease, New Therapies, Regulations, and Patient Perspectives	0286-0000-19-614-L04-P	Knowledge
264	Immuno-Oncology Product Development: Overcoming Scientific and Regulatory Challenges	0286-0000-19-615-L04-P	Application
265	Decision Leadership: How Using a Structured Approach to Decision Making Can Help You Lead Teams Better	0286-0000-19-616-L04-P	Application
266	Electronic Systems: Are Yours Fit for Purpose?	0286-0000-19-617-L04-P	Knowledge
267	Translating Academic Research Into Product Development: The What and Why of cGMP in Translational Science (Part 2 of 4)	0286-0000-19-618-L04-P	Knowledge
268	Current Status of FDA Framework for the Evaluation of Real World Evidence	0286-0000-19-619-L04-P	Knowledge
269	Driving Complex Generics to Approval: What are the Keys to Success	0286-0000-19-620-L04-P	Knowledge
270	Where Quality Meets Safety and Efficacy: An Interactive Experience	0286-0000-19-626-L04-P	Knowledge
271	Master Protocols: Applications in Oncology	0286-0000-19-621-L04-P	Application
272	Aligning Facilitated Regulatory and Access Pathways: Observations from the North American Experience	0286-0000-19-622-L04-P	Knowledge
281	Structured Evidence Planning, Production, and Evaluation (SEPPE): A "Quality-Based" Framework for Drug Development	0286-0000-19-627-L04-P	Knowledge
282	The Elephant in the Room: Meaningful Communication of Near Synonyms as Suspected Adverse Reactions	0286-0000-19-628-L04-P	Knowledge

TUESDAY, JUNE 25

Number	Session Title	Assigned UAN	Type of Activity
283	Let's Talk Risk-Based Monitoring	0286-0000-19-639-L04-P	Knowledge
284	Virtual Clinical Trials	0286-0000-19-640-L04-P	Knowledge
285	Using Mobile Sensors in Clinical Trials and Evidentiary Considerations for Electronic Submissions	0286-0000-19-641-L04-P	Knowledge
286	The Machines are Here! Learn About Real Uses of Machine Learning and Artificial Intelligence in Pharma	0286-0000-19-629-L04-P	Knowledge
287	A Case Study in Structuring Clinical Content and Structured Content Management (SCM)	0286-0000-19-630-L04-P	Knowledge
288	The Changing Landscape of Medical Affairs: Are We Prepared For 2020?	0286-0000-19-644-L04-P	Knowledge
289	Impact of Patient Engagement on the Biopharmaceutical Industry's Business and Organization	0286-0000-19-631-L04-P	Knowledge
290	The Responsibility Industry, Agencies, and Early Education own in Cure-Model Based Therapeutics	0286-0000-19-632-L04-P	Knowledge
291	Transgenic Products: A DNA Construct Goes Regulatory-A Coming of Age Story	0286-0000-19-633-L04-P	Knowledge
292	Conversations with the Participant: Layperson Summaries and Return of Results	0286-0000-19-634-L04-P	Knowledge
293	Real World Evidence: How Does its Use Challenge Quality and Compliance Programs?	0286-0000-19-635-L04-P	Knowledge
294	Update From the US FDA on Progress and Topics of Current Interest in US Biosimilar Policy, Regulation, and Outreach/Education	0286-0000-19-636-L04-P	Knowledge
295	Prescription Drug Labeling: New Guidances from the US FDA	0286-0000-19-643-L04-P	Knowledge
296	Informing Development and Authorizations Using Real World Evidence/Artificial Intelligence	0286-0000-19-645-L04-P	Knowledge
297	Integration of Manufacturing Quality Assessment and Pre-Approval Inspections	0286-0000-19-642-L04-P	Application
298	Clinical Safety Assessment: What's a Statistician Got to Do with It?	0286-0000-19-637-L04-P	Application
299	Public and Regulatory Response To Drug Pricing Concerns	0286-0000-19-638-L04-P	Knowledge

WEDNESDAY, JUNE 26

Number	Session Title	Assigned UAN	Type of Activity
301	So Much Data, So Little Time: Hot Topics in Benefit-Risk Assessment	0286-0000-19-646-L04-P	Knowledge
302	Triple-s (3S) Smart Safety Surveillance	0286-0000-19-682-L04-P	Knowledge
303	Disruptive Technology Transforming Clinical Trials: The Case for Artificial Intelligence, Blockchain, and Mobile Tech/Wearables	0286-0000-19-659-L04-P	Knowledge
304	Operationalizing Master Protocols	0286-0000-19-660-L04-P	Knowledge
305	Demystifying Technology Selection in Mobile Clinical Trials	0286-0000-19-661-L04-P	Knowledge
306	Methods for Integrating EHR Data into EDC and eSource Databases	0286-0000-19-647-L04-P	Application
307	Can Topic-Based Approaches to Document Authoring Help Meet the Demands of Accelerated Marketing Application Timelines?	0286-0000-19-648-L04-P	Knowledge
308	Identifying High-Value Patient Engagement Opportunities: A Collaborative Three-Step Process for Sponsors and Patient Groups	0286-0000-19-649-L04-P	Application
309	Neoantigen-Based Cancer Therapies: Regulatory Challenges and Opportunities	0286-0000-19-650-L04-P	Knowledge
310	Project Planning 101: Turning Strategy into Execution	0286-0000-19-651-L04-P	Knowledge
311	Improving Trial Quality by Better Preparing Site Teams	0286-0000-19-652-L04-P	Knowledge
312	Translating Academic Research into Product Development: The Importance of Understanding GLPs at an Early Stage (Part 3 of 4)	0286-0000-19-653-L04-P	Knowledge
313	Model Integrated Evidence as Pivotal Information for Drug Regulatory Decision Making: When, Where, and Why	0286-0000-19-654-L04-P	Knowledge
314	Medical Devices: EU Medical Device Regulation, PMDA Updates, and US MDUFA IV – Where Are We Now?	0286-0000-19-655-L04-P	Knowledge
315	Measuring and Assessing Product Manufacturing Quality	0286-0000-19-662-L04-P	Knowledge
316	Implementation of Innovative and Adaptive Designs in Clinical Trials	0286-0000-19-656-L04-P	Knowledge
317	Designing Clinical Trials with the Right Endpoints: Applying ICH-E9(R1) - Getting the Questions Right (GTQR),Estimands and Handling Missing Data	0286-0000-19-657-L04-P	Knowledge
318	Opportunities and Challenges of Collecting Data in a Pre-Approval Access Setting: A Multi-Stakeholder Perspective	0286-0000-19-658-L04-P	Knowledge

The content noted on this page was made available to DIA as of April 29, 2019.

WEDNESDAY, JUNE 26

Number	Session Title	Assigned UAN	Type of Activity
319	How to Solve the Problem of Access for Rare Diseases	0286-0000-19-663-L04-P	Knowledge
327	Digital Risk Minimization: The "Next Generation" Risk Management Tools	0286-0000-19-664-L04-P	Knowledge
328	Risk-Based Monitoring: Best Practice Today and Technology for Tomorrow	0286-0000-19-673-L04-P	Knowledge
329	Global Clinical Trials: Make Them Really Global and Involve Africa	0286-0000-19-674-L04-P	Knowledge
330	The Analytics Revolution: Opportunities and Threats for Disrupting Clinical Development Operations	0286-0000-19-675-L04-P	Knowledge
331	A Pharma/CRO Partnership in the Design and Execution of Paperless Clinical Trials from eICF to Database Lock	0286-0000-19-680-L04-P	Knowledge
332	eSource Adoption: Where We Are - Our Experiences from eSource Implementation	0286-0000-19-665-L04-P	Knowledge
333	Pediatric Plans: The Challenges Between Regulations and Reality	0286-0000-19-666-L04-P	Knowledge
334	Understanding and Exploring Elements of a Patient-Focused Product Launch	0286-0000-19-667-L04-P	Knowledge
335	Highlights of the Patient Engagement Preparedness, Capabilities, Experience, and Impact (PEPCEI) Study	0286-0000-19-736-L04-P	Knowledge
336	Exploring the Evolving Requirements for the Clinical Assessment of Abuse and Dependence Potential of CNS-Active Drugs	0286-0000-19-678-L04-P	Knowledge
337	Application of Project Management Methodologies and Tools in NonProfit Institutions	0286-0000-19-668-L04-P	Knowledge
338	Expanding Use of Interactive Response Technologies in Clinical Trials: Maintaining Data Quality and Reliability	0286-0000-19-669-L04-P	Knowledge
339	Hot Topics in Quality and Regulatory Affairs for Combination Products	0286-0000-19-670-L04-P	Application
340	Digital Technology Advances Labeling Management and Patient Access	0286-0000-19-671-L04-P	Knowledge
341	The Evolving Gene Therapy Regulatory Framework: A Brave New World	0286-0000-19-679-L04-P	Knowledge
342	When is Real World Evidence Ready for Prime Time?	0286-0000-19-681-L04-P	Knowledge
343	Efficient Preparation of Global CMC Dossiers	0286-0000-19-676-L04-P	Knowledge
344	Meaningful Patient-Focused Drug Development for Rare Disease and Personalized Medicine	0286-0000-19-672-L04-P	Knowledge
355	History of Risk Evaluation and Mitigation Strategies (REMS): What Have We Learned?	0286-0000-19-683-L04-P	Application
356	Involving Patients in Medicinal Product Benefit-Risk Communication: How're We Doing?	0286-0000-19-732-L04-P	Knowledge
357	Accelerating Drug Development via Structured Content Reuse: Introducing the TransCelerate Clinical Template eSuite	0286-0000-19-696-L04-P	Knowledge
358	Improving the Trial Experience for Rare Disease Patients: Identifying and Overcoming Obstacles	0286-0000-19-697-L04-P	Application
359	Training for the Electronic Capture of PRO Data in Clinical Trials: Views from ePRO Vendors, Sponsors, Sites, and Patients	0286-0000-19-698-L04-P	Knowledge
360	Identification of Medicinal Products: FDA's Perspective and Approach	0286-0000-19-684-L04-P	Knowledge
361	Returning Plain Language Summaries to Research Participants: Best Practices and the Role of the IRB	0286-0000-19-685-L04-P	Application
362	Patient Engagement Quality Guidance: Results and Learnings from Global Multistakeholder Pilots	0286-0000-19-686-L04-P	Application
363	Neurodegenerative Diseases: Early-Stage Challenges and Optimal Models in Drug Development	0286-0000-19-687-L04-P	Knowledge
364	Effective Portfolio Management of Assets Across an Organization	0286-0000-19-688-L04-P	Application
365	Leveraging Data Analytics to Drive Compliance and Quality in a Risk-Based Monitoring Environment	0286-0000-19-689-L04-P	Knowledge
366	Translating Academic Research into Product Development: Integrating GCP Training into the Process (Part 4 of 4)	0286-0000-19-690-L04-P	Knowledge
367	Model-Informed Drug Development (MIDD) and Complex Innovative Designs (CID) Programs: Where are We and What Have We Learned?	0286-0000-19-691-L04-P	Knowledge
368	Global Rare Disease Town Hall	0286-0000-19-692-L04-P	Knowledge
369	User-Fee Programs Myth Busting: General Financial Principles Explained	0286-0000-19-693-L04-P	Knowledge
370	Challenges and Opportunities in Product Quality: Lifecycle Management	0286-0000-19-699-L04-P	Knowledge
371	Efficient Pediatric Drug Development: Incorporating Innovative Techniques Using Extrapolation and Historical Information	0286-0000-19-694-L04-P	Knowledge
372	Advancing Value and Access With Technology	0286-0000-19-695-L04-P	Application
379	From Trials to Real World: How Safety Protocols Impact REMS	0286-0000-19-700-L04-P	Application
380	Incorporating Patient Input into the Design and Conduct of Clinical Trials	0286-0000-19-712-L04-P	Knowledge

WEDNESDAY, JUNE 26

Number	Session Title	Assigned UAN	Type of Activity
381	A New Path Forward for Using Decentralized Clinical Trials	0286-0000-19-713-L04-P	Knowledge
382	Real World Data Quality for Regulatory Decision-Making	0286-0000-19-701-L04-P	Knowledge
383	Next-Generation Approaches for Developing Narratives	0286-0000-19-702-L04-P	Knowledge
384	Patient Preferences in Decision Making and the PREFER Project: Past, Present, and Future	0286-0000-19-703-L04-P	Knowledge
385	The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety	0286-0000-19-704-L04-P	Knowledge
386	Setting the Stage for Effective Stakeholder Collaboration	0286-0000-19-705-L04-P	Application
387	Global Perspective on ICH E8(R1): General Considerations for Clinical Trials	0286-0000-19-677-L04-P	Knowledge
388	Convergence of the Regulatory Pathways for Advanced Therapy Medicinal Products	0286-0000-19-707-L04-P	Application
389	Transparency, Expanded Access Navigator, Right to Try: Helping Patients Get Access to Investigational Medicines?	0286-0000-19-708-L04-P	Knowledge
390	Clinical Trial Innovation: Pathways for Selecting and Developing Novel, Fit-for-Purpose, Technology-Derived Study Endpoints	0286-0000-19-709-L04-P	Knowledge
391	Real World Evidence and Artificial Intelligence to Inform Post-Authorization Studies	0286-0000-19-717-L04-P	Knowledge
392	Breakthrough Therapy and PRIME Expedited Regulatory Pathways: Experience, Analysis, and Reflections from EMA, FDA, and Industry	0286-0000-19-735-L04-P	Knowledge
393	Case Studies in Resolving Quality Issues	0286-0000-19-715-L04-P	Application
394	Demystifying Basic Statistical Concepts for Anyone Involved with Clinical Trials	0286-0000-19-710-L04-P	Application
395	Utilization and Evaluation of Innovative Approaches for Efficient Drug Development	0286-0000-19-716-L04-P	Knowledge
396	Challenges to Access: Bringing Payers to the Table	0286-0000-19-711-L04-P	Knowledge

THURSDAY, JUNE 27

Number	Session Title	Assigned UAN	Type of Activity
403	Successes and Challenges in Pharmacovigilance for Biologics and Biosimilars	0286-0000-19-718-L04-P	Knowledge
404	Investigational Medicinal Products: eLabeling Initiative, Supply Forecasting Strategies, and Patient-Centric Technology for Medicine Adherence	0286-0000-19-725-L04-P	Knowledge
405	eSource and the Sites: Have They Bonded?	0286-0000-19-726-L04-P	Knowledge
406	Electronic Submissions Update	0286-0000-19-719-L04-P	Knowledge
407	A Patient Engagement Wrap Up: Lessons Learned from DIA 2019 and Where Do We Go from Here	0286-0000-19-721-L04-P	Knowledge
408	FDA Botanicals	0286-0000-19-722-L04-P	Knowledge
409	Case Studies From FDA and MHRA: Good Clinical Practices	0286-0000-19-723-L04-P	Application
410	Advancing Benefit-Risk Assessment to Support FDA's Regulatory Review of Human Drugs and Biologics	0286-0000-19-724-L04-P	Knowledge
411	Recent CMC Changes in Emerging Regulatory Agencies	0286-0000-19-727-L04-P	Knowledge
412	Keeping Up with FDA and EMA Collaborations: Question Time	0286-0000-19-728-L04-P	Knowledge
413	FDA Town Hall	0286-0000-19-729-L04-P	Knowledge

The content noted on this page was made available to DIA as of April 29, 2019.

Learn with DIA

Find face-to-face and online training to meet your professional and personal needs.

DIA delivers blended learning curricula that meet the diverse needs of professionals across the healthcare product development spectrum. DIA learners develop a set of practical skills to apply to their current and future careers. Starting a new job? Moving departments? There's a course designed for you!

DIA Learning is offered in all the following areas:

- Drug Safety
- Medical Affairs
- Clinical Research
- Regulatory Affairs
- Drug Development
- Project Management
- Patient Engagement

Can't make one of our face-to-face training courses offered throughout the year? We also have online courses that can be taken anytime, anywhere, and from any device.

- Drug Safety eLearning Program
- Drug Development and Lifecycle Management eLearning Program
- Medical Communications eLearning Program
- Medical Affairs eLearning Program
- Clinical Trial Fundamentals eLearning Program
- Informed Consent: Comprehensive Concepts and Components Module
- Good Clinical Practice Module
- Selecting and Managing Outsourced Safety Providers
- Patient Engagement eLearning Program

Purchasing training for a group? Meet your organization's training needs with DIA's Learning Solutions.

Visit DIA Booth #1531 to learn more and view a demo!

DIA Learning

EXHIBITORS

DIA

ACCESS NEW KNOWLEDGE TO STIMULATE NEW THINKING

DIA is your go-to resource for the latest in healthcare innovation

- ***Global Forum:*** Free, monthly, digital magazine
- **DIA Daily:** Member-only eNewsletter
- ***Therapeutic Innovation & Regulatory Science (TIRS):*** Bi-monthly, member-only, peer-reviewed, scientific journal

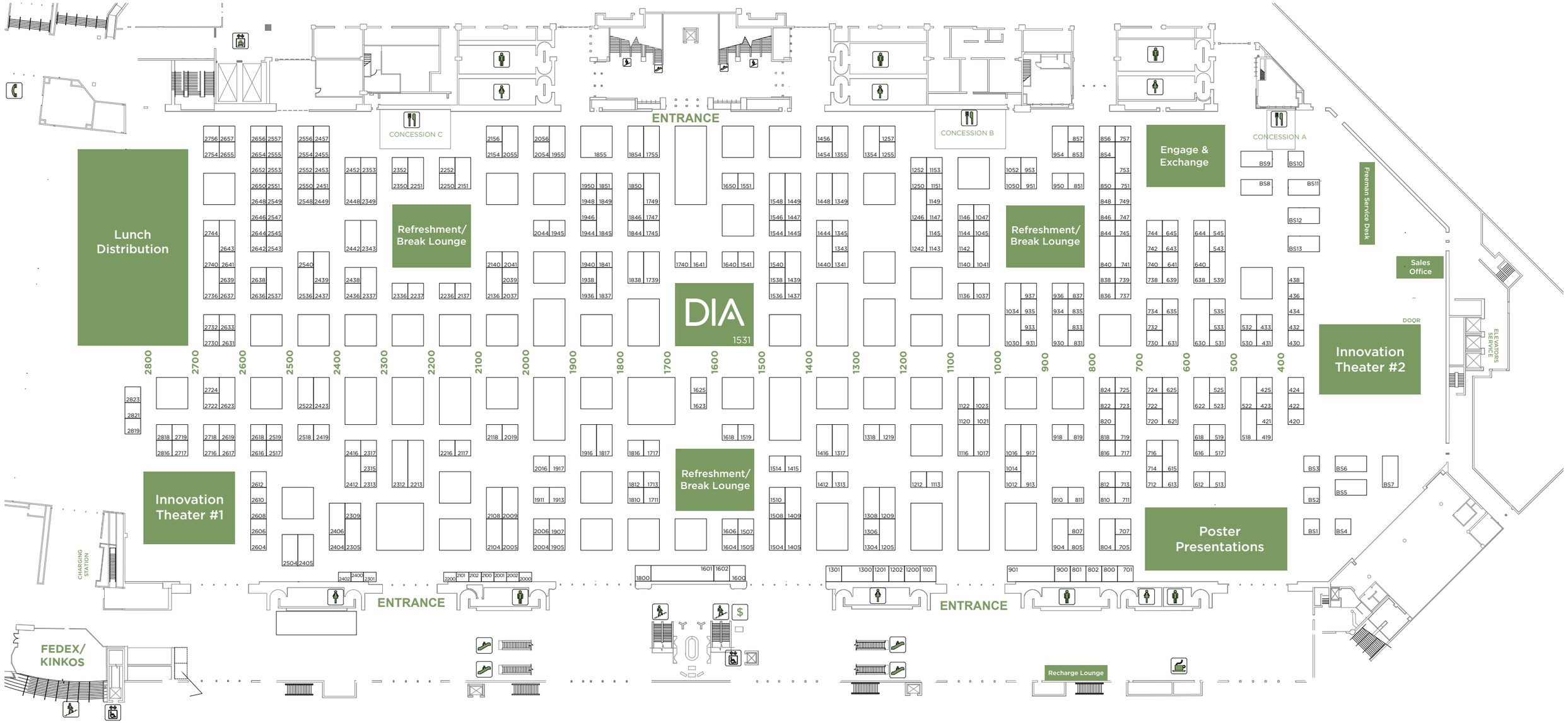
- **DIA Podcasts:** Exclusive conversations on current trends and topics of interest with healthcare experts from around the world

Visit DIA Booth #1531 to Learn More!

DIAglobal.org

Exhibitor Floor Plan

PERFORATION



Map Key

7 Annual Meeting Orientation
7:00–7:45AM
Room 14B | Mezzanine Level

13 Baggage Check
Exhibit Hall C Lobby | Ground Level

11 Business Center (FedEx Office)
Exhibit Hall D Lobby | Ground Level

15 Career Center
Exhibit Hall | Ground Level
DIA Booth #1531

Coffee/Refreshment Breaks
(Early Morning)
3 Monday: 7:00–8:00AM
Ballroom 20 Lobby | Upper Level

4 Tuesday and Wednesday: 7:00–8:00AM
Thursday: 8:00–9:00AM
Sails Pavilion | Upper Level

Coffee/Refreshment Breaks
(Mid-Morning and Mid-Afternoon)
14 Monday: 10:00–11:00AM
Tuesday: 9:15–10:30AM | 3:15–4:15PM
Wednesday: 9:15–10:30AM | 3:15–4:00PM
Exhibit Hall | Ground Level

4 Thursday: 10:15–10:45AM
Sails Pavilion | Upper Level

4 Content Hub
Sails Pavilion | Upper Level

4 DIA Community Zone
Sails Pavilion | Upper Level

3 DIA Community Luncheon
Tuesday: 12:15–1:45PM
Ballroom 20 Lobby

15 DIA Booth
Exhibit Hall | Ground Level
Booth #1531

DIAmond Sessions
2 Monday: 8:00–10:00AM
Ballroom 20 | Upper Level

6 Thursday: 9:00–10:15AM | 10:45AM-12:00PM
Room 6B | Upper Level

19 Engage and Exchange
Exhibit Hall | Ground Level
Aisle 600, Bayside Entrance
Access from Mezzanine Level

20 Exhibit Sales Office
Exhibit Hall | Ground Level
Near Aisle 400

12 First Aid
Exhibit Hall C Lobby | Ground Level

4 Housing Desk
Sails Pavilion | Upper Level

Innovation Theaters
Exhibit Hall | Ground Level
10 Theater 1 | Aisle 2700, Cityside Entrance
21 Theater 2 | Near Aisle 400

4 Lost and Found
Onsite Attendee Registration
Sails Pavilion | Upper Level

9 Luncheon Service
Monday: 12:00–2:00PM
Tuesday and Wednesday: 11:30AM–1:30PM
Exhibit Hall C | Ground Level

1 Media/Press Room
Room 23AB | Upper Level

8 Nursing Mothers Suite
Room 12 | Mezzanine Level
Must pick-up key at Onsite Attendee Registration

2 Opening Plenary, Keynote Address, and DIAmond Session
Monday: 8:00–10:00AM
Ballroom 20 | Upper Level

18 Poster Sessions
Exhibit Hall | Ground Level
Aisle 700, Cityside Entrance

2 *Student Posters*
Monday: 10:00AM–6:00PM
Oral Presentations: 10:30–10:50AM | 12:30–2:10PM | 5:10–5:30PM

3 *Student Poster Awards Ceremony*
Tuesday: 12:15–1:45PM
Ballroom 20 Lobby | Upper Level

18 *Professional Posters*
Tuesday and Wednesday: 9:00AM–4:00PM
Tuesday Oral Presentations: 12:00–1:40PM
Wednesday Oral Presentations: 12:00–1:40PM

14 Reception
Monday: 4:30–6:00PM
Exhibit Hall | Ground Level

17 Recharge Station
Exhibit Hall B Lobby | Ground Level

4 Registration
Sails Pavilion | Upper Level

17 Shuttle Drop off and Pick up
Harbor Drive | Access from Exhibit Hall Lobby | Ground Level

4 Speaker Preparation Room
Sails Pavilion | Upper Level

5 Speaker Training Room
Room 11B | Upper Level
Must reserve at Speaker Registration

17 Taxi
Harbor Drive | Access from Exhibit Hall Lobby | Ground Level, Cityside

16 Visitor Service Desk
Exhibit Hall B Lobby | Ground Level

Breaks and Lunches

Refreshment Breaks

Meet up with your colleagues to plan your day.

Early Morning:
Monday, June 24 | 7:00-8:00AM | Ballroom 20 | Upper Level
Tuesday, June 25 | 7:00–8:00AM | Sails Pavilion | Upper Level
Wednesday, June 26 | 7:00–8:00AM | Sails Pavilion | Upper Level
Thursday, June 27 | 8:00–9:00AM | Sails Pavilion | Upper Level

Visit our 400+ exhibitors during mid-morning and mid-afternoon breaks, available in the Exhibit Hall.

Monday, June 24 | 10:00–11:00AM
Tuesday, June 25 | 9:15–10:30AM | 3:15–4:15PM
Wednesday, June 26 | 9:15–10:30AM | 3:15–4:00PM
Thursday, June 27 | 10:15-10:45AM | Sails Pavilion

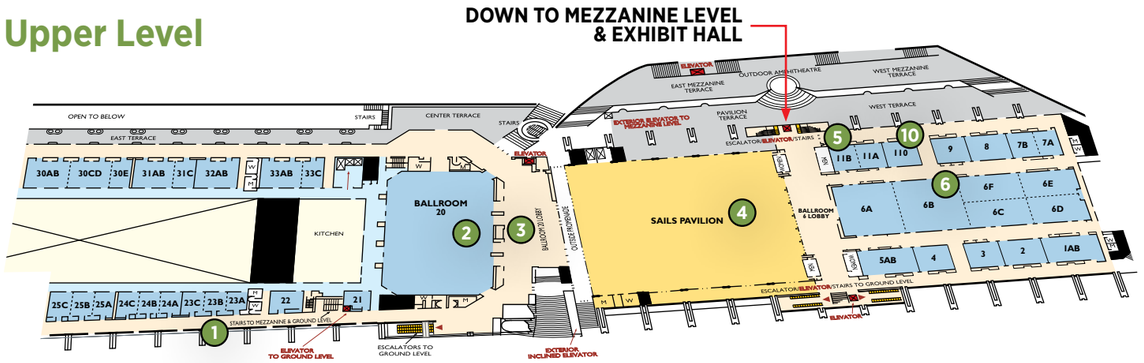
Luncheon Service in the Exhibit Hall

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

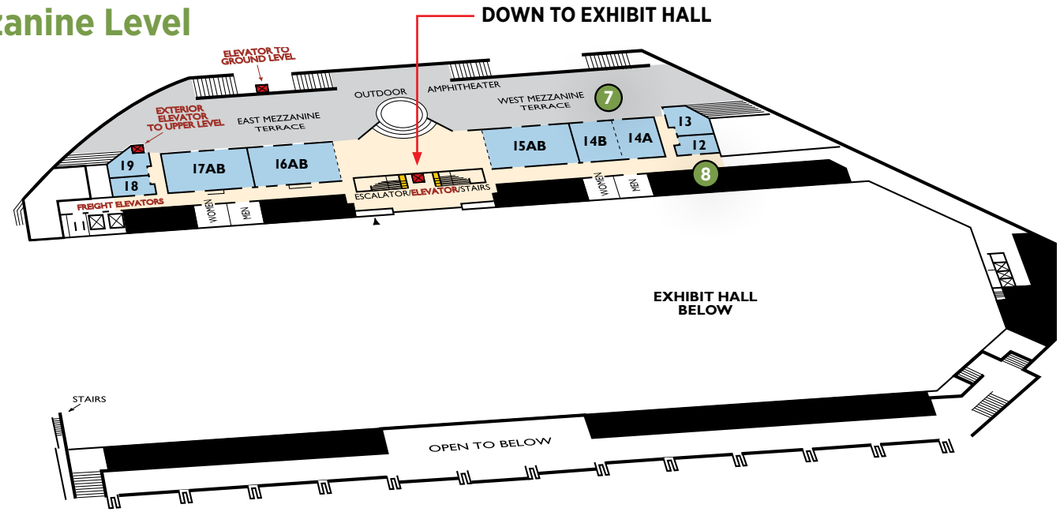
Monday, June 24 | 12:00–2:00PM
Tuesday, June 25 | 11:30AM–1:30PM
Wednesday, June 26 | 11:30AM–1:30PM

Convention Center Floorplan

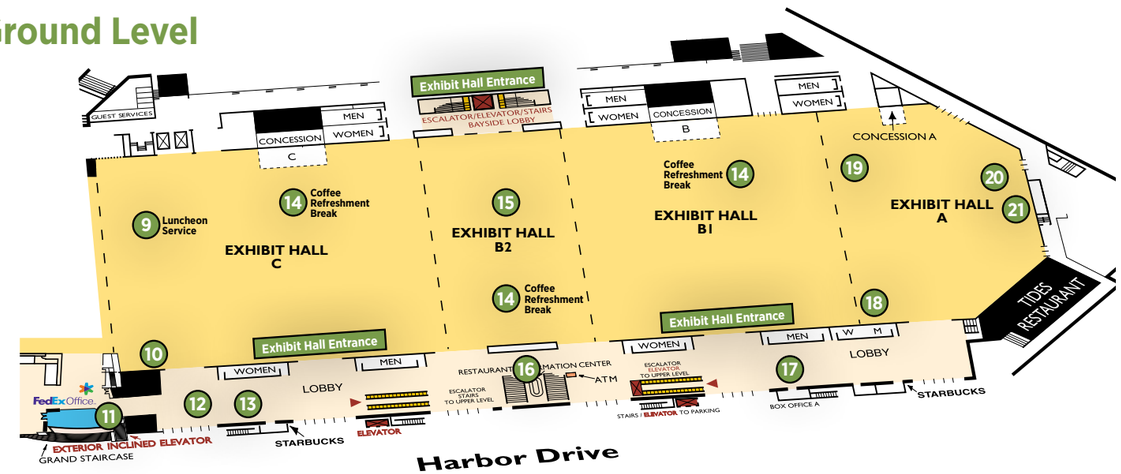
Upper Level



Mezzanine Level



Ground Level



PERFORATION

LIST OF EXHIBITORS

Confirmed Exhibitors as of April 21, 2019
Addendum available at Exhibitor Registration

Exhibiting As	Booth No.	Page No.
.assisTek	Booth: 1301	62
4C Pharma Solutions LLC	Booth: 1255	62
4G Clinical	Booth: 1604	62
AB CUBE	Booth: 2717	62
ACM Global Laboratories	Booth: 1323	62
ACRP	Booth: 2646	62
ActiGraph	Booth: 810	62
ADAMAS Consulting LLC	Booth: 730	62
Adaptive Clinical Systems	Booth: 1144	62
Advanced Clinical	Booth: 2423	62
Advarra	Booth: 2105	63
Aerotek	Booth: 1023	63
Agilex Biolabs	Booth: 2006	63
AiCure	Booth: 1449	63
ALKU	Booth: 2638	63
Alliance for Multispecialty Research	Booth: 1318	63
Alliance for Safe Biologic Medicines	Booth: 2641	63
Almac	Booth: 2523	63
Altasciences	Booth: 2039	63
AMPLEXOR	Booth: 2431	63
AMRA Medical	Booth: 1948	63
Ancillare, LP	Booth: 2213	63
Andwin Scientific	Booth: 1120	64
Anju Software	Booth: 1805	64
APCER Life Sciences	Booth: 2522	64
APDM Wearable Technologies	Booth: 705	64
Apex Health Innovations	Booth: 613	64
Apex Systems	Booth: 1810	64
Appian Corporation	Booth: 1504	64
Applied Clinical Trials/Pharmaceutical Executive	Booth: 1242	64
Aquila Solutions, LLC	Booth: 2237	64
ArcheMedX	Booth: 2101	64
ArisGlobal	Booth: 2231	64
Artcraft Health	Booth: 1945	65
Ascent Therapeutics	Booth: 535	65
Asia CRO Alliance	Booth: 2439	65
Atlant Clinical Inc.	Booth: 2518	65
August Research	Booth: 1304	65
Author-it Software Corporation	Booth: 836	65
Avance Clinical Pty Ltd	Booth: 740	65
AWINSA Life Sciences	Booth: 745	65
Axiom Real-Time Metrics Inc.	Booth: 2531	65
Backpack Health	Booth: 630 BS3	65
BARC Global Central Laboratory	Booth: 1841	66
Barnett International	Booth: 851	66
Barrington James	Booth: 2140	66
BBK Worldwide	Booth: 1440	66
Beijing Clinical Service Center	Booth: 1149	66
Bioclinica	Booth: 1831	66
BioFortis, Inc.	Booth: 2452	66
Bioforum the Data Masters	Booth: 1045	66
BioPhase Solutions	Booth: 2054	66
BioPoint, Inc.	Booth: 2517	66
Biorasi	Booth: 850	67
BioSensics, LLC	Booth: 1212	67
BioTel Research	Booth: 930	67
BizInt Solutions, Inc.	Booth: 937	67
Blinded Diagnostics	Booth: 2131	67
BlueCloud® by HealthCarePoint	Booth: 531	67
Box, Inc.	Booth: 739	67
Brand Institute, Inc.	Booth: 2519	67
Brunel Canada	Booth: 543	67
BSI	Booth: 545	67
Caligor Coghlan	Booth: 2639	67
Cambridge Healthtech Institute	Booth: 1021	68
Canfield Scientific, Inc.	Booth: 2419	68
Cardiabase by Banook Group	Booth: 2104	68
Cardinal Health	Booth: 1122	68
Cato Research LLC	Booth: 645	68
Celerion	Booth: 1548	68
Center for Information and Study on Clinical Research Participation (CISCRP)	Booth: 1142	68
CGI	Booth: 1939	68
Chiba University Hospital	Booth: 2642	68
Ciox Health	BS11	68
Clariness	Booth: 2019	69
ClinCapture	Booth: 1051	69
Clindata Insight Inc	Booth: 934	69
ClinDatrix, Inc.	Booth: 1745	69
ClinEdge, LLC	Booth: 1145	69
Clinerion	Booth: 2716	69
Clinical & Contract Research Association (CCRA)	Booth: 2553	69
Clinical Ink	Booth: 2537	69
Clinical Research Malaysia	Booth: 2617	69
Clinical Resource Network	Booth: 931	69
Clinipace	Booth: 1605	70

Exhibiting As	Booth No.	Page No.
Clinithink Ltd	Booth: 2549	70
CluePoints SA	Booth: 1846	70
Cmed Group Ltd	Booth: 1507	70
CMIC HOLDINGS Co., Ltd.	Booth: 1131	70
CNS Healthcare	Booth: 2619	70
Cognitive Research Corporation	Booth: 722	70
Cognizant	Booth: 2221	70
Comprehend Systems	Booth: 2337 BS9	70
Court Square Group/RegDocs365	Booth: 1012	70
Covance Inc.	Booth: 1921	71
CPi Global CRO	Booth: 816	71
CRF Bracket	Booth: 1305	71
CROèe Inc.	Booth: 2644	71
CROS NT	Booth: 1448	71
CRScube America Inc.	Booth: 1849	71
CSOFT International Ltd.	Booth: 631	71
CSSi Global Patient Recruitment	Booth: 1341	71
CTI Clinical Trial & Consulting Services	Booth: 1030	71
Cubixx Solutions	Booth: 822	71
Cunesoft	Booth: 2448	72
Cytel	Booth: 1454	72
Dacima Software, Inc	Booth: 2154	72
Data Management 365	Booth: 2744	72
DataArt	Booth: 917	72
Datapharm Australia Pty Ltd	Booth: 424	72
DATATRAK International, Inc.	Booth: 2623	72
DAVA Oncology	Booth: 711	72
DBMS Consulting, Inc.	Booth: 804	72
Deep Intelligent Pharma	Booth: 513	72
Deloitte	Booth: 1855	72
DIA	Booth: 1531	73
DIA MEDIA Studio	Booth: 1739	73
DIA Patient Scholars	Booth: 1538	73
DiagnoSearch Life Sciences	Booth: 1223	73
DLRC Ltd	Booth: 2548	73
dMed Biopharmaceutical Co., Ltd.	Booth: 530	73
doLoop Technologies	Booth: 2608	73
Dora Wirth (Languages) Ltd.	Booth: 2543	73
Dot Compliance LTD.	Booth: 425	73
Drexel University Online, LLC	Booth: 1905	73
Drug Development and Regulation	Booth: 833	73
DSG, Inc.	Booth: 2023	74
DZS Clinical Services	Booth: 2037	74

Exhibiting As	Booth No.	Page No.
Early Access Care	Booth: 2416	74
EastHORN Clinical Services in CEE, Ltd.	Booth: 1349	74
EC Innovations (USA), Inc.	Booth: 753	74
Eccolab Group Co	Booth: 525	74
ECG, Inc.	Booth: 2636	74
eClinical Solutions	Booth: 744	74
EDETEK, Inc.	Booth: 2049	74
EMB Statistical Solutions, LLC	Booth: 1136	74
EMSI	Booth: 844	75
endpoint	Booth: 1811	75
EndPoint Technologies	Booth: 848	75
ENNOV	Booth: 2336	75
EPS Holdings, Inc.	Booth: 1755	75
ERT	Booth: 1231 BS1	75
EUDRAC Group	Booth: 951	75
Eurofins	Booth: 1705	75
European Medicines Agency (EMA)	Booth: 1541	75
Everest Clinical Research	Booth: 1845	75
Evid Science	Booth: 2200	76
Evidence Partners Inc.	Booth: 1252	76
ExecuPharm, Inc.	Booth: 1519	76
ExL Pharma	Booth: 1444	76
Express Scripts	Booth: 714	76
EXTEDO, Inc.	Booth: 2041	76
FDA Quality and Regulatory Consultants, LLC	Booth: 1101	76
Firma Clinical	Booth: 1949	76
Flex Databases	Booth: 1037	76
FMD K&L	Booth: 724	76
Focus Investment Banking	Booth: 2606	77
Food and Drug Administration CDER/DDI	Booth: 1536	77
Frontage Laboratories, Inc.	Booth: 1437	77
GCE Solutions	Booth: 1625	77
Generis	Booth: 900	77
German Language Services	Booth: 523	77
Global Instrumentation, LLC	Booth: 720	77
GlobalCare Clinical Trials, LLC	Booth: 2436	77
Govig & Associates	Booth: 2656	77
Grant Thornton LLP	Booth: 1415	77
Greenphire	Booth: 2111	77
GxPeople	Booth: 1200	78
Hangzhou Tigermed Consulting Co., Ltd.	Booth: 1405	78
HCL America Inc.	Booth: 1455	78
HealthiVibe LLC	Booth: 935	78

The content noted on this page was made available to DIA as of April 21, 2019.

Exhibiting As	Booth No.	Page No.
Huron Consulting Group	Booth: 1308	78
hyperCORE International	Booth: 2722	78
IBM Watson Health	Booth: 1123 BS4 & BS5	78
ICON plc	Booth: 2121	78
IDDI	Booth: 1151	78
Ideagen	Booth: 1544	78
Imperial Clinical Research Services	Booth: 1812	78
Industry Standard Research	Booth: 1546	79
Inference Inc.	Booth: 723	79
Informa – Pharma Intelligence	Booth: 1034	79
Infuserve America	Booth: 2453	79
Innomar Strategies Inc.	Booth: 738	79
Innoplexus Holdings Inc.	Booth: 2000	79
Innovaderm Research Inc.	Booth: 1343	79
InnovoCommerce LLC	Booth: 2353	79
Inpharmatis	Booth: 2723	79
Insife	Booth: 2724	79
Insmed Incorporated	Booth: 835	80
Integrated Clinical Systems, Inc.	Booth: 1749	80
IntegReview IRB	Booth: 1917	80
Integron	Booth: 2406	80
International Dermatology Research, Inc.	Booth: 831	80
InterSystems Corporation	Booth: 1354	80
inviCRO	Booth: 2536	80
Iperion Life Sciences Consultancy	Booth: 819	80
IPHARMA / ChemDiv	Booth: 2637	80
IQVIA	Booth: 2205	80
JAF Consulting Inc.	Booth: 950	81
Janus Clinical Research Institute	Booth: 1747	81
Jazz Pharmaceuticals Inc.	Booth: 1257	81
Jeevan Scientific Technology Limited	Booth: 1600	81
Joulé	Booth: 2117	81
Jsure Health Inc.	Booth: 2616	81
K3-Innovations, Inc.	Booth: 953	81
Karma Oncology	Booth: 2550	81
Kayentis	Booth: 2612	81
Kinapse Ltd	Booth: 2719	81
Kinesys Consulting Ltd.	Booth: 1551	81
Klein Hersh International	Booth: 1944	82
KlinEra Global Services	Booth: 2718	82
KoNECT	Booth: 1540	82
LabConnect, LLC	Booth: 823	82
Leidos Life Sciences	Booth: 716	82
Lifelines Neurodiagnostic Systems, Inc.	Booth: 1047	82
Lionbridge Technologies	Booth: 522	82
Litera Microsystems	Booth: 2309	82
LORENZ Life Sciences Group	Booth: 1439	82
LSK Global PS	Booth: 2449	82
Luto Research Limited	Booth: 2540	83
Machaon Diagnostics, Inc.	Booth: 732	83
MakroCare	Booths: 1911 & 1913	83
Mareana Inc.	Booth: 818	83
Marken	Booth: 1601	83
MarkLogic	Booth: 1800	83
Masimo	Booth: 1146	83
MasterControl	Booth: 731	83
Mayo Clinic	Booth: 2250	83
MD Connect	Booth: 717	83
Medable	Booth: 2331	83
MedDRA MSSO	Booth: 1623	84
Medical Vigilance Solutions	Booth: 2740	84
Medicines Evaluation Unit	Booth: 2547	84
Medidata Solutions Worldwide	Booth: 1523	84
MEDIX	Booth: 1306	84
MedNet Solutions, Inc.	Booth: 1031	84
Medpace Inc.	BS6	84
MedPoint Digital, Inc.	Booth: 2405	84
Medrio	Booth: 2004 BS2	84
MESM Ltd	Booth: 2315	84
Metina PharmConsulting Private Limited	Booth: 820	84
Ministry of Food and Drug Safety (MFDS)	Booth: 1640	85
MonitorForHire.com	Booth: 2137	85
Montrium, Inc.	Booth: 2349	85
Muv Inc.	Booth: 1950	85
MyData-TRUST/FGK Representative Service	Booth: 635	85
NACS, Inc.	Booth: 1618	85
National Association of Veterans' Research and Education Foundations	Booth: 734	85
National Disease Research Interchange	Booth: 712	85
National Jewish Health	Booth: 1147	85
Navitas Life Sciences	Booth: 954	85
NCGS Incorporated	Booth: 1219	85
Next Phase Research	Booth: 2005	86
Nippon Control System Corporation	Booth: 2156	86
NNIT	Booth: 2151	86
Novotech	Booth: 1409	86

Exhibiting As	Booth No.	Page No.
OM1	Booth: 1355	86
Omnicia, Inc.	Booth: 539	86
OmniComm Systems, Inc.	Booth: 1823	86
OnePager	Booth: 1052	86
Optum	Booth: 430 BS8	86
Oracle Health Sciences	Booth: 1431	86
Orbis Clinical	Booth: 2352	86
Orbit	Booth: 1508	87
Orlando Clinical Research Center	Booth: 1816	87
Parexel	Booth: 1419	87
Path-Tec	Booth: 701	87
PCM TRIALS	Booth: 1113	87
Pharmaceutical eConsulting	Booth: 1650	87
Pharmaceuticals and Medical Devices Agency (PMDA)	Booth: 1641	87
Pharmalex	Booth: 1209	87
PharmaOut	Booth: 2102	87
Pharmapace	Booth: 612	87
Pharmaron	Booth: 2504	88
PharmaSeek Companies	Booth: 1456	88
PharmaVOICE	Booth: 1844	88
Pharm-Olam, LLC	Booth: 2312	88
Phastar	Booth: 1854	88
Phlexglobal Inc.	Booth: 2136	88
physIQ	Booth: 1317	88
PilotPay Clinical	Booth: 901	88
Pinnacle 21	Booth: 2236	88
Planet Pharma	Booth: 2118	88
PPD	Booth: 2323	89
PQE	Booth: 812	89
PRA Health Sciences	Booth: 1331	89
Praxis Communications, LLC	Booth: 1940	89
PRC Clinical	Booth: 1246	89
Precision for Medicine	Booth: 1313	89
Prevail InfoWorks, Inc.	Booth: 1606	89
Preventice Solutions	Booth: 713	89
PrimeVigilance	Booth: 1555	89
Princeton Blue, Inc.	Booth: 1505	89
Projecis, Inc.	Booth: 1116	90
Project Management Leadership Group, Inc.	Booth: 2404	90
Protocol First	Booth: 2736	90
ProTrials Research, Inc.	Booth: 1916	90
Proventa International	Booth: 854	90
Prudentia Group	Booth: 1153	90
QMENTA	Booth: 1711	90
QPS, LLC	Booth: 2412	90
QST Consultations, Ltd.	Booth: 2252	90
Quality Associates, Inc.	Booth: 2313	90
QuantifiCare	Booth: 918	91
Quartesian	Booth: 2409	91
Quest Diagnostics	Booth: 905	91
Quipment	Booth: 1249	91
Reagan-Udall Foundation for the FDA	Booth: 625	91
Real Regulatory Limited	Booth: 936	91
Real Staffing Group	Booth: 719	91
Realtime Software Solutions	Booth: 1345	91
Redbock	Booth: 1907	91
Rees Scientific	Booth: 1946	91
Regxia Inc.	Booth: 1510	92
Rephine Ltd.	Booth: 2551	92
Rho, Inc.	Booth: 1016	92
Rocky Mountain Poison & Drug Safety	Booth: 725	92
RWS Life Sciences	Booth: 622	92
Rx Values Group Ltd	Booth: 933	92
RxLogix Corporation	Booth: 1545	92
Saama	Booth: 913	92
Salesforce	Booth: 2009 BS7	92
SAS Institute Inc.	Booth: 1205	92
SAS Institute Inc., JMP Division	Booth: 1017	92
Scientia Clinical Research	Booth: 807	93
Self Care Catalysts Inc.	Booth: 2301	93
Senseonics	Booth: 2604	93
SeproTec Multilingual Solutions	Booth: 621	93
SFL Regulatory Affairs & Scientific Communication	Booth: 2648	93
Shimmer Research	Booth: 533	93
snaploT	Booth: 2610	93
Softserve Inc.	Booth: 2455	93
Sonic Clinical Trials	Booth: 904	93
Southern Star Research	Booth: 805	93
Sparta Systems	Booth: 1837	94
Spencer Health Solutions Inc.	Booth: 518	94
Splash Clinical, LLC	Booth: 837	94
spmd Safety Strategies for Health Inc.	Booth: 2451	94
Spotline	Booth: 811	94
Statistics & Data Corporation (SDC)	Booth: 1239	94
Stefanini	Booth: 2343	94

The content noted on this page was made available to DIA as of April 21, 2019.

Exhibiting As	Booth No.	Page No.
Sterling Institutional Review Board	Booth: 1850	94
Stiris Research Inc.	Booth: 1250	94
StudyKik	Booth: 2442	94
SubjectWell	Booth: 923	94
Symbio, LLC	Booth: 1412	95
Symphony Clinical Research	Booth: 2216	95
Synchrogenix, a Certara Company	Booth: 1117	95
Syneos Health	Booth: 1721	95
Synova Health	Booth: 1602	95
Synteract	Booth: 1931	95
Target Health Inc.	Booth: 2305	95
Technical Resources International, Inc.	Booth: 1717	95
Techsol Corporation	Booth: 2108	95
Telelingua Translations	Booth: 1447	95
TFDA / Center for Drug Evaluation, Taiwan	Booth: 1740	96
The Patient Recruiting Agency	Booth: 2437	96
Therapak, LLC	Booth: 2317	96
Therapeutics Inc.	Booth: 1143	96
ThoughtSphere Inc.	Booth: 1050	96
Total Clinical Trial Management	Booth: 2055	96
TransPerfect	Booths: 1731 & 1838	96
Trial By Fire Solutions	Booth: 910	96
Trifecta	Booth: 1137	96
Trilogy Writing & Consulting	Booth: 2251	96
UBC	Booth: 1649	97
Uber	Booth: 2618	97
uMotif	Booth: 2545	97
Uppsala Monitoring Centre	Booth: 838	97
Validated Cloud Inc.	Booth: 840	97
Veeva Systems, Inc.	Booth: 2031	97
Verantos	Booth: 2400	97
Verified Clinical Trials	Booth: 1014	97
Veristat	Booth: 1713	97
Versiti	Booth: 2044	97
Viedoc	Booth: 737	98
Viitai LLC	Booth: 431	98
VirTrial	Booth: 2056	98
Vitalograph, Inc.	Booth: 1817	98
Vitrana	Booth: 2823	98
VivaLNK	Booth: 2438	98
WCCT Global	Booth: 1445	98
WCG Clinical Services	Booth: 1005	98
WebbWrites, LLC	Booth: 1514	98
Welch Allyn	Booth: 1936	98
Welocalize Life Sciences	Booth: 1041	99
Whitsell Innovations, Inc.	Booth: 1140	99
WIRB-Copernicus IRB Group	Booth: 1105	99
Woodley Equipment Company	Booth: 2131	99
WuXi Clinical	Booth: 1416	99
XClinical Services America Inc.	Booth: 1955	99
YPrime Inc.	Booth: 1851	99
Zifo	Booth: 2350	99
Zigzag Associates Ltd	Booth: 2016	99
ZS	Booth: 1300	99

.assisTek
Booth: 1301
Contact: Cindy Howry
Phone: 480-874-9400
Email: info@assisTek.com
Website: www.assistek.com

assisTek has over 22 years of experience in successfully delivering eSource solutions used to collect data, electronically, from patients and clinicians in clinical trials. Our teams bring a history of superior performance, and an unequalled record of innovation to every trial. assisTek's focus is based on delivering advanced solutions used to solve complex data management, patient engagement and cost issues. We provide eDiary, ePRO, eCOA, and BYOD solutions for your clinical trial needs.

4C Pharma Solutions LLC
Booth: 1255
Contact: Muhammad Ahmad, MD MBA
Phone: 732-529-6989
Email: info@4cpharma.com
Website: www.4cpharma.com/

4C Pharma Solutions is an Oracle Gold partner with fully validated Argus in-house, certified in ISO 9001 & 27001 excelling in Pharmacovigilance, Regulatory Affairs, Medical Writing, Healthcare Analytics and Argus Hosting Solutions. 4C provides comprehensive services including setting up processes, systems, certifications, trainings & operations. With our deep understanding of technological and operational challenges, we deliver the most optimal results saving your precious time for R&D.

4G Clinical
Booth: 1604
Contact: Amy Ripston
Phone: 781-694-1400
Email: amy@4gclinical.com
Website: www.4gclinical.com

4G Clinical is a leader in randomization and trial supply management (RTSM) for the global life sciences industry, offering the only fully cloud-based, 100% configurable and flexible solution utilizing natural language processing (NLP) and integrated supply forecasting. 4G Clinical is headquartered in the Boston Biotech corridor of Wellesley, MA, with offices in Europe and Asia. For more information, visit www.4gclinical.com.

AB CUBE
Booth: 2717
Contact: Yasmine Benlahrech
Phone: 33-6-59-36-80-95
Email: yasmine.benlahrech@ab-cube.com
Website: www.ab-cube.com/

AB Cube is Making Safety Easy for more than a decade. By providing the international healthcare industry, from biotechs to larger companies, with intuitive, scalable and cost-effective cloud-based vigilance software solutions for management of adverse events, AB Cube is THE expert of multivigilance. Always compliant with the latest regulations, all the SafetyEasy™ solutions are validated according to GAMP 5 and FDA 21 CFR part 11. Let's start making safety easy together!

ACM Global Laboratories
Booth: 1323
Contact: Mark Engelhart
Phone: 585-429-1990
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. For more information go to www.acmgloballab.com

ACRP
Booth: 2646
Contact: Jenna Rouse
Phone: 703-254-8109
Email: jenna@acrpnet.org
Website: www.acrpnet.org

ACRP makes your people better so your business can soar. Having the best people gives you the best of both worlds: lower costs and risk, and higher quality, efficiency, and certainty. That's why gold standard talent leads to gold standard progress – to the next stage, next trial, or next product launch – helping your business change the world for the better. Learn more at acrpnet.org.

ActiGraph
Booth: 810
Contact: Genevieve Baley
Phone: 850-332-7900
Email: pharma@actigraphcorp.com
Website: www.actigraphcorp.com/

ActiGraph is a leading provider of medical-grade wearable physical activity and sleep monitoring solutions for the global scientific community. Built on nearly two decades of real-world data capture and management expertise, ActiGraph's innovative ecosystem of hardware and software tools leverage cloud, mobile, and wireless technologies to capture and deliver high quality patient insights, in near real time.

ADAMAS Consulting LLC
Booth: 730
Contact: Steve Bliss
Phone: 973-879-0403
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 22 years' experience, we are the only provider with a global full-time staff of dedicated auditors, including former MHRA inspectors. We provide quality assurance consulting services across the entire GxP spectrum. With offices in the US, EMEA and APAC we have the entire world covered for your QA needs. www.adamasconsulting.com

Adaptive Clinical Systems
Booth: 1144
Contact: Mitch Collins
Phone: 856-473-4370
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
Booth: 2423
Contact: Lizzie Evans
Phone: 847-267-1176
Email: eevans@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, 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.

Advarra
Booth: 2105
Contact: Rachel Ruehlman
Phone: 410-884-2900
Email: businessdevelopment@advarra.com
Website: www.advarra.com/

Advarra is the premier provider of IRB, IBC, and global research compliance and administration consulting services in North America for clinical trial sponsors, CROs, hospital systems, academic medical centers, and investigators. With the acquisition of Quorum and Kinetiq, Advarra provides the greatest institutional reach of any IRB, unmatched regulatory expertise, and One-Touch Collaboration™ to accelerate innovation, support faster study startup, and help make research altogether even better.

Aerotek
Booth: 1023
Contact: Kathleen Zazzara
Phone: 888-237-6835
Email: kzazzara@aerotek.com
Website: www.aerotek.com

Twenty-first century business demands agility, and you need the right people to succeed. As your staffing partner, Aerotek® assists your organization by providing the clinical research professionals needed to help your organization win in your unique industry. Since 1983, Aerotek has become a leader in recruiting, staffing and strategic outsourced solutions. We employ more than 16,000 clinical and scientific employees every year — whatever the therapeutic area. To learn more, visit Aerotek.com.

Agilex Biolabs
Booth: 2006
Website: www.agilexbiolabs.com.au/
Phone: 61-881-596-255

AiCure
Booth: 1449
Contact: Ted Kirby
Phone: 800-570-0448
Email: solutions@aicure.com
Website: aicure.com

AiCure's intelligent medical assistant, IMA, leverages a visual recognition platform to monitor patient progress. IMA provides visual dose confirmation, interactive patient support and engagement, and visual diagnostic capabilities. IMA is increasing the probability of trial success and has been clinically-validated to improve patient compliance in randomized controlled trials.

ALKU
Booth: 2638
Contact: Adriana Major
Phone: 978-289-5744
Email: amajor@alku.com
Website: www.alku.com/

ALKU is a highly specialized consulting firm that focuses on the Medical Device, Pharmaceutical, and Biotech industry. ALKU's core competencies include Regulatory Affairs, Clinical Affairs, Biometrics, and Medical Affairs consulting services.

Alliance for Multispecialty Research
Booth: 1318
Contact: Amy Rushing
Phone: 865-305-9100-234
Email: amy.rushing@amrllc.com
Website: www.amrllc.com

Alliance for Multispecialty Research streamlined solutions maximizes economies of scale, expedites start-up, allowing our 17 centers to complete enrollment ahead of schedule and under budget. Centralized processes enable sponsors/CROs to engage multiple centers simultaneously, resulting in shortened timelines and increased savings. With a diverse database > 225,000 volunteers, physician databases >1.3 million pts, allows for detailed searches aiding in meeting/exceeding enrollment targets.

Alliance for Safe Biologic Medicines
Booth: 2641
Contact: Ray Patnaude
Phone: 703-971-1700
Email: ray@safebiologics.org
Website: www.safebiologics.org

The Alliance for Safe Biologic Medicines is a group of physicians, pharmacists, patients, manufacturers of both biologics and biosimilars, researchers, and others working together to promote the safe introduction and use of biosimilars.

Almac
Booth: 2523
Contact: Ellen Diegel
Phone: 215-660-8500
Email: ellen.diegel@almacgroup.com
Website: www.almacgroup.com

Almac Clinical Technologies, part of the Almac Group, offers an industry-leading IRT, biostatistical services, drug accountability and reconciliation tracking, and expert consultancy for pharmaceutical and biotech companies around the globe.

Altasciences
Booth: 2039
Contact: Catherine Moniz
Phone: 450-973-6077
Email: cmoniz@altasciences.com
Website: www.altasciences.com

Altasciences is a forward-thinking, mid-size CRO offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and early phase clinical studies, from lead candidate selection to proof of concept. Altasciences' full-service solutions include preclinical safety testing, clinical pharmacology, bioanalysis, program management, medical writing, biostatistics, and data management.

AMPLEXOR
Booth: 2431
Contact: Sherri Hughes-Smith
Phone: 303-926-7177
Email: sherri.hughes-smith@amplexor.com
Website: www.amplexor.com/lifesciences/en.html

AMPLEXOR Life Sciences is a global provider of language services and regulatory, quality and safety software solutions for drug and device companies as well as CROs. Our Life Sciences Suite enables users to manage multi-lingual master data, content, and documents as well as regulatory submissions, quality and adverse events. Our Language Services provide the technology and translation capabilities to solve global content challenges. Together, our services provide a global end-to-end solution.

AMRA Medical
Booth: 1948
Contact: Nicole Dooley
Phone: 267-337-4588
Email: nicole.dooley@amramedical.com
Website: www.amramedical.com/

AMRA Medical's imaging for clinical trials, provides a global standard in body composition assessment, delivering multiple fat and muscle biomarkers with unrivaled precision – all from a 6-minute whole-body MRI scan. Rapid whole-body MRI and automated, cloud-based image analysis allow you to monitor small, clinically relevant changes in fat and muscle volumes. Simple, safe, and cost-effective – we give precise, individualized body composition measurements and contextual disease insights.

Ancillare, LP
Booth: 2213
Contact: Courtney Wright
Phone: 877-474-5656
Email: courtney.wright@ancillare.com
Website: www.ancillare.com

Ancillare is the leader in global clinical and ancillary supply chain management services for pharmaceutical, biotechnology, CRO and medical research organizations. Our model embraces the complexities and globalization of the clinical and ancillary supply chain by reducing overall costs and cycle times associated with a clinical trial and greatly improves operational efficiency across all levels of the chain. Ancillare is headquartered in the US with regional offices in Europe and Asia-Pacific.

Andwin Scientific
Booth: 1120
Contact: Andrew Billimore
Phone: 818-999-2828
Email: abillimore@andwin.com
Website: www.andwin.com

Andwin specializes in clinical research supply chain management to global life science industry, providing a single source for diagnostics & specimen kits (with over 1 million a year manufactured) and study ancillary supplies. Andwin's focuses on clinical trial supplies and equipment product manufacturing, sourcing, procurement, storage and distribution as a supplier to global life science organizations and a distributor to direct end using companies.

Anju Software
Booth: 1805
Contact: Bob Borysko
Phone: 267-262-6205
Email: bob.borysko@anjusoftware.com
Website: www.anjusoftware.com/

Anju Software provides an integrated software and data platform for pharmaceutical, biotech and CRO clients which enhances trial efficiencies through improved data collection, integration, analyses and reliability across therapeutic areas from compound design in Clinical Operations to Medical Affairs and through Commercialization.

APCER Life Sciences
Booth: 2522
Contact: Deepika Duggal
Phone: 609-455-1600
Email: deepika.duggal@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.

APDM Wearable Technologies
Booth: 705
Contact: Matthew Johnson
Phone: 971-506-8166
Email: matt@apdm.com
Website: apdm.com

APDM Wearable Technologies is focused on discovering sensitive endpoints of disease progression in neurodegenerative conditions by quantifying movement with Opal sensors and sophisticated algorithms. Deployed by thousands of researchers and clinicians worldwide, APDM solutions streamline data collection and analysis to precisely track patient response to intervention, with the goal of customizing and improving healthcare delivery.

Apex Health Innovations
Booth: 613
Contact: Rich Mutell
Phone: 805-428-2983
Email: rmutell@apexhealthinnovations.com
Website: www.apexhealthinnovations.com

Apex Health Innovations is a global technology company that serves the biopharmaceutical, medical device, and healthcare markets. We design highly configurable, web-based solutions that bridge the gap between strategic planning and execution by enabling our clients to manage their budget, projects, publication planning, conference planning, competitive intelligence and launch plans in one central location.

Apex Systems
Booth: 1810
Contact: Jennifer Eanes
Phone: 804-342-9090
Email: jeanes@apexsystems.com
Website: www.apexsystems.com/

Apex Systems, formerly Apex Life Sciences, is an international leader in placing science, technology, engineering, and clinical research professionals at all career levels for contract, contract-to-hire, and direct hire opportunities. Apex Systems is a division of the 3rd largest clinical/scientific staffing and services firm in the U.S. and is proud to have earned ClearlyRated's 2019 Best of Staffing® Client and Talent Awards.

Appian Corporation
Booth: 1504
Contact: Katherine Miller
Phone: 703-442-8844
Email: katherine.miller@appian.com
Website: www.appian.com

Appian provides a low-code development platform that accelerates the creation of high-impact business applications. Many of the world's largest life sciences organizations use Appian applications to improve customer experience, achieve operational excellence, and simplify global risk management and compliance. For more information, visit www.appian.com.

Applied Clinical Trials/Pharmaceutical Executive
Booth: 1242
Contact: Melissa Devlin
Phone: 203-523-7067
Email: melissa.devlin@ubm.com
Website: www.appliedclinicaltrialsonline.com and www.pharmexec.com

Applied Clinical Trials is the thought leader and resource for the global community that initiates, manages and operationalizes clinical trials. Pharmaceutical Executive provides in-depth analysis to help executives navigate through the maze of policy and business challenges that face the industry. Available in-print and online www.AppliedClinicalTrialsOnline.com and www.PharmExec.com

Aquila Solutions, LLC
Booth: 2237
Contact: Joshua Boutwell
Phone: 404-217-9213
Email: jboutwell@aquilasolutions.us
Website: www.aquilasolutions.us

Aquila provides expert eCTD publishing support. We help with both in-sourcing and out-sourcing support. We will strengthen your publishing group or take your publishing project and complete it at quickly and easily. Come check out our eCTD Timeline calculator! We can help you plan your development project.

ArcheMedX
Booth: 2101
Contact: Joel Selzer
Phone: 434-260-1850
Email: joel@archemedx.com
Website: archemedx.com

ArcheMedX provides operational insights and learner readiness solutions for the clinical trials industry. Our intelligent learning platform applies behavioral science and data analytics to improve research staff & site readiness and to identify early warning of underperformance. Research leaders use the ArcheMedX platform to accelerate site initiation, improve trial performance and streamline patient recruitment. For more information, go to www.archemedx.com.

ArisGlobal
Booth: 2231
Contact: Gregory Belkin
Phone: 609-360-4042
Email: gbelkin@arisglobal.com
Website: www.arisglobal.com

ArisGlobal is a visionary technology company that's transforming the way today's successful pharmaceutical, med device, CRO and biotech companies brings new products to market. The ArisGlobal LifeSphere® cognitive technology platform integrates machine learning capabilities to automate all core functions of the product lifecycle. With expertise spanning more than 30 years, our cognitive platform delivers insights, efficiency, compliance, and lowers total cost of ownership through multi-tenancy.

Artcraft Health
Booth: 1945
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

Ascent Therapeutics
Booth: 535
Contact: Shasta Triumfante
Phone: 81-9064937711
Email: shasta.triumfante@ascentthereapeutics.com
Website: www.ascenttherapeutics.com

Ascent works with emerging biopharma to prospectively integrate Asia, particularly Japan and China, into global drug development thus enabling rapid market entry, increasing global product value, and enhancing the value of licensing partnerships. Ascent can provide either targeted, short-term consulting in support of rapid out-licensing deals, or comprehensive, long-term regulatory and clinical development services in support of ambitious strategic/commercial goals in Asia.

Asia CRO Alliance
Booth: 2439
Contact: Young Jack Lee
Phone: 82-2-2014-9500
Email: jacklee@lskglobal.com
Website: www.lskglobal.com

The Asia CRO Alliance supports drug, biotech, medical device companies, and CROs planning studies in Asia. The ACA led by LSK Global Pharma Services, the largest local Korean CRO, meets the increasing demand for Asian studies. ACA members function individually or in team as the sponsor demands. At present LSK is engaged in a pivotal oncology study of 95 sites from 12 countries in Asia, US, and Europe with some ACA members. ACA services are of global quality, timely and price-conscious.

Atlant Clinical Inc.
Booth: 2518
Contact: Marietta Sarkisyan
Phone: 201-616-0037
Email: marietta.sarkisyan@atlantclinical.com
Website: www.atlantclinical.com

Atlant Clinical is an international CRO, offering a full range of clinical trial (Phases I-IV) and relevant support services throughout the US, Europe, Russia, and Middle Asia. Our company has over 10 years of strong experience, including conduct of 200+ clinical trials in all major therapeutic areas. Atlant Clinical employs a capable team of over 150 experienced employees worldwide. All our people have strong background in natural sciences and/or medicine.

August Research
Booth: 1304
Contact: Dana Niedzielska
Phone: 359-2-971-4593
Email: dniedzielska@augustresearch.com
Website: www.augustresearch.com

August Research is a European-focused CRO with clinical operations across both Western and Eastern Europe. American-owned, with nearly 20 years in the industry, the company's staff is a highly experienced, stable team of professionals providing the highest quality in both trials operations and customer service. Our experience covers all major therapeutic areas and all Phases of trials. From Spain to Georgia, August Research is your clinical trial partner for Europe.

Author-it Software Corporation
Booth: 836
Contact: Maureen Noble
Phone: 888-999-1021
Email: maureen.noble@author-it.com
Website: www.author-it.com/docuvera

Author-it Software Corporation (ASC) is a world leader in component authoring solutions, purpose-built for Life Sciences. Our solutions enable the efficient authoring, sharing and reuse of information across a number of document sets represented in the drug production life cycle.

Avance Clinical Pty Ltd
Booth: 740
Contact: Yvonne Lungershausen
Phone: 61-417-889-4620
Email: yvonne.lungershausen@avancecro.com
Website: avancecro.com

Avance Clinical is a premier provider of clinical services headquartered in South Australia. Avance has extensive experience in the following: protocol and report writing, project management, site monitoring, safety reporting, data management, statistical services, pharmacokinetics, QA consulting and auditing, clinical kit management. Phase I to III studies are conducted to the highest ethical and regulatory standards. Avance customizes its approach to meet the specific objectives of each client

AWINSA Life Sciences
Booth: 745
Contact: Dr. Sanjeev Miglani MD
Phone: 991-053-3655
Email: sanjeev.miglani@awinsals.com
Website: www.awinsals.com

Planning for a paradigm shift in the delivery of Pharmacovigilance services, AWINSA Life Sciences aims to provide end to end Post marketing and Clinical trial Pharmacovigilance services. Manned by people with discernment and an eye for quality, we at AWINSA ensure astute analysis of safety reports so that clinical scenarios emerge in perspicuity. Intricate and deep-rooted knowledge of the subject will ensure that you are delivered services of the highest order within the stringent timelines.

Axiom Real-Time Metrics Inc.
Booth: 2531
Contact: Andrew Schachter
Phone: 866-912-9466
Email: solutions@axiom.cc
Website: www.axiommetrics.com

Axiom Real-Time Metrics delivers intuitive, powerful and cost-effective services and solutions focused on successful clinical trial execution and management. Axiom's eClinical suite, Fusion, with over 15 optional modules, has served as a complete connected hub for clinical data and operational needs since 2001. Fusion enables sponsors to tailor their product and service solution based on evolving study requirements.

Backpack Health
Booth: 630 | BS3
Contact: Jim Cavan
Phone: 508-785-9899
Email: rob.goldman@backpackhealth.com
Website: backpackhealth.com/

Backpack Health is Transforming the Pharmaceutical and Biotech Industry Backpack Health empowers individuals, families and caregivers by making them personal health historians with better control of their own health data. Backpack Health provides a platform for organizations to engage patients, collect up-to-date data and build communities around the globe all while encouraging participation in research and breaking down wasteful data silos. Come see us at Booth 630 during DIA to learn more!

BARC Global Central Laboratory
Booth: 1841
Contact: Sofie Vandevyver
Phone: 347-219-2020
Email: svandevyver@barclab.com
Website: www.barclab.com

For 35 years, Barc Lab provides the (bio)pharmaceutical industry with central lab services, both in routine and specialized testing within a wide range of fields including oncology, immunology, genetics, microbiology and clinical pathology. We encourage that our scientific experts are integrated in our customer's R&D processes, hence providing a critical advantage in the ever-increasing complex setting of clinical trials.

Barnett International
Booth: 851
Contact: Ms. Naila Ganatra
Phone: 215-413-2471
Email: nganatra@barnettinternational.com
Website: www.barnettinternational.com

Leaders in Clinical Research Training - Founded in 1979, Barnett International is widely recognized for its superior consulting services and its targeted education and training programs. Barnett helps clients get the most out of their training budgets 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.

Barrington James
Booth: 2140
Contact: Paul Oldfield
Phone: 919-838-7478
Email: poldfield@barringtonjames.com
Website: www.barringtonjames.com

Barrington James is a Global specialist recruitment consultancy with offices in the USA, Europe and APAC that works across the healthcare sector. Our structure, with separate divisions and dedicated consultants for the markets we serve, ensures a thorough, professional and intelligent approach in both permanent and interim solutions. Our tailored methodologies include contingency database search and executive search.

BBK Worldwide
Booth: 1440
Contact: Founding Principals: Joan F. Bachenheimer and Bonnie A. Brescia
Phone: 617-630-4477
Email: info@bbkworldwide.com
Website: www.bbkworldwide.com

BBK Worldwide is the patient experience company, providing a range of patient recruitment and engagement solutions to pharmaceutical and biopharmaceutical companies and their outsourced suppliers. Committed to providing creative and technology-driven solutions needed to enhance the patient experience, enroll clinical studies on time, and expedite time-to-market, BBK delivers a suite of products and services to address patient and site engagement challenges in multinational studies.

Beijing Clinical Service Center
Booth: 1149
Contact: Richard Tadd
Phone: 86-010-84098841
Email: richard@clinicalservice.cn
Website: www.clinicalservicecenter.com

For more than a decade, Beijing Clinical Service Center has been conducting top-quality clinical trial services in China for Pharmaceutical, Biotech & Medical Device companies the world over. As a full-service Clinical Research Organization (CRO) we can support you with everything from IND to NDA, conduct your clinical studies with a focus on quality and efficiency, and finally, produce a submission-ready file to get your product on the China market as fast as possible.

Bioclinica
Booth: 1831
Contact: Kimberly Salgueiro
Phone: 877-632-9432
Email: kimberly.salgueiro@bioclinica.com
Website: www.bioclinica.com/

Bioclinica is a global life sciences solution provider that utilizes science and technology to bring clarity to clinical trials – helping companies to develop new life-improving therapies more efficiently and safely. Bioclinica's hundreds of experienced scientific, medical, and domain experts bring unmatched insight across the development lifecycle, from the initial protocol to post-approval.

BioFortis, Inc.
Booth: 2452
Contact: Steve Chen
Phone: 443-276-2464
Email: shchen@biofortis.com
Website: www.biofortis.com

BioFortis is a leading provider of clinical development technology solutions, which empower total biospecimen lifecycle management. Its flagship product, Labmatrix, provides data management for subjects, clinical trial samples & consent tracking, and biobanking. With enterprise-level capabilities for integrating eClinical and research data in a harmonized & regulatory-compliant manner, Labmatrix users can easily ask sophisticated ad hoc questions, and generate insights from reports & dashboards.

Bioforum the Data Masters
Booth: 1045
Contact: Chen Levi Duman
Phone: 972-0547394546
Email: chen.levi@bioforumgroup.com
Website: www.bioforumgroup.com/

Bioforum is a data focused CRO with over 10 years of clinical research experience. Our goal is to consistently improve and innovate data processes to support our clients in the utilization of their clinical data and guarantee its integrity and accuracy. We offer a wide range of clinical data services to include medical writing, data management, biostatistics and pharmacovigilance. We are multinational company with offices in Israel, the US, Australia and South Africa.

BioPhase Solutions
Booth: 2054
Contact: James Whittington
Phone: 858-552-2000
Email: james@biophaseinc.com
Website: www.biophaseinc.com

BioPhase is where California's top Pharmaceutical and Biotech companies turn to when searching for the right individuals to join their team. We maintain a reputation of excellence in the industry by developing long lasting and professional relationships that are built on a foundation of trust with our clients, candidates, and employees. Stop by our booth at DIA and let's discuss how BioPhase Solutions can help you connect with the right people and companies in California.

BioPoint, Inc.
Booth: 2517
Contact: Kevin Pike
Phone: 781-218-3790
Email: info@biopointinc.com
Website: www.biopointinc.com

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
Booth: 850
Contact: Alex Mouravskiy
Phone: 786-388-0700
Email: amouravskiy@biorasi.com
Website: www.biorasi.com

Biorasi is an award-winning contract research organization accelerating drug and device clinical development for life sciences companies around the world. Since 2002, Biorasi has achieved success in bringing innovative therapies to market by forming true partnerships with sponsors, and focusing on processes, methodologies, and technologies that move the industry forward. Biorasi is headquartered in Miami, Florida, and has regional offices around the globe.

BioSensics, LLC
Booth: 1212
Contact: Kelly Urbany
Phone: 888-589-6213
Email: kelly.urbany@biosensics.com
Website: www.biosensics.com/

BioSensics is a globally recognized provider of wearable sensor technologies for clinical research and medical applications. BioSensics technologies include innovative solutions for aging-in-place, telehealth, chronic disease management, physical therapy, rehabilitation, fall risk assessment, and clinical research and trials.

BioTel Research
Booth: 930
Contact: Amanda Myers
Phone: 301-841-0362
Email: amanda.myers@gobio.com
Website: www.gobio.com/clinical-research/

As an industry leader in testing services for clinical trials, BioTel Research combines the expert medical imaging of VirtualScopics and the cardiac core lab leadership of Cardiocore. BioTel Research offers global operational support for cardiovascular monitoring in all therapeutic areas, and advanced imaging services in oncology, cardiovascular, metabolic, musculoskeletal, neurologic and medical device studies. For more information please visit www.gobio.com/clinical-research/.

BizInt Solutions, Inc.
Booth: 937
Contact: Diane Webb
Phone: 714-289-1000
Email: products@bizint.com
Website: www.bizint.com

Looking for new ways to support your competitor intelligence, strategy and clinical trial design? Our BizInt Smart Charts software helps you create polished reports and visualizations integrating trials intelligence from the leading commercial and registry databases -- Citeline TrialTrove, Cortellis Clinical Trials Intelligence, Adis Clinical Trials Insight, ClinicalTrials.gov, EU Clinical Trials, and WHO ICTRP.

Blinded Diagnostics
Booth: 2131
Contact: Paul Savuto
Phone: 201-291-2822
Email: paul.savuto@blindeddiagnostics.com
Website: www.blindeddiagnostics.com

Blinded Diagnostics is a contract service organization providing same day lab test results for global clinical trials. We offer over 100 test analytes on accurate and proven point of care diagnostics systems. To see the test menu visit www.pointofcaresearch.com or for more information on our services go to www.blindeddiagnostics.com

BlueCloud® by HealthCarePoint
Booth: 531
Contact: Sheri Campbell
Phone: 512-302-3113
Email: shericampbell@bluecloud.net
Website: www.bluecloud.net

A global innovation providing Delivery, Distribution, Implementation & Tracking (DDIT) mechanisms. Available in 167 countries and used by over 1.5 million healthcare professionals and thousands of industry stakeholders. A centralized system to connect and share verifiable information in real-time for required activities. Proven to save industry millions of dollars by eliminating redundancies, expediting study start up, ensuring compliance and building Site study pipelines.

Box, Inc.
Booth: 739
Email: sales@box.com
Phone: 877-729-4269
Website: www.box.com

Box (NYSE:BOX) is the Cloud Content Management company that empowers enterprises to revolutionize how they work by securely connecting their people, information and applications. Founded in 2005, Box powers more than 90,000 businesses globally, including AstraZeneca, General Electric, P&G and The GAP. Box is headquartered in Redwood City, CA, with offices across the United States, Europe and Asia. To learn more about Box, visit http://www.box.com/.

Brand Institute, Inc.
Booth: 2519
Contact: Anabel Morales
Phone: 305-374-2500
Email: amorales@brandinstitute.com
Website: www.brandinstitute.com

Brand Institute is a premier international branding agency that partners with healthcare, pharmaceutical and consumer companies to develop brand names. In operation since 1993, Brand Institute offers a comprehensive list of branding services including brand strategy/architecture, name development, market research, regulatory, and visual identity solutions. With regional offices strategically located, we offer the highest level of in-house expertise.

Brunel Canada
Booth: 543
Contact: Angelina Brathwaite
Phone: 416-244-2402-2132
Email: a.brathwaite@brunel.net
Website: www.brunel.net

Brunel's life sciences division focuses on delivering staffing, contracting & payroll solutions globally. From individual specialists to entire teams, we're passionate about finding the perfect match for our clients and specialists. Our expertise lies in the areas of Clinical, Medical, Regulatory, QA, PV & commercial. As partners of some of the world's largest pharmaceutical companies, we collaborate closely with them to find the most cost efficient & effective solutions to meet their needs.

BSI
Booth: 545
Contact: Jan Nielsen
Phone: 41-564841622
Email: jan.nielsen@bsi-software.com
Website: www.bsi-software.com/us-en/home.html

BSI Business Systems Integration AG, a Swiss corporation founded in 1996, offers a full-service eClinical suite (cloud or on-premise) including a complete Clinical Trial Management System (BSI CTMS). Global acting life science companies (pharma, biotech, CRO and SMO) rely on BSI products for their outstanding user experience, innovation and easy integration with other clinical systems.

Caligor Coghlan
Booth: 2639
Contact: Kerry Myers
Phone: 813-480-6557
Email: kerrymyers@calcog.com
Website: www.caligorcoghlan.com

Cambridge Healthtech Institute
Booth: 1021
Contact: Bethany Gray
Phone: 781-972-5400
Email: chi@healthtech.com
Website: www.healthtech.com

Cambridge Healthtech Institute (CHI) is the preeminent life science network for leading researchers and business experts from top pharmaceutical, biotech and academic organizations. CHI's portfolio of products includes Cambridge Healthtech Institute Conferences, Insight Pharma Reports, Cambridge Marketing Consultants, Barnett International, Cambridge Meeting Planners and Healthtech Publishing, which includes Bio-IT World, Clinical Informatics News and Diagnostics World.

IMAGING EXCELLENCE FROM
CANFIELD

Canfield Scientific, Inc.
Booth: 2419
Contact: Monet Sinclair
Phone: 973-434-1200
Email: monet.davis-sinclair@canfieldsci.com
Website: www.canfieldsci.com/

Canfield Scientific, Inc. is the global leader in photography services and products for clinical research and healthcare applications, including the pharmaceutical, biotechnology, cosmetics, medical, and skin care industries. Driven by a quality-focused mission to provide best-in-class imaging solutions and services, Canfield has achieved an industry-wide reputation for excellence and innovation throughout its product lines, industry services and customer support.

Cardiabase by Banook Group
Booth: 2104
Contact: Alexandre Durand-Salmon
Phone: 33-038-339-1010
Email: alexandre.durand-salmon@banookgroup.com
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) , Montreal (Canada) and Shanghai (China).

Cardinal Health
Booth: 1122
Contact: Todd Perkins
Phone: 847-887-1942
Email: todd.perkins@cardinalhealth.com
Website: www.cardinalhealth.com/en/services/manufacturer/pharma-manufacturer/cardinal-health-specialty-solutions/business-solutions/regulatory-consulting-services.html

For 40 years, Cardinal Health Regulatory Sciences (CHRS) has assisted global companies with the development of pharmaceutical, biotechnology and medical device products. Our industry- and FDA-trained regulatory consultants provide expertise throughout the entire product development continuum to help companies get their products to market quickly and keep those products on the market.

Cato Research LLC
Booth: 645
Contact: Jessica Bliven
Phone: 919-361-2286
Email: jbliven@cato.com
Website: www.cato.com

Cato Research (CATO) is an international regulatory and clinical contract research organization (CRO) that has been delivering successful outcomes for its clients since 1988. CATO has played a significant role in over 50 successful marketing applications. Our highly talented and experienced international team offers services from preclinical through IND (or equivalent), clinical development, and marketing approvals to Phase 4 postmarketing research. Contact our experts to learn more!

Celerion
Booth: 1548
Contact: Melody Huang
Phone: 402-476-2811
Email: melody.huang@celerion.com
Website: www.celerion.com

Celerion, a global leader in early clinical research services, offers the unique combination of medical expertise, clinical operations experience and scientific excellence giving you the confidence to make fast, accurate decisions about your development path. We provide clinical development services from Phase 1-2b, including patient dose response studies, cardiovascular safety and product labeling studies. We offer data management, site monitoring, biostatistics, and bioanalytical services.

Center for Information and Study on Clinical Research Participation (CISCRP)
Booth: 1142
Contact: Jim Keen
Phone: 617-725-2750
Email: jkeen@ciscrp.org
Website: www.ciscrp.org

The Center for Information and Study on Clinical Research Participation (CISCRP) is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process. CISCRP is committed to engaging and building relationships among members of the public, clinical research volunteers, and clinical research professionals.

CGI
Booth: 1939
Contact: Che Dildy
Phone: 484-653-8240
Email: che.dildy@cgi.com
Website: www.cgi.com

CGI is one of the largest IT and business process services providers in the world with a deep commitment to providing innovative services and solutions. CGI works with life sciences companies from early stage development, to data capture, to regulatory submission and even late stage development. Through our deep industry expertise, we help pharma, biotech, and medical device firms drive digital transformation for patient-centered care. For more information, visit cgi.com/en/life-sciences

Chiba University Hospital
Booth: 2642
Contact: Hideki Hanaoka
Phone: 81-43-226-2737
Email: hanaoka.hideki@faculty.chiba-u.jp
Website: www.chiba-crc.jp/

Chiba University Hospital is eager to carry out clinical research with new medication/treatment/etc. Projects on going are nationwide and global studies. ARO of Chiba University Hospital has many Medical Doctors, Project Managers, CRAs, Data Managers, Biostatisticians, CRCs, Pharmacists with more than 100 staff. Chiba University Hospital is recognized as one of Core Hospitals on Medical Law for clinical research. We are at the key position of multi-sites clinical studies.

Ciox Health
BS11
Contact: Julie Krommenhoek, SVP Life Sciences
Phone: 800-737-2585
Email: Arika.Wilkerson@cioxhealth.com
Website: www.cioxhealth.com

Ciox connects the right real-world data with the right researcher at the right time. Ciox is a health technology company dedicated to significantly improving U.S. health outcomes by transforming clinical data into actionable insights. Learn more about our Digital Patient Clone™ at CioxHealth.com

Clariness
Booth: 2019
Contact: Daniela Zierke
Phone: 908-219-6131
Email: sales@clariness.com
Website: www.clariness.com/

Clariness's global reach accelerates your study's enrollment in all study countries. With 13 years of patient recruitment and engagement experience, we quickly and cost effectively find well qualified subjects that sites will enroll. Our ClinLife technology is live in 45 counties and has been used by thousands of sites. Our Enrollment Management Center, staffed by 70+ Clariness employees who speak 29 languages, is the key to success. They help sites convert referrals to randomizations.

ClinCapture
Booth: 1051
Contact: Alexia Chalita
Phone: 800-987-6007
Email: marketing@clincapture.com
Website: www.clincapture.com

ClinCapture provides a powerful eClinical platform that enables sponsors and CROs to rapidly build and deploy studies, lower clinical trials costs, and streamline data capture processes. Offering a host of private cloud solutions, ClinCapture's technologies help advance the evaluation and development of drugs, biologics, and devices that demonstrate promise for the diagnosis and/or treatment of a wide range of diseases or medical conditions. For more information, visit clincapture.com.

Clindata Insight Inc
Booth: 934
Contact: Mylinh Paolieri
Phone: 925-320-7600
Email: mpaolieri@clindatainsight.com
Website: www.clindatainsight.com

Premier biometrics consulting firm specializing in biostatistics, statistical programming, CDISC implementation, clinical data management, big data for life science, and talent solutions.

ClinDatrix, Inc.
Booth: 1745
Contact: Brian Murphy
Phone: 949-428-6605
Email: brian.murphy@clindatrix.com
Website: www.clindatrix.com

ClinDatrix is committed to providing world class, full service clinical research capabilities and expertise to the biotechnology, medical device, and pharmaceutical industries. Partnering with its clients, ClinDatrix manages, monitors, collects, validates, analyzes, reports, and delivers quality global clinical data with efficiency and accuracy. The company offers pre-clinical and Phase I through Phase IV services to drug developers and pre-IDE, IDE and 501K support to device innovators.

ClinEdge, LLC
Booth: 1145
Contact: Simonne Valdez
Phone: 857-496-0054
Email: simonne@clin-edge.com
Website: www.clin-edge.com

ClinEdge and BTC Network provide a full range of clinical and outsourced business services to clinical research sites, pharmaceutical companies and CROs. Together, ClinEdge & BTC Network are comprised of: two global networks of research clinics with over 1,000 physician investigators, a division of site financial services, and a division of patient recruitment/retention services, which includes online advertising, patient travel services, and an in-house call center, among other services.

Clinerion
Booth: 2716
Contact: Diana Aghekyan
Phone: 41-61-865-60-60
Email: diana.aghekyan@clinerion.com
Website: www.clinerion.com/index.html

Clinerion's medical data analytics radically improves efficiency in patient recruitment, increases effectiveness in clinical research and accelerates drug development to ensure a faster availability of medicines. Our partner hospitals gain access to leading-edge sponsored trials; our life sciences company clients save time and costs. Clinerion's platform also generates data for real-world evidence and market access for precision medicines for rare and orphan diseases.

Clinical & Contract Research Association (CCRA)
Booth: 2553
Contact: Sue Dilks
Phone: 44-116-271-9727
Email: mail@ccra.org.uk
Website: www.ccra.org.uk

The Clinical and Contract Research Association (CCRA) provides a gateway to expertise in the clinical research, and other contract services, sector in the UK and Europe. It demands the highest standards of its members, some of whom will be showcased on its booth. CCRA offers international membership to non-UK companies in the sector who share the same ideals and who seek the benefit of being profiled on its busy website and having easy access to other members with a view to collaboration.

Clinical Ink
Booth: 2537
Contact: Jessica Romero
Phone: 800-301-5033
Email: jessica.romero@clinicalink.com
Website: www.clinicalink.com

Founded in 2007, Clinical Ink® is transforming clinical development with innovative technologies that make clinical research easier for sites, sponsors and patients. Clinical Ink's SureSource® platform directly captures eSource data and documents and improves patient engagement while streamlining clinical development. Clinical Ink maintains offices in Winston-Salem, NC, and Philadelphia, PA.

Clinical Research Malaysia
Booth: 2617
Contact: Audrey Ooi
Phone: 60-379315566
Email: audrey.ooi@clinicalresearch.my
Website: www.clinicalresearch.my

Established by Malaysian Ministry of Health in 2012, Clinical Research Malaysia exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy & reliable end-to-end clinical research support for quality studies. Our innate understanding of the local clinical research landscape with the international standards of operations coupled with fundamental backing of the government ministries provide us an incomparable advantage.

Clinical Resource Network
Booth: 931
Contact: David Iannucci
Phone: 919-863-4110
Email: diannucci@crnspg.com
Website: solomonpage.com/crn/

Clinical Resource Network (CRN), a division of Solomon Page, specializes in developing and customizing resourcing solutions for a range of clients throughout North America and Europe—from biotechs and CROs to major pharmaceutical and device companies. With a focus on cultivating long-term relationships, CRN has built a deep network of candidates, contacts, and sources across many disciplines and all major therapeutic areas.

Clinipace
Booth: 1605
Contact: Tara Wasenius
Phone: 919-224-8800
Email: tara.wasenius@clinipace.com
Website: www.clinipace.com/

Clinipace is a global, full-service CRO with a CHALLENGE ACCEPTED approach. We are collaborative and flexible, and provide personalized services and solutions, local regulatory expertise and therapeutic leadership for your drug discovery projects.

Clinithink Ltd
Booth: 2549
Contact: Taryn Springhall
Phone: 978-296-5275
Email: taryn@evoluu.com
Website: clinithink.com/

Founded in 2009, Clinithink is a market leading Clinical Natural Language Processing (CNLP) software solution provider that gives life sciences organizations and healthcare providers coveted access to valuable unstructured clinical narrative found in patient medical records. We value data-driven innovation in healthcare and have a proven track record of helping our clients and partners solve complex challenges with existing data.

CluePoints SA
Booth: 1846
Contact: Gemma Telfer
Phone: 617-576-2005
Email: gemma.telfer@cluepoints.com
Website: www.cluepoints.com/

CluePoints is the premier provider of Risk-Based Study Execution (RBx) and Data Quality Oversight Software. Our products utilize comprehensive statistical algorithms to determine the quality, accuracy, and integrity of clinical trial data both during and after study conduct. Aligned with guidance from the FDA, EMA, and ICH E6 (R2), CluePoints® is deployed to support central and on-site monitoring, medical review, quality risk management and to drive a holistic Risk-Based strategy in all trials.

Cmed Group Ltd
Booth: 1507
Contact: Claudia Cernea
Phone: 919-595-6900
Email: ccernea@cmedgroup.com
Website: www.cmedresearch.com

Cmed is a technology-led CRO that specializes in oncology, immuno-oncology, cell and gene therapy and other specialty therapeutics. Our experienced professionals provide full CRO services, functional data management and analysis. We also developed encapsia®, a new generation data suite using a single data platform for capture, management and analysis of clinical trial data. The cloud based system provides analytics of live trial data for faster and better informed decisions, saving time and cost.

CMIC HOLDINGS Co., Ltd.
Booth: 1131
Contact: Mizuho Arai
Phone: 81-3-6779-8024
Email: mizuho-arai@cmic.co.jp
Website: www.cmic-holdings.co.jp/e/

CMIC Group is the largest clinical CRO in Japan, providing comprehensive services in drug development, clinical site management, clinical to commercial GMP manufacturing, regulatory consulting and contract sales. We can help pharmaceutical, biotech and medical device companies to enter Japan market, to conduct clinical trials in Asia, or to bridge your drug development needs between the US and Japan.

CNS Healthcare
Booth: 2619
Contact: Brian Hunter
Phone: 407-903-1680
Email: bhunter@cnshealthcare.com
Website: www.cnshealthcare.com/

We are dedicated clinical research sites specializing in medical and CNS trials. With sites in Orlando, Jacksonville, and Memphis, we offer access to diverse patient populations and have multi-specialty affiliations. For over 2 decades, our investigators have worked with hundreds of compounds across a wide range of indications. The data we've supplied has resulted in 68 FDA approvals and millions of patient lives made better. Stop by to find out how we can put our experience to work for you.

Cognitive Research Corporation
Booth: 722
Contact: Thomas Hochadel
Phone: 727-897-9000
Email: tomhochadel@cogres.com
Website: www.cogres.com

CRC is a full-service CRO specializing in CNS and early phase research. CRC also has proprietary technologies, including CogScreen and the industries most advanced Driving Simulator (CRCDS-MiniSim), to evaluate the e_ects of medications on cognition and driving performance in both healthy and patient populations. CRC has provided comprehensive, flexible, quality-driven, and cost-effective services for 70+ sponsors on hundreds of phase I-IV single- and multi-center projects.

Cognizant
Booth: 2221
Contact: James J. Lee
Phone: 201-801-0233
Email: inquiry@cognizant.com
Website: www.cognizant.com/life-sciences

Cognizant is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Our Life Sciences business unit serves the top 30 global pharmaceutical companies, 9 of the top 10 biotech companies, and 12 of the top 15 medical device companies. Visit us at www.cognizant.com/life-sciences

Comprehend Systems
Booth: 2337 | BS9
Contact: Julie Peacock
Phone: 650-521-5449
Email: jpeacock@comprehend.com
Website: www.comprehend.com

Comprehend's cloud applications and consulting services deliver actionable risk and performance insights across studies, systems, sites, and vendors. Our Clinical Intelligence Solutions help sponsors and CROs unify, monitor, and analyze data to reduce risk, achieve milestones, and cut costs. As a trusted partner, Comprehend speeds the time to quality results.

Court Square Group/RegDocs365
Booth: 1012
Contact: Keith Parent, CEO
Phone: 413-746-0054
Email: sales@courtsquaregroup.com
Website: www.courtsquaregroup.com

RegDocs365 is a qualified SharePoint offering with the DIA EDM and eTMF reference models on a per user per month basis so that anyone regardless of size can have an audit ready infrastructure for validated applications. CSG provides our ARCC (Audit Ready Compliant Cloud) environment as the platform for RegDocs365 and we also offer our Validated Disaster Recovery and Validated Long Term Archiving solutions. We offer a full range of submission services using cloud based eCTD systems.

Covance Inc.
Booth: 1921
Email: covance.inc@covance.com
Phone: 888-268-2623
Website: www.covance.com

Covance Inc., the drug development business of Laboratory Corporation of America Holdings (LabCorp) headquartered in Princeton, New Jersey, USA, is the world's most comprehensive drug development company, dedicated to advancing healthcare and delivering Solutions Made Real®. Information on Covance's solutions can be obtained through its website at www.covance.com

CPi Global CRO
Booth: 816
Contact: Lee King M.Ed.
Phone: 910-200-5235
Email: lking@cpiglobalcro.com
Website: www.cpiglobalcro.com

CPI Global is a contract research organization committed to ensuring drugs and treatments that can truly make a difference are given the best chance to do so acknowledged by our partners, patients and employees as the People-First CRO.

CRF Bracket
Booth: 1305
Contact: Briana Dunham
Phone: 267-467-1522
Email: briana.miller@crfhealth.com
Website: www.bracketglobal.com

CRF Bracket provides life science companies with patient-centric technology for clinical research including electronic clinical outcome assessments (eCOAs), eConsent, patient engagement, interactive response technology (IRT), clinical supply forecasting and management, and endpoint quality analytics and services. In 20 years the company has delivered solutions to over 4,000 global clinical trials.

CROèe Inc.
Booth: 2644
Contact: Mohammad Imran
Phone: 81-3-5953-2108
Email: imran@croee.com
Website: www.croeeglobal.com

CROee Inc provide proprietary services to pharmaceutical companies and CROs to facilitate the identification, selection and management of human subjects for clinical trials in Asian countries mainly Japan, China, Korea, Taiwan and Malaysia. (culturally adaptive patient recruitment service) One of the proprietary product is "The Seikatsu-Kojo" Patient Database of 800,000+ categorized by medical history, that allows for targeted eligibility searches to recruit participants.

CROS NT
Booth: 1448
Contact: Mary Wieder
Phone: 919-929-5015
Email: info@crosnt.com
Website: www.crosnt.com

Founded in 1992, CROS NT is a global CRO with a mission to to enhance the clinical research and development value chain through data-driven expertise, solutions and technology. Focused on biometrics, services include data management, biostatistics and programming and medical writing - supported by industry-leading technologies and eClinical solutions including data visualization, clinical analytics, EDC, eCOA, IVR, wearables and data anonymization.

CRScube America Inc.
Booth: 1849
Contact: Juny Kim
Phone: 240-499-2854
Email: junykim@crscube.co.kr
Website: www.crscube.io

CRScube America is an e-Clinical Solution provider company. All our cube-Solution is in-house developed and is in a one-platform system. Our solution has been deployed and used more than 1,200 trials of any phase or therapeutic area. cubeCDMS Key Features -External data uploads (DICOM files, central lab data) -Medical coding (WHODD, ATC Index) -Data management and SDV tracking capabilities -Annotated CRFs and subject PDFs -ODM exports -Dataset downloads (SAS, Excel, XPT, CSV) -21 CRF Part 11 compliant

CSOFT International Ltd.
Booth: 631
Contact: Mina Hostage
Phone: 415-889-8989
Email: Mina.Hostage@csoftintl.com
Website: www.csoftintl.com

CSOFT International is a leader in global communications services, providing turnkey solutions for companies facing the challenges of engaging customers and markets across linguistic and cultural barriers. CSOFT's Life Sciences Business Unit, MedL10N, leads the way in providing the highest quality language services to these demanding industries. We understand the medical, pharmaceutical, and healthcare business and regulatory requirements. With CSOFT, you can be confident that your brand, message, and content will be received by your target audience the way you had intended.

CSSi Global Patient Recruitment
Booth: 1341
Contact: Chris Trizna
Phone: 443-308-5801
Email: ctrizna@CSSiEnroll.com
Website: www.CSSiEnroll.com

CSSi is a global full-service patient recruitment and retention company that focuses on providing customized services to help sites maximize their enrollment. Led by our team of Local Enrollment Specialists, CSSi is able to reduce the costs and timelines associated with recruitment and retention of subjects for clinical studies.

CTI Clinical Trial & Consulting Services
Booth: 1030
Contact: Allison Schroeder
Phone: 513-598-9290
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.

Cubixx Solutions
Booth: 822
Contact: Glenda Womack
Phone: 469-400-6654
Email: glenda.womack@cubixxsolutions.com
Website: www.cubixxsolutions.com/

Innovative Cubixx® Solutions provides continuous temperature monitoring and inventory management of specialty pharmaceuticals and clinical trial medication, using RFID technology, for hospital pharmacies, distributors, physicians, veterinary pharmacies and pharmaceutical and medical device manufacturers located worldwide.

Cunesoft
Booth: 2448
Contact: James Nichols
Phone: 609-955-3468
Email: info@cunesoft.com
Website: www.cunesoft.com/

Cunesoft specializes in providing intelligent software for the life sciences industry by offering innovative ways to automate regulatory processes that result in rapid ROI. For regulatory users, we provide a single source of regulatory truth, that gives them an end to end solution of all their regulatory needs. Our data mining software is used for regulatory compliance, data migration, labelling, safety and more! Cunesoft is the only provider who has trained AI models offering > 80% accuracy.

Cytel
Booth: 1454
Contact: Sean Cronin
Phone: 617-661-2011
Email: support@cytel.com
Website: www.cytel.com

Cytel is the world's largest biostatistics CRO, providing software solutions for the design and analysis of clinical trials, and data-focused clinical research services. We help our pharmaceutical, biotech and medical device customers improve their clinical success rates through optimal study design, effective data management, and accurate statistical analysis. www.cytel.com

Dacima Software, Inc
Booth: 2154
Contact: Dr. John Podoba
Phone: 514-656-9199
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 Management 365
Booth: 2744
Contact: Anna Ageeva
Phone: 7-(812)-4267307
Email: anna.ageeva@datamanagement365.com
Website: datamanagement365.com

DM 365 is an innovative software development company with profound experience in clinical trials. We provide data management services on our own EDC & IWRS platform – MainEDC™ that was created by our developers. MainEDC™ is a reliable (GCP E6 R2, GA_P 5, 21 CFR Part 11, GDPR, HIPAA compliant; Private cloud hosting (SaaS)), convenient (integrated EDC & IWRS, all types of randomization and dose regimens, drug supply, eCRF builder, blockchain technology in the audit trail) and functional solution.

DataArt
Booth: 917
Contact: Daniel Piekarz
Phone: 212-378-4108
Email: Daniel.Piekarz@dataart.com
Website: www.dataart.com/industry/healthcare-and-life-sciences

DataArt is a global technology consultancy that designs, develops and supports unique software solutions, helping clients take their businesses forward. Recognized for their deep domain expertise and superior technical talent, DataArt teams create new products and modernize complex legacy systems that affect technology transformation in select industries. DataArt has earned the trust of some of the world's leading brands and most discerning clients, including Charles River Laboratories, Nasdaq.

Datapharm Australia Pty Ltd
Booth: 424
Contact: Luke Edington
Phone: 61-(0)408-206-011
Email: luke.edington@datapharmaustralia.com
Website: www.datapharmaustralia.com

Run your clinical trials in (or from) Australia: • Up to 43.5% 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 Aussie support

DATATRAK International, Inc.
Booth: 2623
Contact: James Herold
Phone: 440-443-0082-112
Email: james.herold@datatrak.com
Website: www.datatrak.com

Datatrak is a SaaS cloud-based technology company supporting clinical research in the Life Sciences industry. We work with Pharmaceutical, Biotech, CRO, Device and Diagnostic companies to make informed decisions faster using our cutting edge technologies. Our innovative enterprise system architecture allows us to match or exceed our competitor's technology, at a portion of the price. Products include Business Intelligence, CTMS, EDC, IRT, Coding, Image Data Capture and Adjudication and ePRO.

DAVA Oncology
Booth: 711
Contact: Jim Montgomery
Phone: 281-475-9708
Email: jmontgomery@davaonc.com
Website: www.davaonc.com

DAVA Oncology's mission is to facilitate successful drug development through innovative solutions and services that accelerate the patient enrollment process. DAVA maximizes the recruitment potential of each investigator participating in a given study through peer to peer interactions with our team of clinically experienced medical oncologists and oncology professionals.

DBMS Consulting, Inc.
Booth: 804
Contact: Sunil G. Singh, CEO
Phone: 888-737-8819
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

Deep Intelligent Pharma
Booth: 513
Contact: Gao Shi
Phone: 86-186-002-0130-5

Deloitte
Booth: 1855
Contact: April Burrows
Phone: 617-610-8318
Email: apburrows@deloitte.com
Website: www2.deloitte.com/us/en/pages/consulting/topics/life-sciences-convergehealth.html?icid=converge_life-sciences

Life sciences companies continue to respond to a changing global landscape, and strive to pursue innovative solutions for patients. Deloitte's LS specialists understand the complexity of these challenges, and work with clients to drive progress and bring discoveries to life. We engage the breadth and depth of consulting services, plus the product development maturity of ConvergeHEALTH for comprehensive, integrated solutions to challenges and opportunities of the evolving health care ecosystem.

DIA

DIA **Booth: 1531**
Email: Americas@DIAglobal.org
Phone: 215-442-6100
Website: www.DIAglobal.org

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 MEDIA Studio **Booth: 1739**
Email: Americas@DIAglobal.org
Phone: 215-442-6100
Website: www.DIAglobal.org

Watch live interviews with DIAmond session speakers and other key opinion leaders on current topics of interest.

DIA Patient Scholars **Booth: 1538**
Contact: Debra Michaels
Phone: 215-442-6166
Email: Debra.Michaels@diaglobal.org
Website: www.DIAglobal.org

Each year, DIA facilitates attendance at the Global Annual Meeting for a limited number of patients and patient partners through the Patient Scholars program. The booth is a place to meet the 2019 Patient Scholars, as well as other patient representatives attending DIA 2019 and members of the DIA Patient Engagement Community. Come to learn about the many patient organizations and communities represented at the meeting and exchange ideas for collaboration throughout the medical product life cycle.

DiagnoSearch Life Sciences **Booth: 1223**
Contact: Kevat Joshi
Phone: 91-22-6777-6300
Email: kevat.joshi@diagnosearch.com
Website: www.diagnosearch.com

DiagnoSearch, a 23 year old full-service clinical trial company, leverages its rich experience & technology to offer innovative Risk Management & Central Monitoring using Wide-Angle-Data, a fully integrated data sciences platform. Intuitive customized algorithms, smart data reduction, advanced analytics, machine learning & powerful visualization enable efficient, comprehensive data review, real-time risk management, signal detection & adjudication & trend analysis and thus improve data quality.

DLRC Ltd **Booth: 2548**
Contact: Dianne Lee
Phone: 44-146-237-2472
Email: dianne.lee@dlrc.co.uk
Website: www.dlrc.co.uk/

DLRC - Regulatory Consultancy - Strategic Expertise and Operational Excellence The pathway to market can often be complex but we can simplify your journey. With more than 450 years of combined experience we provide a full range of Regulatory services from strategic advice in early development to compilation and management of regulatory submissions throughout lifecycle. Our innovative strategies and collaborative interactions with regulatory authorities, dramatically increase the rate of approval.

dMed Biopharmaceutical Co., Ltd. **Booth: 530**
Contact: Zibao Zhang
Phone: 86-13918546055
Email: zibao.zhang@dmedglobal.com
Website: www.dmedglobal.com/index.aspx

dMed is providing professional full services to innovative biopharma and medical device companies in China and globally. We define ourselves as a "next generation" CRO committed to building China's best-in-class capability to deliver clinical services at global quality standards. Led by a seasoned team with deep global experience in MNC, dMed is uniquely positioned to leverage China's new regulatory framework to access the world's second largest market and help Chinese Biotechs expand globally

doLoop Technologies **Booth: 2608**
Contact: Jitesh Nagaria
Phone: 91-9869149962
Email: info@dolooptech.com
Website: www.dolooptech.com/

doLoop Technologies is a specialised AI product startup for clinical trial and healthcare data. Our solution Clinical NLP is an AI engine for Medical Writing and Medical Coding use cases. Our Clinical eBridge solution is an intelligent clinical data integration solution capable of real-time data integration from Oracle InForm, Medidata RAVE and OmniComm TrialMaster.

Dora Wirth (Languages) Ltd. **Booth: 2543**
Contact: Craig Brown
Phone: 44-20-7229-4552
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

Dot Compliance LTD. **Booth: 425**
Contact: Gal Haselkorn
Phone: 972-8-6527070
Email: gal@dotbcs.com
Website: www.dotbcs.com

DOT Compliance Suite is a cloud Quality and Compliance management solution for highly regulated industries, providing full customization and integration capabilities. DOT Compliance Suite contains industry's best practices as starting point for easier and cost effective deployment of large set of processes. Solution is compliant with strict industry standards and provided with Validation Package and Project validation services. DOT Compliance Suite is developed as a native Force.com application.

Drexel University Online, LLC **Booth: 1905**
Contact: John Alessi
Phone: 215-571-3905
Email: jja84@drexel.edu
Website: www.drexel.edu

Boasting renowned faculty and specialized curriculum designed for your career, Drexel University offers graduate-level online programs and certificates that address the need for formal training in clinical research administration and development, drug discovery and development, pharmaceutical research, biomedicine, pre-medicine, science, laboratory animal science, immunology, infectious disease, medical and healthcare simulation, and molecular medicine. Learn more at: Online.Drexel.Edu/DUCOM

Drug Development and Regulation **Booth: 833**
Contact: Xavier Luria
Phone: 34-629-213-841
Email: info@ddrmedic.com
Website: ddrmedic.com/

We have extensive experience with regulatory strategies and procedures in Europe both at the EMA and national regulatory agencies. The DDR team and its Network of experts successfully conduct regulatory applications (Orphans, Scientific Advice, CTA/IND, PIP/iPSP, SME designations and MAA/NDA) and Expedited Regulatory Pathways (PRIME, BTD). DDR has also regulatory expertise to support Medical Devices and In-vitro Diagnostics in Europe and to adapt all of them to the new Regulations.

DSG, Inc.
Booth: 2023
Contact: Jack Minster
Phone: 484-913-0210
Email: jminster@dsg-us.com
Website: www.dsg-us.com

DSG, Inc. is a leading global eClinical provider with a fully unified suite of innovative technology solutions and data management services for the global clinical research community. DSG's eClinical software platform provides competitive advantage that is cost effective with on time project delivery. DSG solutions have been used in thousands of clinical trials around the globe with our award-winning eCaseLink™ platform and DSG Designer for enterprise licensing.

DZS Clinical Services
Booth: 2037
Contact: Greg Ambra
Phone: 732-764-6970
Email: gambra@dzs.com
Website: www.dzs.com

DZS Clinical Services is a global CRO offering strategic support for clinical development, clinical operations, data analytics, medical affairs, pharmacovigilance and risk management. From Top 25 to small startups, our clients are biopharm and device sponsors from the public and private sectors, government agencies, universities and nonprofits. With over 30 years in the industry, we provide service flexibility and custom solutions covering a wide range of therapeutic areas and levels of support.

Early Access Care
Booth: 2416
Contact: Anne Cropp
Phone: 203-441-7938
Email: contact@earlyaccesscare.com
Website: www.earlyaccesscare.com

Early Access Care is a full-scale service provider for Expanded Access and Compassionate Use. We provide end-to-end solutions for pharmaceutical companies for single-patient or group (cohort) compassionate use. In addition to operational support, we provide consultative services for simple and complex programs. Expanded Access Protocol development and implementation is just one of our areas of expertise. Access Innovation creates value for our clients and enables compliance.

EastHORN Clinical Services in CEE, Ltd.
Booth: 1349
Contact: Cristina Tatareanu
Phone: 40-724353215
Email: cristina.tatareanu@easthorn.eu
Website: www.easthorn.com/

Founded in 2004, EastHORN is one of the leading CROs in Western, Central and Eastern Europe. With resources and offices in Spain, Italy, Germany, Austria and 17 countries in the CEE region, our experience is driven largely by the availability of patient populations in our regions and covers areas such as oncology, cardiology, gastroenterology, immunology, ophthalmology, rheumatology, nephrology, metabolic, central nervous system, women's health disorders, infectious disease and paediatrics.

EC Innovations (USA), Inc.
Booth: 753
Contact: Tyson Lake
Phone: 773-541-2174
Email: USA@ecinnovations.com
Website: www.ecinnovations.com

EC Innovations is a world-leading translation and localization provider with ISO 13485:2016, ISO 9001:2015, and ISO 1710:2015 certifications. For 21 years, EC Innovations has grown into 3 regional headquarters (Beijing, Budapest, Chicago) and a total of 11 strategic global offices, 5000 plus qualified linguists; offering full localization support into 120+ languages.

Eccolab Group Co
Booth: 525
Contact: Oliver MIGUEL
Phone: 800-616-1770
Email: OMIGUEL@ECCOLABGROUP.COM
Website: www.eccolabgroup.com

Eccolab Group is a central laboratory strategically located in Miami, FL and Tampa, FL. Since 2001, Eccolab has been providing accurate and expeditious safety and efficacy testing services to pharmaceutical developers and researchers. Our data management capabilities offer transparency, data lineage, and metadata management that are fully compliant with CFR 21 part 11. Our study data is maintained on an integrated ORACLE® platform, with REAL-TIME back-up and replicated on demand.

ECG, Inc.
Booth: 2636
Contact: Kate O'Reilly
Phone: 201-894-8200
Email: kate@ecglink.com
Website: ecghealthcare.com/

At ECG Healthcare, a division of ECG, we use our communication expertise to ensure that bad communication does not ruin good science and delay the timely approval of drugs, devices, and biologics. We provide a broad range of strategic communication services including preparing submission messaging, Advisory Committee and Oral Explanation presentations, and supporting Investigator Meetings, Advisory Boards, and more. We also provide complete meeting logistics, including off-site technology.

eClinical Solutions
Booth: 744
Contact: Sheila Rocchio
Phone: 508-594-6368
Email: srocchio@eclinicalsol.com
Website: www.eclinicalsol.com

eClinical Solutions helps life sciences organizations regain control of their data through intelligent software and technology-enabled services that are easy to use, fast to implement and provide users with meaningful insights and self-service access to their clinical data. More than 80 Life Sciences companies have selected eCS products and services to optimize clinical data flows, deliver high quality data streams and improve clinical decision-making.

EDETEK, Inc.
Booth: 2049
Contact: Jian Chen
Phone: 609-720-0888
Email: info@edetek.com
Website: www.edetek.com

EDETEK, Inc. is an innovative clinical solutions company that provides high-quality technology and services to pharmaceutical, biotechnology, and medical device companies. We utilize our clinical platforms, Panther CTMP™ and CONFORM™, to fulfill our clients' data engineering and business analytics needs. Our comprehensive metadata driven solutions offer unparalleled advantages in data quality, time to completion, and cost efficiency. Visit us at www.EDETEK.com.

EMB Statistical Solutions, LLC
Booth: 1136
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".

EMSI
Booth: 844
Contact: John Corcoran
Phone: 214-689-3620
Email: jcorcoran@emsinet.com
Website: www.emsinet.com/

EMSI supports life science companies with in-home biospecimen collection services essential for expanding patient access to lifesaving medical therapies. We alleviate the stress of complex studies for sponsors and participants, maximizing participation and compliance for studies large and small. From recruitment and data collection to post-marketing services and medical record retrieval/abstraction, we have the national coverage, experience and flexibility our clients require for study success.

endpoint
Booth: 1811
Contact: Alessandra Mongardi
Phone: 415-688-3713
Email: amongardi@endpointclinical.com
Website: www.endpointclinical.com

endpoint is the IRT partner you can trust to deliver innovative solutions to meet all your supply chain needs. For the past decade, our customer-obsessed team of professionals have been evolving our suite of technologies to help Sponsors achieve clinical trial success. Our solutions have proven to maximize the supply chain, minimize operational costs, and ensure timely and accurate patient dosing. endpoint is headquartered in San Francisco, Calif., with offices across the US, EU, and Asia.

EndPoint Technologies
Booth: 848
Contact: Alexa Bonanno
Phone: 855-254-0815
Email: alexa.bonanno@endpointtech.com
Website: www.endpointtech.com/

Our mission is to support pharmaceutical and biotechnology clients in the management and operation of medical affairs, including the delivery of quality medical information.

ENNOV
Booth: 2336
Contact: Chet Shemanski
Phone: 833-366-6887
Email: cshemanski@ennov.com
Website: www.ennov.com

With over 19 years' experience and more than 150 life sciences clients worldwide, Ennov provides the industry's most comprehensive, integrated, cost-effective and user-friendly solution suite available today. Our Quality, Regulatory, Clinical and Pharmacovigilance solutions integrate seamlessly with your business processes to improve efficiency, productivity and compliance. Ennov software is highly configurable and requires no IT skills to implement and maintain. Visit us at www.ennov.com.

EPS Holdings, Inc.
Booth: 1755
Contact: Askold Kozbur
Phone: 708-657-4321
Email: akozbur@epsgr.com
Website: www.eps-holdings.co.jp/en

EPS is a full-service CRO operating in Japan, China, USA, South Korea, Taiwan, Vietnam, Philippines, Singapore, Australia, Malaysia,, Indonesia, and Hong Kong. With over 6,000 staff, EPS Group Companies provide support to pharmaceutical, biotech, regenerative medicine, and medical device companies in Oncology, Cardiology, CNS and more. EPS also provides Site Management Organization, Clinical IT, Professional Call Center, pre-clinical supply, and Contract Sales Organization services.

ERT
Booth: 1231 | BS1
Contact: Jillian Tygh
Phone: 215-972-0420
Email: jillian.tygh@ert.com
Website: www.ert.com

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so its customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next. In 2018, ERT supported more than 60 percent of all FDA drug approvals. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.

EUDRAC Group
Booth: 951
Contact: Carole Pugh
Phone: 44-186-5670860
Email: carole.pugh@eudrac.com
Website: www.eudrac.com

EUDRAC is a regulatory affairs & pharmacovigilance consultancy based in UK, Germany & France. Our services to pharma & medical device companies extend through the development, registration, market launch & life cycle management phases, including e-CTD publishing. Our clients value our high quality work performed according to project timelines.

Eurofins
Booth: 1705
Contact: Jesse Gehris
Phone: 717-556-3870
Email: clinicaltrials@eurofins.com
Website: www.eurofinscentrallaboratory.com/

Eurofins Biopharma Services, Laboratory Testing is the largest, wholly owned network of BioPharma dedicated laboratories in the world. We offer the most integrated end-to-end solutions to help clients progress through the drug development cycle through a single, experienced provider. Our integrated solutions deliver the most comprehensive range of state-of-the-art analytical technologies with an expansive geographic reach in order to support our clients' drug development requirements.

European Medicines Agency (EMA)
Booth: 1541
Contact: Marie-Agnes Heine
Phone: 31-887817805
Email: Marie-Agnes.Heine@ema.europa.eu
Website: www.ema.europa.eu

The European Medicines Agency is a decentralised agency of the European Union, located in Amsterdam. It began operating in 1995. EMA 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 all 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.

Everest Clinical Research
Booth: 1845
Contact: Brian Wettlaufer
Phone: 905-752-5208
Email: brian.wettlaufer@ecrscorp.com
Website: www.ecrscorp.com

Everest Clinical Research is a Full Service CRO providing Clinical Operations, Data Management, Biostatistics, Statistical Programming, IRT (IWRS), Pharmacovigilance/Drug Safety, DMC/DSMB, Medical and Scientific Writing, and Regulatory Submission services to pharmaceutical, biotechnology, and medical device companies worldwide. We provide quality, customer-focus, and flexibility, working with many of the most advanced drugs in development today. Welcome to our corporate website www.ecrscorp.com

Evid Science

Booth: 2200
Contact: Matthew Michelson
Phone: 626-765-1903
Email: mmichelson@evidscience.com
Website: www.evidscience.com/

Evid Science unlocks the medical literature at the speed of A.I. Gather patient-level results across end points, therapy areas and interventions, in seconds. What used to take weeks of reading can now be done in a few clicks. Then export and share your data, generate and manage advanced content, or develop comparative analyses. Evid Science is your robotic research associate.

Evidence Partners Inc.

Booth: 1252
Contact: Marc Dufresne
Phone: 613-212-0051
Email: sales@evidencepartners.com
Website: www.evidencepartners.com

Evidence Partners is the developer of DistillerSR, the world's most advanced literature review software. DistillerSR is a fully compliant, transparent, and audit-ready solution that automates many of the manual tasks involved in the preparation of pharmacovigilance literature reviews. Our cloud-based software solutions are used globally by regulatory groups, government agencies, NGOs and academic institutions to accelerate high quality evidence-based research.

ExecuPharm, Inc.

Booth: 1519
Contact: Russell Bland
Phone: 484-804-2495
Email: rbland@execupharm.com
Website: www.execupharm.com/

ExecuPharm, a PAREXEL Company, is a Global Functional Service Contract Research Organization, who provides clinical research support services for the pharmaceutical industry, utilizing flexible models of service and technologies. ExecuPharm's distinctive business model incorporates a full service staffing model, services and technologies to support every aspect of a clinical study.

ExL Pharma

Booth: 1444
Contact: Andrew Sinetar
Phone: 212-400-6237
Email: asinetar@exlpharma.com
Website: www.exlpharma.com

ExL Pharma, a division of ExL Events, Inc., develops innovative, educational forums that serve the pharmaceutical community in the US, Europe, Asia and Latin America. Our primary sectors include: Pharmaceuticals, Biopharma, Biotechnology, CRO, Medical Devices, Academic Research Institutions. With over 65 pharmaceutical events a year, ExL Pharma has widely recognized global brands with the Digital Pharma Series, Medical Affairs Strategic Summit, CROWN and our Clinical Quality suite of events.

Express Scripts

Booth: 714
Contact: Ria Westergaard
Phone: 201-269-6071
Email: ria_westergaard@express-scripts.com
Website: lab.express-scripts.com/

Express Scripts provides pharmacy benefits and services for 83 million consumers. Chat with our Data & Analytic Solutions Team to learn how we'll work with you to fully leverage our robust access to data and differentiated analytical capabilities to drive better clinical insights and health outcomes, leading to more stakeholder value. Examples include RWD, product development and commercialization, custom analytics, clinical trial design, direct mail for patient recruiting, and RWE studies.

EXTEDO, Inc.

Booth: 2041
Contact: Thomas Kessler
Phone: 855-328-3500
Email: info@extedo.com
Website: www.extedo.com/

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

FDA Quality and Regulatory Consultants, LLC

Booth: 1101
Contact: Sean MacBean
Phone: 919-777-8850
Email: s.macbean@fdaqrc.com
Website: www.fdaqrc.com

FDAQRC is a global quality and regulatory consultancy firm founded in 2009. The global team is recognized as experts in QA and compliance providing expert advice to pharmaceutical, medical device and contract research organizations (CROs) in pre-clinical, clinical and commercialized sectors. Our team includes former US Food and Drug Administration (FDA) national experts, Field Investigators, Compliance Officers, and center personnel along with global industry experts and consultants.

Firma Clinical

Booth: 1949
Contact: Jennifer Mintz
Phone: 888-330-1726
Email: Jennifer.Mintz@firmaclinical.com
Website: www.firmaclinicalresearch.com/

Firma is a boutique contract research organization that believes a patient-centric approach is the key to unlocking positive outcomes in the drug and medical device development process. Using an integrated suite of specialized solutions, Firma makes the clinical trials process easier and more valuable for patients, and produces higher-quality data for sites and sponsors.

Flex Databases

Booth: 1037
Contact: Nadya Morozova
Phone: 844-335-1270
Email: events@flexdatabases.com
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 combines traditional features related to management of clinical trials (CTMS, TMF, Pharmacovigilance) with the functionality for running pharma companies and CROs processes (HR & LMS, resource utilization, time sheets) as well as a capability to manage financial data, invoicing and expenses (PM & Budgeting, Subject Tracking & Invoicing).

FMD K&L

Booth: 724
Contact: Catherine Ditzler
Phone: 215-283-6035
Email: market@klserv.com
Website: www.klserv.com

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.

Focus Investment Banking
Booth: 2606
Contact: Jim Hawkins
Website: www.focusbankers.com

Food and Drug Administration CDER/DDI
Booth: 1536
Contact: Danielle Cook
Phone: 240-402-7763
Email: Danielle.Cook@fda.hhs.gov
Website: www.fda.gov/

"The FDA's Center for Drug Evaluation and Research (CDER) makes sure that safe and effective drugs are available to improve the health of the American people. CDER ensures that prescription and over-the-counter drugs, both brand name and generic, work correctly and that the health benefits outweigh known risks."

Frontage Laboratories, Inc.
Booth: 1437
Contact: Bryan Newman
Phone: 484-202-6442
Email: BNewman@frontagelab.com
Website: www.frontagelab.com

Frontage is a global CRO focused on early stage drug development, delivering services including bioanalysis, DMPK, Phase I-IIA clinical studies, and CMC product development. Our team of dedicated scientists and skilled business professionals across multiple business units gives us the ability to maneuver the drug development process in a timely and cost-effective manner. We work with small and large molecules for novel biopharmaceuticals as well as generic-equivalent and consumer products.

GCE Solutions
Booth: 1625
Contact: Shweta Shukla
Phone: 309-807-5879
Email: shweta.shukla@gcesolutions.com
Website: www.gcesolutions.com/

GCE is a CRO serving in the biometrics function. We serve clients in Pharmaceutical, Biotechnology and Medical Device industries on various stages, diverse therapeutic areas and different aspects of clinical trial Our Services-SAS Programming, Biostatistics, Data Management, DMC Administration, Data Visualization, Real World Data, Medical Writing, CDISC Implementation, Clinical IT, Strategic Consulting Our Service Model: FSP|FPO|SCS|Fusion Delivery Model Our Locations: USA, Europe, India & Mexico

Generis
Booth: 900
Contact: James Kelleher
Phone: 877-244-2022
Email: james.kelleher@generiscorp.com
Website: www.generiscorp.com

Generis provides leading-edge software for content management systems including Box, Documentum, SharePoint, Alfresco and Oracle WebCenter. CARA, our flagship product, is a fast, friendly and highly configurable user interface making it simple for users to create, access, search, review, approve and publish information. Over 400,000 users from nearly 60 companies use CARA worldwide, including 8 out of the 10 largest Life Science companies. For more information visit: http://generiscorp.com

German Language Services
Booth: 523
Contact: Maia Costa
Phone: 206-938-3600
Email: maia@germanlanguageservices.com
Website: www.germanlanguageservices.com

We are particularly known for our commitment to quality and for producing accurate, well-written translations. Specializing in only one language pair sets us apart from other multilingual agencies, and allows us to maintain a much greater measure of quality assurance. Our research and in-house quality control are meticulous and comprehensive. We know that every client is different, and we know how to assemble the right team of professionals for each individual project.

Global Instrumentation, LLC
Booth: 720
Contact: Doug Linquest
Phone: 315-727-6659
Email: doug.linquest@gmail.com
Website: www.globalinstrumentation.com

The Global Instrumentation M12A Enterprise Platform streamlines the flow of Holter, ECG & ABP data to enable faster data delivery, distribution and analysis across sites. The system provides investigators & trial managers with a single unified system of acquisition devices and data management tools for all cardiac safety tests. The M12A platform can scale for concurrent studies while ensuring seamless data exchange to a centralized location and the export of FDA-HL7 compliant data.

GlobalCare Clinical Trials, LLC
Booth: 2436
Contact: Gail Adinamis
Phone: 847-282-3280
Email: gadinamis@globalcarect.com
Website: www.globalcarect.com

GlobalCare conducts study visits (eg. blood draws, drug admin) at patients' homes or other convenient locations in over 60 countries 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. GlobalCare also provides a variety of site support services.

Govig & Associates
Booth: 2656
Contact: Erin Dombey
Phone: 480-718-6127
Email: erin.dombey@govig.com
Website: www.govig.com

Since 1978, Govig & Associates is an Executive Recruitment firm that specializes in Retained Search for the Pharmaceutical and BioTech Industry. Our emerging and midsized clients retain us repeatedly when they face timing challenges, knowledge and network gaps, resource scarcity or scope and reputation challenges in the employment market. We put our tenure, relationships and expertise to work so you can meet your deadlines, keep your promises to investors and build a successful organization.

Grant Thornton LLP
Booth: 1415
Contact: Lisa Walkush
Phone: 610-659-9277
Email: Lisa.Walkush@us.gt.com
Website: www.gt.com

Grant Thornton's Life Sciences practice - consulting, audit, tax services - can help you achieve a competitive advantage, now and into the future. Our depth of industry knowledge, combined with our commitment to client service, make us the firm of choice for life sciences companies.

Greenphire
Booth: 2111
Contact: Amy Sitnick
Phone: 215-609-4365
Email: amy.sitnick@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 801.

GxPeople
Booth: 1200
Contact: Nadia Di Meo
Phone: 44-20-363-7439-3
Email: nadia.dimeo@gxpeople.com
Website: www.gxpeople.com/

GxPeople - Senior QA and QC talent search for the global life sciences industry. GxPeople is a global leader in the provision of senior Quality professionals across the pharmaceutical, biotechnology & medical device industries. As the only global search agency to specialise exclusively in this area, we are uniquely positioned to identify senior Quality leaders across all GxP areas internationally. Our method can be described as ethical talent search with a commitment to 'right first time' results

Hangzhou Tigermed Consulting Co., Ltd.
Booth: 1405
Contact: Jenny Zhang
Phone: 86-10-65889599
Email: jenny.zhang@tigermed.net
Website: www.tigermed.net

HCL America Inc.
Booth: 1455
Contact: AbhishekSingh
Phone: 91-120-258-6417
Website: www.hcltech.com/

HCL Technologies is a next-generation global technology company that helps enterprises reimagine their businesses for the digital age. Our technology products, services and engineering are built on four decades of innovation, with a world-renowned management philosophy, a strong culture of invention and risk-taking, and a relentless focus on customer relationships. With a worldwide network of R&D, innovation labs and delivery centers, and 124,000+ 'Ideapreneurs' working in 41 countries.

HealthiVibe LLC
Booth: 935
Contact: Tammy Calvert
Phone: 866-961-6400
Email: Tammy.Calvert@healthivibe.com
Website: www.healthivibe.com

HealthiVibe offers a systematic, evidence-based process for companies to engage the patient at every stage of the pharmaceutical project lifecycle: from clinical trial design through post-approval activities and research. We offer full-service patient initiatives, with a focus on patient insights and communication, to help biopharmaceutical companies create more patient-centered programs. For more information, please visit us online at www.HealthiVibe.com.

Huron Consulting Group
Booth: 1308
Contact: Laura Waite
Phone: 44-1480300300
Email: lwaite@huronconsultinggroup.com
Website: www.huronconsultinggroup.com/industry/life-sciences

Huron's life science practice is part of Huron's continuum of healthcare offerings supporting the development & commercialization of pharmaceutical products & services. Discover how we can help you to harness new developments & stay ahead of the curve: Corporate & Business Unit Strategy, Research & Development Portfolio Strategy, MA & Pricing, Business Development Strategy, Asset Commercial Strategy, Organization & Innovation Development, Drug Safety & Regulatory, Digital Solutions & Technology

hyperCORE International
Booth: 2722
Contact: Van Johnson
Phone: 469-854-0294
Email: vanjohnson@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 three Urgent & Family Care centers, 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.

IBM Watson Health

IBM Watson Health
Booth: 1123 | BS4 & BS5
Contact: Robin Cantey
Phone: 800-426-4968
Email: Robin.Cantey@IBM.com
Website: www.ibm.com/life-sciences

IBM Watson Health aspires to improve lives and give hope by delivering innovation, through data and cognitive insights, to address the world's most pressing health challenges. The organization aims to provide customers with the technology and expertise they need to power thriving organizations, support vibrant communities, and solve health challenges for people everywhere. For more information on IBM Watson Health, visit: http://www.ibm.com/life-sciences

ICON plc
Booth: 2121
Contact: Laura Saklad
Phone: 353-1-291-2000
Email: laura.saklad@iconplc.com
Website: www.iconplc.com

ICON plc is a global provider of outsourced development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programmes that support clinical development. With headquarters in Dublin, Ireland, ICON currently operates from 97 locations in 38 countries and has approximately 13,380 employees. Further information is available at ICONplc.com.

IDDI
Booth: 1151
Contact: Dominique GRISARD
Phone: 984-227-8599
Email: dominique.grisard@iddi.com
Website: www.iddi.com

Biostatistical Services and eClinical services for phase I - IV clinical trials since 1991. Trial Design - Randomization - Data Management - Biostatistics - Medical Writing. IDDI is as a major service provider in the design, collection, analysis and reporting of clinical data combining expert methodology in biostatistics (incl. Biomarkers validation and Support to IDMCs) with integrated technology (IRT and coding integrated to EDC). IDDI has contributed to 20 EMA/FDA market approvals.

Ideagen
Booth: 1544
Contact: Sales
Phone: 44-(0)-1629-699100
Email: info@ideagen.com
Website: www.ideagen.com

Ideagen provides quality, safety, audit, performance and risk management software and expertise to help the world's leading brands achieve operational excellence, ensure compliance and prevent undesirable events. Ideagen's solutions for document collaboration and control, PleaseReview and Q-Pulse, make reviewing, co-authoring and editing documents more effective and efficient, from change requests through review, acceptance or rejection of changes, approval, distribution and acknowledgement.

Imperial Clinical Research Services
Booth: 1812
Contact: Kari Stuart
Phone: 800-777-2591
Email: kstuart@360blue.net
Website: www.imperialcrs.com

Imperial Clinical Research Services optimizes clinical trial outcomes through evidence-based patient engagement programs and robust site support. Our services cover every step from protocol design to study closeout, including equipment and ancillary supplies, patient engagement, clinical translation management, and study and materials. We have decades of industry experience and efficiently deliver our products and services into more than 110 countries every year.

Industry Standard Research
Booth: 1546
Contact: Kevin Olson
Phone: 919-301-0106-705
Email: info@ISRreports.com
Website: www.ISRreports.com

Industry Standard Research (ISR) is a full-service market research organization serving the pharmaceutical and pharmaceutical services industry. ISR leverages our industry experience, market research rigor, and our global proprietary Health Panel of over 1,500 healthcare and pharmaceutical professionals to provide our customers with leading-edge off-the-shelf market intelligence and custom market research services.

Inference Inc.
Booth: 723
Contact: Kalyan Ghosh
Phone: 484-505-6891
Email: info@inferenceinc.com
Website: www.inferenceinc.com

Inference Inc. provides biometrics consulting and operational services for clinical development of drugs, biologics, vaccines, and devices. Leveraging our combined 100+ years of industry experience in all phases, we offer high-quality, cost-effective, personalized data management, programming and biostatistical services through our unique onshore-offshore model. Our data reporting and analytical methodology reflect an acute knowledge of current international regulatory standards.

Informa – Pharma Intelligence
Booth: 1034
Contact: David Horvath
Phone: 617-722-4636
Email: david.horvath@informa.com
Website: 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.

Infuserve America
Booth: 2453
Contact: David Kazarian
Phone: 727-573-7847
Email: davidk@infuserveamerica.com
Website: www.infuserveamerica.com/

Infuserve America provides central pharmacy support and coordination for all size clinical trials anywhere in the United States. We have honed our processes to be the most efficient and effective, and can customize to any trial's needs. We have the all the advantages of a large, state of the art facility while providing exceptional customer service, customization, quality and follow through.

Innomar Strategies Inc.
Booth: 738
Contact: Tasneem Khairullah
Phone: 905-847-4310
Email: marketing@innomar-strategies.com
Website: www.innomar-strategies.com/

Innomar Strategies, a part of AmerisourceBergen, is the leading service provider in the Canadian specialty biopharmaceutical market. Our integrated service model delivers customized solutions to improve product access, increase supply chain efficiency, and enhance patient care. Specialty biopharmaceutical firms turn to Innomar Strategies for superior knowledge, market-leading experience, and an unwavering commitment to patients.

INNOPLEXUS™

Innoplexus Holdings Inc.
Booth: 2000
Contact: Robert Schraf
Phone: 201-257-3217
Email: robert.schraf@innoplexus.com
Website: www.innoplexus.com/

Innoplexus AG is a leading global AI champion with over 80 patent application in AI, Machine Learning and Blockchain. We apply our proprietary tech stack in all stages of drug development via smart Data and Continuous Analytics as a Service solutions. Generating real-time insights from 100s of TBs of structured, unstructured, private and public data, we help organizations move towards continuous decision-making.

Innovaderm Research Inc.
Booth: 1343
Contact: Anne-Marie Gaulin
Phone: 514-521-4285
Email: amgaulin@innovaderm.ca
Website: www.innovaderm.ca/

Innovaderm Research has been managing and conducting phase I-IV clinical trials for over 16 years. Our expertise in the management of complex studies includes dose escalating early phase studies and, studies with complex analytical devices multiple lab analyses and biopsies. Innovaderm network of sites in North America gives us access to sites in dermatology, allowing us to initiate studies quickly. We maintain up to date SOPs to meet and exceed ICH, TPD and FDA requirements.

InnovoCommerce LLC
Booth: 2353
Contact: Hollie Van Dyke
Phone: 949-398-6550
Email: holliev@innovocommerce.com
Website: www.innovocommerce.com

InnovoCommerce, founded in 2008 in Irvine, CA is a company dedicated to delivering cloud-based eClinical collaboration solutions to the global life science industry. The company's innovoPOINT® clinical and investigator portal enables process and quality improvement in the study start-up, study conduct and study close out processes for clinical trials. The solution has the most advanced, purpose-built sponsor to investigator site document distribution engine worldwide.

Inpharmatis
Booth: 2723
Contact: Dace Vilka
Phone: 371-67210500
Email: info@inpharmatis.com
Website: www.inpharmatis.com

Inpharmatis provides full pharmaceutical product life-cycle management over the whole of EU & CIS in pharmacovigilance, regulatory affairs, medical writing, GMP, GDP, GxP audits, market access services and a range of specific software to pharmaceutical industry. Inpharmatis has a global team of experts operating across U.S., Europe and CIS, boasting the coverage, the linguistics, and in-depth understanding of local requirements. We are offering global coverage with the local competence.

Insife
Booth: 2724
Contact: John Buchan
Phone: 45-28105202
Email: john.buchan@insife.com
Website: insife.com

Insife is a software / technology and consultancy company delivering innovation, insight and best in breed solutions to Pharmacovigilance, Regulatory Affairs and clinical departments in pharma, biotech and CRO's. We understand Life Science companies, the pharma value chain and the challenging regulatory environment in which pharma operates. Trust us to help you harness the power of technology to optimize and organize your process to deliver what you need, both today and tomorrow.

Insmed Incorporated **Booth: 835**
Contact: Tammy Roman-White
Phone: 908-947-4370
Email: tammy.roman-white@insmed.com
Website: www.insmed.com

Insmed is dedicated to improving the lives of patients battling serious and rare diseases. Our mission is to develop novel, transformational therapies that make a real difference to patients.

Integrated Clinical Systems, Inc. **Booth: 1749**
Contact: Eric Herbel
Phone: 908-996-3312
Email: eherbel@i-review.com
Website: www.i-review.com

Integrated Clinical Systems - developers of JReview® - the fastest and easiest way to review, graph, visualize, report, analyze, do patient profiles and patient narratives, and Risk Based Monitoring for your clinical data. Works with OC,Clintrial,SAS datasets, Oracle LSH, SAS DD, Medidata Rave. Also providers of the JReview Cloud - managed hosting solution.

IntegReview IRB **Booth: 1917**
Contact: Sarah Attwood
Phone: 512-326-3001
Email: sattwood@integreview.com
Website: www.integreview.com

IntegReview IRB provides ethical review for pharma, device and biotech research studies. Daily meetings for U.S./ Latin America, weekly for Canada. Customer Support 24/7 with 24-48 hour document turnaround. Concierge site start-up. Compliant online document management system. Pre-reviews and Consulting services. Translation services. Responsive, experienced and flexible to meet client needs while maintaining ethical integrity and quality. Fully accredited AAHRPP. Woman-owned since 1999.

Integron **Booth: 2406**
Contact: Andy Maloy
Phone: 585-426-6200
Email: andy.maloy@integron.com
Website: www.integron.com

Integron is an Internet of Things (IoT) Managed Services company that serves the connected health, clinical drug trial, telehealth and remote patient monitoring sectors of the healthcare industry. We manage the complexities of enterprise IoT solutions by offering a comprehensive set of services, technology and strong vendor relationships across the entire IoT landscape. IoT services include wireless connectivity, software defined networks, security, provisioning, device management and support.

International Dermatology Research, Inc. **Booth: 831**
Contact: Irene Marino, CCRC. CCRP
Phone: 305-225-0400
Email: info@intldermresearch.com
Website: www.internationalderm.com

International Dermatology Research, Inc. is a research Site specializing in dermatology. Headquartered in Miami, FL, it provides state-of-the-art facilities, highly qualified staff and 13 additional sites in Latin America. Over the past 25 years IDR has gained excellent recognition for conducting successful Phase I, II , III and IV studies.

InterSystems Corporation **Booth: 1354**
Contact: Robin Moritz
Phone: 800-753-2571
Email: robin.moritz@intersystems.com
Website: www.intersystems.com

InterSystems Corporation is the worldwide leader in software for connected healthcare. Our advanced data management, integration, and active analytics technologies enable hospitals, IDNs, and regional or national HIEs to capture, share, analyze, and act upon their data. InterSystems products are used by thousands of hospitals and labs worldwide, including all 14 hospitals on the Honor Roll of America's Best Hospitals as rated by U.S.News and World Report.

inviCRO **Booth: 2536**
Contact: Sarah Escher
Phone: 617-904-2117
Email: sescher@invicro.com
Website: www.invicro.com

We are the quantitative imaging experts working across the entire drug development spectrum to better diagnose, characterize, treat and cure disease. Invicro is leading innovation to elucidate biological processes for our pharmaceutical and biotechnology partners around the world.

Iperion Life Sciences Consultancy **Booth: 819**
Contact: Marjan Leenders
Phone: 31-736-488-000
Email: marjan.leenders@iperion.nl
Website: iperion.nl/

Our mission is to develop, deliver and integrate the right technology and systems as enabler for the life sciences industry to improve business processes and supply chains leading to faster and more efficient delivery of medicines and tools to health care professionals and patients. Using the knowledge and understanding of technology, processes and people, Iperion has the unique position to stimulate change. Iperion offers Consultancy in Information management using content creativity and insight

IPHARMA / ChemDiv **Booth: 2637**
Contact: Anna Rashina
Phone: 7-903-578-33-23
Email: aar@ipharma.ru
Website: ipharma.ru/

IPHARMA is a fast-growing innovative CRO in Russia and EAEU.
Our pipeline consists of over 60 clinical trials in oncology, virology, endocrinology, neurology, transplantology, etc. We provide agile clinical services in both early-phase and registration trials, as well as medical, regulatory, and PV expertise to ensure optimal timeline for your drug development. According to Association of Clinical Trials Organizations, IPHARMA has been ranked as a market leader of Russian innovative drugs.

IQVIA **Booth: 2205**
Contact: Timika Brown
Phone: 984-439-3839
Email: timika.brown@iqvia.com
Website: www.iqvia.com

IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services dedicated to using analytics and science to help healthcare stakeholders find better solutions for their patients. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 55,000 employees worldwide. Learn more at iqvia.com.

JAF Consulting Inc.
Booth: 950
Contact: Joseph Franchetti
Phone: 856-241-1900
Email: info@jafconsulting.com
Website: www.jafconsulting.com

JAF Consulting, Inc. is a Global Quality & Regulatory Compliance Services consulting firm specializing in the auditing, management & execution of Computer System Validation Projects. JAF's services are Validation, Clinical QA, Quality Management, GxP Auditing & Assessment, Training & Education. When you partner with JAF you receive high quality services that have earned a reputation for being practical and cost effective to assist our clients in complying with today's regulatory requirements.

Janus Clinical Research Institute
Booth: 1747
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.

Jazz Pharmaceuticals Inc.
Booth: 1257
Contact: Lynette Lapola
Phone: 908-566-5385
Email: lynette.lapola@jazzpharma.com
Website: www.jazzpharma.com

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company that develops life-changing medicines for people with limited or no options, so they can live their lives more fully. By transforming biopharmaceutical discoveries into novel medicines, we are working to give people around the world the opportunity to redefine what's possible – to make the "small wins" big again.

Jeevan Scientific Technology Limited
Booth: 1600
Contact: Dr. Rajendra Prasad Muppavarapu
Phone: 91-7659004466
Email: rajendra.prasad@jeevanscientific.com
Website: www.jeevanscientific.com/

Jeevan Scientific is an independent public held CRO offering Clinical Trial, Pharmacovigilance and BA/BE solutions to Pharmaceutical & Biotechnology companies. Our commitment to quality and customer focused approach bundled with outstanding expertise distinguishes us from others. Our highly qualified & experienced workforce enable us to meet client expectations. Our State of the art facilities are located in Hyderabad, India which are audited by USFDA and WHO for it's BA/BE Services.

Joulé
Booth: 2117
Contact: Meghan Ciminello
Phone: 800-382-0382
Email: jcsinfo@jouleinc.com
Website: www.jouleclinical.com/

At Joulé, the Right Match is in our DNA. For more than 25 years we've connected pharmaceutical, biotech, clinical research and medical device firms to professionals nationwide. Our specialized experience and national network enable us to provide the most qualified clinical research, regulatory and drug safety specialists. Recognized for superior service, Joulé provides complete integrated services and workforce solutions.

Jsure Health Inc.
Booth: 2616
Contact: Mr. Kevin Lin
Phone: 86-2131228187
Website: www.jsure.com

K3-Innovations, Inc.
Booth: 953
Contact: Anil Mogha
Phone: 732-645-8366
Email: anil.mogha@k3-innovations.com
Website: k3-innovations.com/

K3-Innovations provides services in biometrics and regulatory affairs. We provide expert knowledge from the start of data lifecycles to statistical planning and completion of all CSR deliverables and the submission package. We offer flexible resourcing models, FSP model for minimum oversight from your end without compromising your involvement during project planning and execution, and completely outsourced project wherein you receive quality deliverables.

Karma Oncology
Booth: 2550
Contact: Dr Karen J Williams
Phone: 44-1475-522156
Email: karen.williams@karmaoncology.com
Website: www.karmaoncology.com

A unique oncology clinical development company supporting biotech companies with their development planning and clinical trials. Our team of experts cover North America and Europe. Core services include consultancy, protocol design, clinical project management, monitoring, medical writing, data review, EU Legal representation (Karma Oncology BV), Data Privacy and Data Protection Officer. Headquartered in Scotland with offices in Amsterdam, Dublin and Wilmington, Delaware.

Kayentis
Booth: 2612
Contact: Frederique Marion
Phone: 33-4-76-00-54-20
Email: fmarion@kayentis.com
Website: www.kayentis.com

Kayentis is a global provider of electronic Clinical Outcome Assessment (eCOA) solutions for patient data collection in clinical trials. Today, with experience of more than 150 clinical trials in 75 countries (6500 sites, 50,000 patients, 90 languages) and in a broad range of therapeutic areas, Kayentis adds value to data quality and clinical trial efficiency with innovative and intuitive solutions, and has two development priorities: Patient Engagement and Risk-based Monitoring.

Kinapse Ltd
Booth: 2719
Contact: Ed Ricketts
Phone: +44(0)-208-946-7600
Email: ed.ricketts@kinapse.com
Website: www.kinapse.com

Kinapse is recognised as a leading advisory and operational services provider to the global Life Sciences industry. The company provides its services across the full R&D and commercialization life-cycle, collaborating with its clients to improve the lives of patients, through a unique Advise – Build – Operate delivery model. 19 of the global top 25 life sciences companies rely on the breadth of Kinapse's world class advisory and operational services.

Kinesys Consulting Ltd.
Booth: 1551
Contact: Gerry McGettigan
Phone: 44-1418990081
Email: info@kinesysconsulting.com
Website: www.kinesysconsulting.com/

Kinesys provides Strategic & Operational Regulatory Affairs Services. This extends to Strategic Planning & Writing for all types of Applications – Scientific Advice, Orphans, CTA/IND, PIPs/iPSP, Early Access/Expedited Pathways (PRIME, BT, PIM etc.) & MAA. We are experts in Hemato-oncology, Neurology & Rare Diseases and our experience covers NCEs, biologics, ATMPs & devices. We have a unique platform, EMA Solutions, of ex-EMA & other EU Agency experts to support clients at critical timepoints.

Klein Hersh International
Booth: 1944
Contact: Jason Hersh
Phone: 215-830-9211
Email: jhersh@kleinhersh.com
Website: www.kleinhersh.com

Klein Hersh delivers strategic placement solutions to the world's foremost pharma, biotech, eClinical and CRO companies. From discovery through commercialization, in the laboratory or the boardroom, when you've got big seats to fill, trust Klein Hersh to deliver your experts. Call 215.830.9211, visit KleinHersh.com, or see us at DIA booth 1944.

KlinEra Global Services
Booth: 2718
Contact: Iftekhar Kazmi
Phone: 408-365-3231
Email: ikazmi@KilnEra.com
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.

KoNECT
Booth: 1540
Contact: Hyejin Joo
Phone: 82-2-398-5044
Email: Hyejin.joo@konect.or.kr
Website: kcc.konect.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.konect.or.kr/ for more information.

LabConnect, LLC
Booth: 823
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.

Leidos Life Sciences
Booth: 716
Contact: Mr. Brian Roberts
Phone: 240-529-0455
Email: brian.a.roberts@leidos.com
Website: www.leidos.com/health/life-sciences

Leidos is a Fortune 500® information technology, engineering, and science solutions and services leader working to solve the world's toughest challenges. Leidos Life Sciences executes a diverse portfolio of drug, biologic, and medical device services that span the full product development lifecycle. We deliver customized solutions that support groundbreaking medical research, optimize business operations, and expedite the discovery of safe and effective medical treatments.

Lifelines Neurodiagnostic Systems, Inc.
Booth: 1047
Contact: Pam Massa
Phone: 618-667-6445
Email: Pamela.Massa@lifelinesneuro.com
Website: www.lifelinesneuro.com

Lifelines Neuro's Research Services division delivers proven experience supporting pharmaceutical, therapeutic devices, and other research trials around the globe. With extensive neurodiagnostics experience, a dedicated support staff, and widespread access to physicians and EEG technologists, Lifelines is a respected partner of pharmaceutical researchers worldwide. Our solution is founded on four main pillars: Technology, Global Support, Vigilance, and Logistics.

Lionbridge Technologies
Booth: 522
Contact: Julie Estrada
Phone: 978-964-4757
Email: julie.estrada@lionbridge.com
Website: www.lifesciences.lionbridge.com/

Lionbridge Life Sciences 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.

Litera Microsystems
Booth: 2309
Contact: Matt Miller
Phone: 630-598-1100
Email: mmiller@litera.com
Website: www.litera.com

Litera Microsystems is the leading provider of document technology solutions worldwide. Our products optimize eCTD production; improving quality and identifying errors to mitigate risk and enhance production efficiency. Litera Microsystems supports document-intensive companies, helping them satisfy the complex demands of regulators.

LORENZ Life Sciences Group
Booth: 1439
Contact: Yaprak Eisinger, Maria DeRose
Phone: 866-956-7369
Email: mderose@lorenz.cc
Website: www.lorenz.cc

LORENZ Life Sciences Group has an array of RIM solutions geared towards industry, health authorities and academia which enable enforcing compliance globally. LORENZ offers Product Registration/IDMP, Submission Assembly, Validation and Management, Publishing/eCTD, Regulatory Planning and Tracking products and related services. Interoperability between LORENZ products and third party solutions, as well as the ability to automate processes allow LORENZ customers to enhance operational efficiencies.

LSK Global PS
Booth: 2449
Contact: Jung Min Lee
Phone: 82-2-546-1008
Email: information@lskglobal.com
Website: www.lskglobal.com

LSK Global Pharma Services established in March 2000 is a full service Korean CRO in Seoul, Korea, currently staffed with over 300 employees. LSK provides clinical development consulting services as well as strategic clinical operations, pharmacovigilance, data management and analysis services to a number of pharmaceutical companies and other organizations in over 100 multinational studies. LSK also has experience in data submissions to PMDA, US FDA and EMEA.

Luto Research Limited
Booth: 2540
Contact: Wayne Middleton
Phone: 44-113-487-2500
Email: solutions@lutoresearch.com
Website: www.lutoresearch.com

Luto are experts in producing clear communications through good information design. We write and design great digital and print communications and test them with real people to make sure the information meets their needs. This includes Package Inserts; IFUs; REMS Communications; Clinical Trials Information; Educational Materials; Apps and Videos. We also provide full Human Factors Usability and Readability Testing services throughout the US and Europe to support your regulatory submissions.

Machaon Diagnostics, Inc.
Booth: 732
Contact: Bjorn Stromsness
Phone: 510-839-5600
Email: bjorn@machaondiagnostics.com
Website: www.machaondiagnostics.com

Machaon Diagnostics offers laboratory testing in a Good Lab Practices environment with expertise in coagulation, CRO capabilities, next generation sequencing, and assay development. We are a CLIA laboratory with 14 years of experience.

MakroCare
Booths: 1911 & 1913
Contact: Ashok Ghone
Phone: 973-900-2728
Email: ashok.ghone@makrocare.com
Website: www.makrocare.com

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.

Mareana Inc.
Booth: 818
Contact: Lisa Sarachman
Phone: 609-921-0917
Email: marketing@mareana.com
Website: www.mareana.com

Marken
Booth: 1601
Contact: Christine Noble
Phone: 919-474-6890
Email: christine.noble@marken.com
Website: www.marken.com

Marken is the clinical trial supply chain subsidiary of UPS and the only patient-centric supply chain organization 100% dedicated to the pharma industry. We hold the leading position for Direct to/from Patient services and offer a state-of-the-art GMP-compliant depot network and logistic hubs in 49 locations. 50,000 drug and biological shipments are managed every month at all temperature ranges with other services such as biological kit production, global drug storage and distribution.

MarkLogic
Booth: 1800
Contact: Charlene Williams
Phone: 877-992-8885
Email: charlene.williams@marklogic.com
Website: marklogic.com/drugdiscovery

As the world's best database for integrating data from silos, MarkLogic enables up to 10X faster data integration, a complete view of data, intelligent search, improved data governance, and government-grade security. MarkLogic's platform empowers pharmaceuticals to build innovative solutions that support mission-critical initiatives for R&D, pharmacovigilance, and supply chain modernization.

Masimo
Booth: 1146
Contact: Lori Flores
Phone: 949-297-7000
Email: loflores@masimo.com
Website: www.masimo.com

Masimo is a global medical technology company responsible for the invention of award-winning noninvasive technologies, medical devices, and sensors that are revolutionizing patient monitoring, including SET® pulse oximetry, rainbow® Pulse CO-Oximetry, noninvasive and continuous hemoglobin (SpHb®), acoustic respiration rate (RRa®), Patient SafetyNet™, SedLine® brain function monitoring, O3® regional oximetry, NomoLine™ capnography, and a variety of connectivity solutions.

MasterControl
Booth: 731
Contact: Eliana Valcarcel
Phone: 801-942-4000
Email: info@mastercontrol.com
Website: www.mastercontrol.com

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.

Mayo Clinic
Booth: 2250
Contact: Katie Allen Ziegler
Phone: 866-873-8963
Email: MVSS@mayo.edu
Website: www.mayovalidation.com

Mayo Clinic is targeting clients in the pharmaceutical, biotechnology, diagnostic and CRO industries by commercializing Mayo Clinic expertise, logistics, and laboratory capabilities. This suite of services complements the full breadth of the pharmaceutical development pipeline and includes diagnostic discovery; testing services for sponsored testing programs, research/translational endpoints, and clinical trials; and access to biospecimens and data.

MD Connect
Booth: 717
Contact: Jonathan Catley
Phone: 781-235-0999
Email: jcatley@mdconnectinc.com
Website: www.mdconnectinc.com/

MD Connect is a leading, global patient recruitment provider, with end-to-end solutions to optimize clinical trial recruitment and enrollment. Combining technology and people, we utilize cost-efficient digital strategies, social media, online communities and health networks to identify and engage active, interested patients. We leverage multi-channel digital outreach, pre-screening/qualification and an advanced reporting management solution to support sponsors, CROs, sites and patients.

Medable
Booth: 2331
Contact: Tyler Pugsley
Phone: 415-265-4261
Email: tyler@medable.com
Website: www.medable.com

Medable is the first application platform purpose-built for clinical trials. On our secure, "no coding required" platform, patient and site-facing apps are easy to build and quick to deploy, enabling rapid enrollment, meaningful engagement, and actionable, real-world insights. Join us as we work with leading research teams to map the human digitome - providing the first digital signature of health and disease. Medable is transforming the way you work, treat, cure, and dream at medable.com.

MedDRA MSSO
Booth: 1623
Contact: Kendra Skelton
Phone: 703-556-2955
Email: MSSOHelp@MedDRA.org
Website: www.meddra.org

MedDRA is a clinically validated terminology used for coding adverse events for the biopharmaceutical industry and regulators. The MSSO maintains MedDRA and provides support services (e.g., training, tools and other related MedDRA support services).

Medical Vigilance Solutions
Booth: 2740
Contact: Todd Tierney
Phone: 513-803-6690
Email: Todd.Tierney@cchmc.org
Website: www.cincinnatichildrens.org/mvs

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

Medicines Evaluation Unit
Booth: 2547
Contact: David Rogers
Phone: 44-161-946-4080
Email: drogers@meu.org.uk
Website: meu.org.uk

The Medicines Evaluation Unit is the UK's leading contract research organisation specialising in Respiratory and Health Volunteer clinical trials. Possessing extensive pharmaceutical, scientific, clinical and volunteer recruitment expertise, within a state-of-the-art research facility. Our 36-bed facility also holds MHRA Phase I accreditation.

Medidata Solutions Worldwide
Booth: 1523
Contact: Craig Strauss
Phone: 212-918-1800
Email: cstrauss@mdsol.com
Website: www.medidata.com

Medidata is leading the digital transformation of life science, with the world's most used platform for clinical development, commercial, and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Discover the future of life science: www.medidata.com

MEDIX
Booth: 1306
Contact: Nick Burrows
Phone: 630-330-6445
Email: nburrows@medixteam.com
Website: www.medixteam.com

Medix Scientific/Clinical Research delivers a sustainable workforce solution to pharmaceutical, biopharmaceutical, biotechnology, and medical device organizations. Through projecting your needs and pipelining top performing talent, we can provide your organization the flexibility and agility you need to meet goals with a quality workforce. Medix services include the placement of contract, contract-to-hire and direct hire talent to top organizations.

MedNet Solutions, Inc.
Booth: 1031
Contact: Sarah Hanson
Phone: 763-258-2735
Email: contact@mednetstudy.com
Website: www.mednetstudy.com

MedNet Solutions, an innovative cloud-based eClinical solution provider, supports the entire spectrum of clinical trials from early to late phase. Since 2001, we have been trusted by pharmaceutical, medical device, biotechnology and Contract Research Organizations (CROs) around the world to deliver on our promise of agile, effective, and efficient eClinical solutions. Visit booth #2505 for a live demonstration.

Medpace Inc.
BS6
Contact: Beth Cullen
Phone: 513-579-9911
Email: info@medpace.com
Website: www.medpace.com/

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas.

MedPoint Digital, Inc.
Booth: 2405
Contact: Sarah Nolan
Phone: 847-869-4700
Email: sarah.nolan@medpt.com
Website: www.medpt.com

MedPoint Digital develops specialty eClinical platforms for clinical trial portals, virtual investigator meetings, study document exchange, and virtual monitoring visits. Our digital solutions enable sites, sponsors and CROs to be more productive, with online study training, communications, safety reports, patient visit guides, site engagement, single sign-on and metrics displays.

Medrio
Booth: 2004 | BS2
Contact: Megan Lomazzi
Phone: 415-276-9261
Email: mlomazzi@medrio.com
Website: www.medrio.com

Medrio is a leading technology company providing eClinical solutions for clinical research. Our cloud-based platform and mobile products deliver fast, flexible, and easy tools for data managers across all industries. Medrio serves over 500 customers, with headquarters in San Francisco and numerous global offices. Learn more at www.medrio.com.

MESM Ltd
Booth: 2315
Contact: Rebecca Davis
Phone: 863-999-3073
Email: rebecca.davis@mesm.com
Website: www.mesm.com

MESM specialises in the Sourcing, Supply, Service of medical equipment and End of Study services for Clinical Trials. We help clinical trial providers and healthcare professionals create positive patient outcomes and put you in control of your trial – globally. We manage the whole product life cycle and at every step of the way, there's a trusted expert guaranteeing you a reliable, flexible, solution-focused service. At MESM, we work collaboratively with you to understand your project needs.

Metina PharmConsulting Private Limited
Booth: 820
Contact: Hasumati Rahalkar
Phone: 91-9820113613
Email: hasumati@metinapharmconsulting.com
Website: www.metinapharmconsulting.com

Metina Services: 1.Drug Product Development, CDMA identification & Technology transfer of product: 2. Regulatory Services: End to end regulatory services as due diligence, gap analysis, regulatory strategy, scientific writing of dossier, submission to HA, query response and approval for API and Formulation for USA, EU, WHO PQP and Emerging Markets. 3. GMP / Third Party GMP audits: We perform GMP and third party audit for GMP compliance for USA and EU.

Ministry of Food and Drug Safety (MFDS)
Booth: 1640
Contact: Cheol Seung Lee
Phone:

MonitorForHire.com
Booth: 2137
Contact: Scott Freedman
Phone: 610-862-0909
Email: scott.freedman@monitorforhire.com
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 over 4,000 registered and pre-qualified monitors in 60 countries including the North American, Latin America, Europe, Asia & MENA. For more information contact us at: +1 (610) 862 0909.

Montrium, Inc.
Booth: 2349
Contact: Oliver Pearce
Phone: 514-223-9153-219
Email: opearce@montrium.com
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

Muv Inc.
Booth: 1950
Contact: Jennifer Marley
Phone: 214-775-0156
Email: jmarley@muvpeople.com
Website: www.muvpeople.com

muv is a global ground transportation provider for Life Sciences - including clinical trials, speaker bureaus, and medical meetings and events. muv deploys innovative technology and data reporting solutions to make your program more efficient and effective. HCP client reporting and customized billing GDPR Compliant and Data Shield Certified $5 million comprehensive insurance coverage 24/7/365 customer service We muv people further than ordinary and beyond the expected! www.muvpeople.com

MyData-TRUST/FGK Representative Service
Booth: 635
Contact: Gautier Sobczak
Phone: 32-65-55-41-20
Email: g.c.sobczak@mydata-trust.com
Website: www.mydata-trust.eu

The aim of "MyData-TRUST" consists in supporting the Life Sciences Industry in leveraging their compliance related to Data Protection. We are providing a services and solutions aligned with both Health R&D and Data Protection requirements (GDPR, HIPAA, Privacy Shield). Via our partner "FGK Representative Service" we also offer the required legal representation for pharmaceutical and biotechnology companies which are conducting clinical research in the EU or CH without having a subsidiary there.

NACS, Inc.
Booth: 1618
Contact: Robert Doty
Phone: 763-444-4747
Email: Rdoty@nacsinc.com
Website: www.nacsinc.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
Booth: 734
Contact: Hawk Tran
Phone: 202-813-6681
Email: htran@navref.org
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.

National Disease Research Interchange
Booth: 712
Contact: Gene Kopen
Phone: 215-557-7361
Email: szakarewsky@ndriresource.org
Website: ndriresource.org/

The National Disease Research Interchange (NDRI) is a 501(c)(3) not-for-profit, NIH-funded organization that provides project-driven human biospecimen service to academic and corporate scientists. NDRI has 35 years of experience globally distributing human biospecimens for research. Our extensive recovery network has the expertise to provide anatomical structures, organs, and tissues with annotated data.

National Jewish Health
Booth: 1147
Contact: Tom Kaczka
Phone: 303-398-1303
Email: kaczkat@njhealth.org
Website: www.njlabs.org

National Jewish Health offers pre-clinical and clinical biomarker testing under CAP/CLIA/ISO15189 and GLP guidelines. The Complement Laboratory menu of 50 assays measure complement activation, cytokine modulation and immune complex formation in response to biologics, vaccines, nanoparticles and oligonucleotides. Our Mycobacteriology & Microbiology laboratories identify pulmonary pathogens, including non-tuberculous mycobacteria seen in cystic fibrosis patients & antimicrobial susceptibility.

Navitas Life Sciences
Booth: 954
Contact: Mr. Patrick Mullen
Phone: 609-454-7753
Email: patrick.mullen@navitaslifesciences.com
Website: www.navitaslifesciences.com

Navitas Life Sciences, the dedicated life sciences company of TAKE Solutions, harnesses the combined knowledge and experience of three legacy companies—Ecron Acunova, Navitas, and Intelent—to provide end-to-end services and solutions. We help our clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory & safety, & a life sciences big data services and analytics provider.

NCGS Incorporated
Booth: 1219
Contact: David McCrary
Phone: 843-722-8330
Email: dmccrary@ncgs.com
Website: www.ncgs.com

NCGS, Inc. is a full-service, global CRO. We have been in business for 35 years, have helped with 80 approved products, and have ZERO 483s or other warnings from the FDA, EMA, or other global agencies. We are a privately-held, WBENC Certified company offering our Sponsors exclusive, tenured teams with very low turnover, creating a level of collaboration that makes each clinical effort more quality based, thorough, timely and cost-effective.

Next Phase Research
Booth: 2005
Contact: Victoria Alvarez
Phone: 305-965-2256
Email: valvarez@npresearch.net
Website: www.npresearch.net

Innovative, cost-containment solutions for your clinical research needs. We facilitate and simplify the research process by providing one point of contact. Our consolidated study management provides our partners with a comprehensive solution from beginning to end, providing study start up together with administrative services such as standard operating procedures, regulatory document formation, budgets and contracts.

Nippon Control System Corporation
Booth: 2156
Contact: Akiyoshi Tokoyoda
Phone: 81-80-1000-5633
Email: tokoyoda@nippon-control-system.co.jp
Website: www.nippon-control-system.co.jp/en/integration/safety/index.html

We introduce the drug safety system, SopharmaPV, to support your pharmacovigilance business processes, which provides you with Adverse Events intake and assessment as well as comprehensive reporting to regulatory agencies. It supports the ICH E2B(R2) and E2B(R3) ICSR formats. We can present you the demonstration at booth #2156, please visit us!

NNIT
Booth: 2151
Contact: Nicoline Poulsen
Phone: 609-945-5650
Email: nlpo@nnit.com
Website: www.nnit.com

NNIT is a leading international 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.

Novotech
Booth: 1409
Contact: Barry Murphy
Phone: 61-285-691-400
Email: Barry.Murphy@novotech-cro.com
Website: www.novotech-cro.com/

Novotech is internationally recognized as the leading regional full-service contract research organization (CRO) in the Asia Pacific region. Novotech provides clinical development services across all therapeutic areas and has been instrumental in the success of hundreds of Phase I - IV clinical trials.

OM1
Booth: 1355
Contact: Renee Hurley
Phone: 888-324-3899
Email: rhurley@om1.com
Website: www.om1.com

OM1 is a leading health outcomes and registries company focused on the measurement, comparison, and prediction of treatment outcomes. Leveraging big data, standardized outcomes measurement, and artificial intelligence technology, OM1 built the first intelligent data cloud for healthcare, enabling more precise information and better decision making for stakeholders across the healthcare ecosystem.

Omnicia, Inc.
Booth: 539
Contact: Jonathan Pierce
Phone: 818-299-4953
Email: jonathan.pierce@omniciainc.com
Website: www.omniciainc.com

Omnicia was founded in San Francisco's Biotech Bay in 2001 by life sciences industry veterans looking to simplify the increasingly complex global electronic submission process with innovative software solutions and expert consulting services. Our intuitive software electronically creates, publishes, and views compliant documents, reports, and eCTD submissions for US, EU, and CA review. Omnicia's integrated solution simplifies document creation and electronic publishing.

OmniComm Systems, Inc.
Booth: 1823
Contact: Sherri Dicken
Phone: 954-473-1254
Email: sdicken@omnicomm.com
Website: www.omnicomm.com

OmniComm Systems, Inc. is a leading strategic software solutions provider to the life sciences industry. With global experience from more than 6,000 clinical trials, OmniComm provides comprehensive solutions for clinical research. OmniComm helps organizations to drive efficiency in clinical development, better manage risks, enhance regulatory compliance and manage clinical operations performance.

OnePager
Booth: 1052
Contact: Jason Leslie
Phone: 303-990-5282
Email: jleslie@onepager.com
Website: www.onepager.com

OnePager automates Gantt Charts and Timelines using data from Project or any other PPM tool, for the purposes of presentation. It helps project managers and planners avoid dragging shapes around for hours and hours, by using their existing project files. OnePager is the premier data visualization tool for anyone in the pharmaceutical industry who needs to report their plan.

Optum
Booth: 430 | BS8
Contact: Sheila Hetu
Phone: 888-445-8745
Email: sheila.hetu@optum.com
Website: www.optum.com/campaign/ls-ms/optum-drn.html

Optum is a leading health services innovation company dedicated to helping make the health system work better for everyone. With more than 160,000 people collaborating worldwide, Optum combines technology, data and expertise to improve the delivery, quality and efficiency of health care.

Oracle Health Sciences
Booth: 1431
Contact: Rachel Weinstein
Phone: 408-595-3077
Email: Rachel.weinstein@oracle.com
Website: www.oracle.com/healthsciences

Oracle Health Sciences provides the only eClinical platform made up of best-of-breed solutions powered by the #1 data and cloud technology in the world. With Oracle Heath Sciences, Life Sciences organizations can manage and unify all elements of the Clinical Development Lifecycle in a safe, secure and compliant manner, while also being open, collaborative and adaptive to change.

Orbis Clinical
Booth: 2352
Contact: Michael Celata
Phone: 781-496-3129
Email: mcelata@orbisclinical.com
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.

Orbit
Booth: 1508
Contact: Dan Feith
Phone: 215-540-5488
Email: dan@feith.com
Website: www.workinorbit.com

Orbit compliance center: Inspection-ready software trackers for global and local compliance. Whether you're tracking RMPs, USREMS, ARMMs, PVAs, Safety Signals, or Label Changes, you'll benefit from Orbit's global view into your company's compliance activities. Learn more @ workinorbit.com

Orlando Clinical Research Center
Booth: 1816
Contact: Thomas Marbury
Phone: 407-240-7878
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, SAD/MAD, & BA/BE studies in healthy, hepatic, hemodialysis, renal, and diabetic.

Parexel
Booth: 1419
Contact: Jo Sudore
Phone: 781-487-9900
Email: info@parexel.com
Website: www.parexel.com

Parexel is focused on supporting the development of innovative new therapies to improve patient health. We do this through a suite of services that help life science and biopharmaceutical customers across the globe transform scientific discoveries into new treatments for patients. From clinical trials to regulatory and consulting services to commercial and market access, our therapeutic, technical and functional ability is underpinned by a deep conviction in what we do. www.parexel.com

Path-Tec
Booth: 701
Contact: Erin Young
Phone: 706-569-6368
Email: erin@path-tec.com
Website: www.path-tec.com

Path-Tec is a leading provider of specimen management solutions that include kit design, production, distribution and inventory management. Our secure web-based system provides laboratories with the tools to improve client service levels, track couriers and specimens, improve client inventory management and effectively manage client supply orders and distribution.

PCM TRIALS
Booth: 1113
Contact: Julie Church-Thomas
Phone: 888-628-9707
Email: info@pcmtrials.com
Website: www.pcmtrials.com

PCM TRIALS is moving the needle on clinical research. Our Certified Mobile Research Nurses (CMRNs) travel directly to clinical trial participants—wherever they may be. This helps reduce dropout rates resulting in improved recruitment, retention, and compliance. We directly employ our CMRNs, so there is less administration and risk and more control offering a higher quality of services. Since 2008, we've worked on 180+ protocols for 90+ sponsors and completed 20,000+ clinical trial remote visits.

Pharmaceutical eConsulting
Booth: 1650
Contact: Yolanda Hall
Phone: 978-422-0227
Email: yh@pec-services.com
Website: 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.

Pharmaceuticals and Medical Devices Agency (PMDA)
Booth: 1641
Contact: Kyoko Suwa
Phone: 81-3-3506-9456
Email: suwa-kyoko@pmda.go.jp
Website: www.pmda.go.jp/english/index.html

The Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency that focuses on three key service areas: scientific reviews of medical products, safety measures, and relief services for persons suffering from adverse health effects, in collaboration with the Ministry of Health, Labour and Welfare (MHLW). PMDA will continue to endeavor proactively to safeguard and promote the nation's health and safety, while strengthening its partnerships with other countries and regions.

Pharmalex
Booth: 1209
Contact: Josefine Cladd
Phone: 49-621-18-15-38-150
Email: josefine.cladd@pharmalex.com
Website: www.pharmalex.com

PharmaLex offers end-to-end regulated services that provide real value to our clients. We differ from other contract service providers by focusing on specialized regulatory services to deliver and comply with all health agency obligations. Our global team has more than 850 local knowledge experts. PharmaLex supports pharma companies throughout the entire product lifecycle, ensuring compliance with pharmaceutical regulations and providing vital scientific and strategic advice on drug development.

PharmaOut
Booth: 2102
Contact: Lynn Sansosti
Phone: 603-682-1164
Email: lynn@pharmaout.com
Website: www.pharmaout.com

PharmaOut is a full-service global consulting, business process outsourcing and staffing firm. We specialize in the pharmaceutical, biotech, medical device and CRO industries with clients across North America, South America, and Europe. The services we offer are Consulting, Risk Mitigation, Vendor Management, Project Management, Protocol Development, HR/Recruitment Process Outsourcing, Payroll Services, Executive Level Search, Permanent, Contract and Contract-to-Hire Staffing Services.

Pharmapace
Booth: 612
Contact: Larry Shen PhD
Phone: 858-263-0510
Email: info@pharmapace.com
Website: www.pharmapace.com

Pharmapace, Inc. is a niche CRO providing clinical biometrics services to the biopharmaceutical, medical device, and diagnostic industries. Located in the heart of the pharmaceutical and biotechnology hub in San Diego, our mission is to unleash the power of your data for the advancement of human health. • Clinical Development Consulting • Bio statistics consulting and outsourcing • Clinical and Statistical Programming • Clinical Data Integration • CDISC (SEND, CDASH, SDTM, & ADaM) • Data Management

Pharmaron
Booth: 2504
Contact: Chris Hickey
Phone: 781-710-4950
Email: chickey@pharmaron-us.com
Website: www.pharmaron.com

Pharmaron is a premier R&D service provider supporting the life science industry with diverse drug R&D service capabilities, from early discovery to clinical development. With operations in China, US and UK staffed by over 6,000, Pharmaron has an excellent track record in the delivery of R&D solutions to its partners. Our Clinical Pharmacology Center is located in Baltimore, Maryland and offers services focused on phase I/II complex clinical research, including FIH TQT 14C/hADME, ethnobridging.

PharmaSeek Companies
Booth: 1456
Contact: Lindsay McCarthy
Phone: 608-664-9000
Email: lmccarthy@pharmaseek.com
Website: www.pharmaseek.com

PharmaSeek connects sponsors and CROs with experienced clinical research sites and expedites study start-up timelines by streamlining the site selection process by providing one point of contact for multiple sites. PharmaSeek also assists sponsors and CROs in conducting a comprehensive review of clinical procedures and other protocol items with a focus on determining billable items under the Medicare Clinical Trial Policy (National Coverage Determination 310.1).

PharmaVOICE
Booth: 1844
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, covering a range of issues from molecule through market. PharmaVOICE's more than 46,000 BPA-qualified subscribers 60,000 digital users are also kept abreast of the latest trends through additional media resources, including WebSeminars, Podcasts, Videocasts, and White Papers.

Pharm-Olam, LLC
Booth: 2312
Contact: John W. Colby III
Phone: 713-559-7900
Email: info@pharm-olam.com
Website: www.pharm-olam.com

At Pharm-Olam, our goal is to help create a healthier world by supporting sponsors like you in Phases I-IV. Pharm-Olam is a global full-service CRO with operations in more than 40 countries, and extensive expertise in Infectious Disease, Vaccines, Oncology, Rare/Orphan indications and Pediatrics. Pharm-Olam's global team brings the local expertise, relationships and regulatory knowledge needed to successfully deliver your next study. For more information, visit www.Pharm-Olam.com.

Phastar
Booth: 1854
Contact: Kevin Kane
Phone: 44-2071837062
Email: kevink@phastar.com
Website: phastar.com/

Phastar is a specialist provider of statistics, programming and data management services to the pharmaceutical, biotechnology and medical devices industries. We are one of the largest CRO statistics groups worldwide with seven offices across four continents. We provide expert consultants and manage deliver in-house projects, adopting our unique approach to data analysis that ensures quality, "The PHASTAR Discipline".

Phlexglobal Inc.
Booth: 2136
Contact: Chris Englerth
Phone: 44-(0)-1494-720420
Email: cenglerth@phlexglobal.com
Website: www.phlexglobal.com

Phlexglobal is unique among eTMF providers. We leverage dedicated and authoritative TMF technologies and expert services to bring order, stability, and control to your Trial Master File – helping you achieve the highest standards for completeness, timeliness, and quality. Optimum TMF health stems from experienced people trained on effective processes using the right technology. Phlexglobal balances these areas to help you reach The TMF Health Zone.

physIQ
Booth: 1317
Contact: Chris Economos
Phone: 800-516-7902
Email: Chris.Economos@physIQ.com
Website: www.physiq.com/

PhysIQ transforms wearable biosensor data into actionable insight. Our enterprise ready, device-agnostic platform, coupled with our portfolio of FDA-cleared AI-based physiology analytics, continuously captures data from wearable biosensors and transforms it into patient insight. We are providing this solution to life science companies who are integrating biosensor data into their clinical trials, as well as to payers and health systems to proactively manage their ambulatory at-risk population.

PilotPay Clinical
Booth: 901
Contact: Riki Aihara
Phone: 310-265-0133
Email: assistant@pilotpayinc.com
Website: pilotpayinc.com

PilotPay Clinical is a trusted facilitator of global payment solutions and transportation bookings for clinical research. Developed by industry leaders, PilotPay Clinical reduces the administrative burden of sites; provides the study participant the flexibility of choice concerning timely payment methods of stipend payments and expense reimbursements; and provides customized features such as executive reporting at a "click of a button". We make your experiences seamless.

Pinnacle 21
Booth: 2236
Contact: Max Kanevsky
Phone: 267-570-3255
Email: jkireeva@pinnacle21.com
Website: www.pinnacle21.net

Pinnacle 21 is an established startup making a big impact on the regulatory review process. Our industry leading software is helping life sciences companies prepare and health authorities review submission data. Our Enterprise software is an integral part of FDA's 21st Century Review Initiative, ensuring that submission data is compliant, useful and ready for review. With thousands of global users, we continue to automate and innovate ways to bring life-changing medicines to patients faster.

Planet Pharma
Booth: 2118
Contact: Sarah Callaghan
Phone: 708-286-1342
Email: scallaghan@theplanetgroup.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

PPD
Booth: 2323
Contact: Laura Mullaney
Phone: 919-456-5600
Email: account.development@ppdi.com
Website: www.ppdi.com

PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. With offices in 48 countries and more than 21,000 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. For more information, visit www.ppdi.com.

PQE
Booth: 812
Contact: Francesco Amorosi
Phone: 267-254-8589
Email: info@pqegroup.com
Website: www.pqegroup.com

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
Booth: 1331
Contact: Tami Klerr
Phone: 610-935-0318
Email: Klerrtami@prahs.com
Website: www.prahs.com

PRA Health Sciences delivers innovative drug development solutions that improve patients' lives. Our people work tirelessly for our clients, offering exceptional experience across all phases and therapeutic areas and a broad spectrum of services. With 16,000+ employees covering 90+ countries, we provide an impressive global presence and in-depth knowledge of local regulations, standards of care, and cultural customs.

Praxis Communications, LLC
Booth: 1940
Contact: Robert Loll
Phone: 716-249-5111
Email: rloll@gopraxis.com
Website: www.gopraxis.com

Praxis provides focused patient recruitment solutions to the world's leading pharmaceutical, biotech, and medical device companies. It's all we do. As each research study is unique, so is each Praxis patient recruitment program. We utilize sophisticated research and predictive analytics to create sound strategies which translate into engagement campaigns and experiences that resonate with the patients we're trying to reach. Visit www.gopraxis.com to learn more.

PRC Clinical
Booth: 1246
Contact: Joshua Elvert
Phone: 877-519-6001
Email: jelvert@prcclinical.com
Website: www.prcclinical.com

PRC Clinical is the CRO of choice for many pharmaceutical, biotech and regenerative medicine developers worldwide, offering a next-level clinical trial management experience. PRC Clinical offers full Clinical Trial Management services in a wide range of therapeutic areas: Regenerative Medicine / Stem Cells / Gene Therapy, Ophthalmology, CNS, Oncology, Neurology, ALS, Parkinson's, Pain, GI, Device, Anti-infective, Cardiovascular, and Pulmonary. Call 877-519-6001 or email info@prcclinical.com.

Precision for Medicine
Booth: 1313
Contact: Melissa Malski
Phone: 240-654-0730
Email: melissa.malski@precisionformedicine.com
Website: www.precisionmedicinegrp.com/pfm/

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.

Prevail InfoWorks, Inc.
Booth: 1606
Contact: Mats Olsen
Phone: 267-797-2037
Email: mats.olsen@prevailinfoworks.com
Website: www.prevailinfoworks.com

For over a decade, we have been dedicated to providing biotech, pharmaceutical, and medical device enterprises with the most innovative and complete technology solutions. Drug and medical device development has been made easier, faster and less risky thanks to our pioneering means for integrating, normalizing, reconciling and presenting the aggregated data, analysis, trends and metrics of all (not just some) study-related data sources through a single-user interface.

Preventice Solutions
Booth: 713
Contact: Thomas Campbell
Phone: 281-760-0500
Email: tcampbell@preventice.com
Website: www.preventicesolutions.com

Preventice Solutions is a leading developer of mobile health solutions and remote monitoring services, connecting patients threatened by cardiac arrhythmias. Creating revolutionary monitoring technologies, this tech-enabled, service-based approach can ultimately reduce the cost of care and improve health outcomes. The Preventice wearable portfolio includes the PatientCare Platform and BodyGuardian family.

PrimeVigilance
Booth: 1555
Contact: Florence Denance Habek
Phone: 44-(0)-1483-307920
Email: florence.denance.habek@primevigilance.com
Website: www.primevigilance.com

As part of the Ergomed group, PrimeVigilance is a leading provider of high quality global life cycle management services including pharmacovigilance, medical information, regulatory science, pharmacoepidemiology & real word evidence (RWE). Our highly qualified professionals provide expert consulting services enabling our clients and partners to manage their products' global drug safety, regulatory obligations and to maximise product value. For more information please visit www.primevigilance.com

Princeton Blue, Inc.
Booth: 1505
Contact: Pramod Sachdeva
Phone: 908-369-0961
Email: pramod.sachdeva@princetonblue.com
Website: www.princetonblue.com

Princeton Blue is a leader in intelligent automation with technologies like Business Process Management (BPM), Low-code Application Development, Robotic Process Automation (RPA) and Artificial Intelligence (AI) to improve customer experience and operational efficiency. With 466 successful automation projects in 12 years, and solutions for Pharmacovogilance, Label Management, Clinical Study Management and IND Product Registration, leverage our experience to accelerate your automation journey.

Projecis, Inc.
Booth: 1116
Contact: Russell Holmes
Phone: 858-774-1128
Email: russ@projecis.com
Website: www.projecis.com

Projecis is a content management and data visualization platform enabling project stakeholders to connect teams, organize data, and disseminate information for better business decision making. Project team members can access documents, dashboards, metrics, milestones, assignments, Gantt charts, and more. All content is searchable, and maintained in one place with real-time commenting for all posted artifacts. The platform can be extended to add custom applications for targeted client needs.

Project Management Leadership Group, Inc.
Booth: 2404
Contact: Mr. Bill Stewart
Phone: 678-325-1100
Email: bstewart@pmlg.com
Website: www.pmlg.com

Project Management Leadership Group, Inc. (PMLG) is a leading international professional services firm with a proven approach for helping our clients rapidly achieve strategic execution excellence. We have supported hundreds of health care firms and their professionals. Our unique experiential-based training and turn-key approach to implementing project, program and and portfolio management reduces product development and introduction lifecycles by over 30%.

Protocol First
Booth: 2736
Contact: Joseph Collins
Phone: 801-996-7150
Email: joe@protocolfirst.com
Website: www.protocolfirst.com

Protocol First (P1) is a next-gen EDC Software-as-a-Service (SaaS), purpose-built to handle complex oncology trials. P1 is a site-friendly EHR-EDC-SDTM platform. Clinical Pipe (CP) is a sister stand-alone EHR-to-EDC app. Whereas P1 is built to be an integrated EDC platform, CP is a powerful productivity tools to collect EHR data with the click of a button. CP works with existing or new studies and connect major EHRs and EDCs--e.g., Epic and Rave. Welcome to hybrid EHR/EDC data entry!

ProTrials Research, Inc.
Booth: 1916
Contact: Wendy Powers
Phone: 650-864-9195
Email: wpowers@protrials.com
Website: www.protrials.com

As a clinical research organization serving the pharmaceutical, biotechnology and device industries for more than 20 years, ProTrials professionals have one of the industry's highest staff retention and experience. We offer a suite of services including clinical operations and data management, in addition to: • Experience in a broad range of therapeutic areas • Phase I-IV clinical trials • Highly-skilled project management services • Operational experience in North America and throughout Europe

Proventa International
Booth: 854
Contact: Nicholas Williams
Phone: 44-2070961222
Email: nw@proventainternational.com
Website: proventainternational.com

Proventa International is a global management consultancy specialising in business development within the Life Sciences sector. With our end-end domain expertise in R&D, Clinical Operations, PV, Regulatory, Manufacturing & Supply Chain engaging with key stakeholders is at the core of our business. With our integrated platforms from BuySupplyConnect, BD Outsourcing, Strategy Meetings & Innovation Spotlight Sessions we act as a true extension to your overall business development strategy.

Prudentia Group
Booth: 1153
Contact: Punit Sinha
Phone: 732-470-8260
Email: psinha@prudentia-grp.com
Website: www.prudentia-grp.com

Prudentia's global team of Drug Safety professionals provide management and technology consulting and coding services to the pharmaceutical industry, advising companies on processes, technologies and pharmacovigilance management. Additionally, we implement and upgrade safety databases, provide managed services to maintain these databases, offer simple turnkey applications including our medical coding application, MedCodr and Coding Services to improve efficiency.

QMENTA
Booth: 1711
Contact: Amelia Hocine
Phone: 34-933282007
Email: amelia@qmenta.com
Website: www.qmenta.com

QMENTA accelerates and improves the chances of successful drug development and clinical care for brain diseases. We designed a cloud-based platform using AI techniques and large amounts of MRI and CT brain images. QMENTA AI Reader is the perfect environment to store, share and analyze multi-site medical imaging data during clinical studies and trials. It allows experts to save time and money in drug development and empowers their objective decision-making based on imaging data insights.

QPS, LLC
Booth: 2412
Contact: Suzanne Canfield
Phone: 302-369-5601
Email: suzanne.canfield@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.

QST Consultations, Ltd.
Booth: 2252
Contact: Jason Proos
Phone: 616-892-3749
Email: info@qstconsultations.com
Website: www.qstconsultations.com

The mission of QST Consultations is to build meaningful relationships with our clients._ We strive to exceed expectations and provide the highest possible quality clinical development services available to the medical research industry. QST is responsive to client's needs through persistent attention to detail and demonstrated leadership in overcoming clinical development challenges.

Quality Associates, Inc.
Booth: 2313
Contact: Paul Swidersky
Phone: 410-884-9100
Email: pswidersky@qualityassociatesqa.com
Website: www.qualityassociatesQA.com

Quality Associates, Inc., established in 1986 as a 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, SOPs, etc. QAI has a staff of auditors with various scientific experience. QAI also maintains a large GLP archive for storage of documents and specimens.

QuantifiCare
Booth: 918
Contact: Deborah Poole
Phone: 678-779-9935
Email: info.usa@quantificare.com
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.

Quartesian
Booth: 2409
Contact: Stephen Boccardo
Phone: 609-454-3312
Email: stephen.boccardo@quartesian.com
Website: www.quartesian.com

Quartesian was formed in January 2003 and is headquartered in Princeton, N.J. with the goal of providing "Clinical Data Your Way" helping clients maintain control of their studies. This is accomplished by providing clinical data services faster, more efficient and cost-effective than ever thought possible. We have worked for over 165+ pharmaceutical, biotechnology and medical device companies with 100% repeat business and no change orders. . Learn more about Quartesian at www.quartesian.com.

Quest Diagnostics
Booth: 905
Contact: Charles Martin
Phone: 917-327-2418
Email: Charles.R.Martin@questdiagnostics.com
Website: www.questdiagnostics.com

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. We serve half of the physicians and hospitals in the United States. QuestDiagnostics.com

Quipment
Booth: 1249
Contact: Valere Horath
Phone: 770-575-9117
Email: valere.horath@quipment-inc.com
Website: www.quipment.fr/en/home.html

Quipment provides medical and laboratory equipment as well as ancillary supplies for clinical trials worldwide. In addition to catering more than 30,000 investigator sites per year, Quipment also offers cutting-edge tools to manage and track shipments, supplies & equipment calibrations real-time online.

Reagan-Udall Foundation for the FDA
Booth: 625
Contact: Lea Ann McNee
Phone: 202-849-2071
Email: lmcnee@reaganudall.org
Website: www.reaganudall.org

Home to the Innovation in Medical Evidence Development and Surveillance (IMEDS) program and the Expanded Access Navigator, the Reagan-Udall Foundation for the FDA is a Congressionally chartered nonprofit that supports the mission of the FDA to improve America's public health. The Foundation creates public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today's rapidly evolving science.

Real Regulatory Limited
Booth: 936
Contact: Ms Fiona Windsor
Phone: 353-18851710
Email: fwindsor@realregulatory.com
Website: www.realregulatory.com

Real Regulatory is your independent EU and UK based regulatory services provider. From small molecule through to ATMP biotech products, we've been adding invaluable experience to our clients projects since 2002. We are the 'Virtual Regulatory Affairs Department' for SMEs who have insufficient internal resource to properly develop their EU and UK strategy. For hands on support with the creation of or conversion of FDA documents into submission ready eCTD files, chat with us.

Real Staffing Group
Booth: 719
Contact: Jesse Norton
Phone: 858-243-8737
Email: j.norton@realstaffing.com
Website: www.realstaffing.com/our-divisions/pharma-biotech

Real Life Sciences is a global leader in the provision of pharma, biotech and medical devices recruitment services and has one of the largest networks of specialist recruiters in the world. By recognizing talent and valuing relationships we are able to consistently deliver local, global and industry expertise to ensure success time after time.

Realtime Software Solutions
Booth: 1345
Contact: Kathleen Clary
Phone: 210-852-4310
Email: kclary@realtime-ctms.com
Website: www.realtime-ctms.com

RealTime Software Solutions is dedicated to creating solutions that make sites and site networks more efficient and connects sites and sponsors together like never before. RealTime-CTMS is a leading CTMS platform that boasts intuitive interfaces and unmatched capabilities. Our compliant eRegulatory solution, eDOCS, costs less and does more than the competition. Contact RealTime today for more information.

Redbock
Booth: 1907
Contact: Gaurav Sharma
Phone: 760-642-5409
Email: info@redbock.com
Website: www.redbock.com

Redbock is a consultancy that delivers highly skilled professionals, serving in the pharmaceutical, biotechnology and medical device industries. We provide expert solutions to resource-challenged companies, and positively impact the lives of the consultants helping them. Over the years, our consultants have brought solutions to some of the largest, high-profile companies in the industry.

Rees Scientific
Booth: 1946
Contact: June Spitz
Phone: 609-530-1055
Email: sales@reesscientific.com
Website: www.reesscientific.com

Rees Scientific is the leader of continuous automated monitoring in the pharmaceutical and healthcare industries. The top 10 global pharmaceutical companies have utilized our system to protect their valuable assets. We set the standard for monitoring cold storage (refrigerators, freezers, cold rooms) and ambient conditions. Our monitoring solution is a major asset that our customers use to keep their product integrity and meet many regulatory requirements.

Regxia Inc. **Booth: 1510**
Contact: Cameron McGregor
Phone: 416-278-1023
Email: mcgregor@regxia.com
Website: www.regxia.com

Regxia Inc. is a unique Scientific and Regulatory Consulting Firm serving the pharma and biotech industries. Supporting products at all stages of development and throughout their lifecycle as part of overall regulatory project management, on a stand-alone basis, or simply as your chosen e-Publisher. Regulatory, eCTD and Quality Services: FDA, Health Canada, EMA: RA Strategy; Dossier Compilation & Management; eCTD (compilation & publishing); CMC; CTA, IND, NDA, NDS, ANDA, etc.; online GCP Training.

Rephine Ltd. **Booth: 2551**
Contact: Daniel Veress
Phone: 44-1-763-8531-35
Website: rephine.com

Rho, Inc. **Booth: 1016**
Contact: Karley St. Pierre
Phone: 919-408-8000
Email: karley_stpierre@rhoworld.com
Website: www.rhoworld.com

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.

Rocky Mountain Poison & Drug Safety **Booth: 725**
Contact: Christine Kremzar
Phone: 866-871-4980
Email: christine.kremzar@rmpdc.org
Website: www.rmpds.org

Rocky Mountain Poison & Drug Safety, a division of Denver Health, provides specialized research, education, prevention and treatment services to meet the unique and complex needs of public health, government agencies, and the pharmaceutical and consumer products industries. Our solutions span the life-cycle of a drug or consumer product and are designed to ensure safety, reduce risk, safeguard compliance and galvanize industry innovation.

RWS Life Sciences **Booth: 622**
Contact: Berett Garbus
Phone: 860-727-6048
Email: berett.garbus@rws.com
Website: www.rws.com/lifesciences

RWS Life Sciences is the world's second largest life sciences translation practice providing a full suite of language solutions exclusively for life sciences. Our proven methodology and specialized translation professionals make us well qualified to translate all types of content across the life sciences industry. Our Quality Management System (QMS) is certified to ISO 9001, ISO 13485 and ISO 17100 and our life science expertise is crucial to our success.

Rx Values Group Ltd **Booth: 933**
Contact: Ruth Whittington
Phone: 64-(0)-21-759-179
Email: ruth.whittington@rxcomms.com
Website: www.rxcomms.com

Rx Communications is a global medical communications agency with several specialties: health economics and outcomes expertise, superb project management, educational tools and booklets, and medical writing services of the highest quality. We are also developing a seamlessly integrated app platform for patients, clinicians and HCPs that will transform clinical trial recruitment; this disruptive innovation will be a standout product.

RxLogix Corporation **Booth: 1545**
Contact: Shalini Modi
Phone: 949-362-1247
Email: shalini.modi@rxlogix.com
Website: www.rxlogix.com

RxLogix is a global PV solutions company specializing in innovative software & consulting services. Our team of business & technology innovators works with PV & Risk Mgt Professionals to help increase the compliance, productivity & quality for the entire Drug Safety value chain. We are business transformers, digital thinkers, tech innovators, business mavericks, driven individuals. Our goal is to make the most innovative industry standard software for the life sciences domain.

Saama **Booth: 913**
Contact: Crystal Black
Phone: 650-823-6622
Email: crystal.black@saama.com
Website: www.saama.com

Saama Technologies is the advanced clinical data and analytics company, unleashing wisdom from data to deliver better business outcomes for the life sciences industry. Saama's unified AI-driven clinical data analytics platform, seamlessly integrates, curates, and animates unlimited sources of structured, unstructured, and real-world data to delivering actionable insights.

Salesforce **Booth: 2009 | BS7**
Contact: Jason Martial
Phone: 415-278-1842
Email: jmartial@salesforce.com
Website: www.salesforce.com/industries/healthcare/life-sciences/

Salesforce is driving a new era of connected relationships between life science companies, providers, and patients. Biotech, pharmaceutical, and medical device companies are innovating faster than ever with the Salesforce Customer Success Platform, with cloud solutions for sales, marketing, service, analytics, communities, IoT, and application development. Each solution is backed by the world's most trusted enterprise cloud and brings the benefits of mobile, social, and collaborative design.

SAS Institute Inc. **Booth: 1205**
Contact: Erin Hathaway
Phone: 919-677-8000
Email: erin.hathaway@sas.com
Website: www.sas.com/

As the leader in advanced analytics, SAS helps you quickly visualize, analyze and share clinical, research and business data to bring therapies to the market faster and more reliably. One hundred percent of biopharmaceutical companies on the Fortune Global 500® chose SAS®, the industry standard for their medicinal development and commercialization analytics. Since 1976, SAS has given users THE POWER TO KNOW®. sas.com/dia

SAS Institute Inc., JMP Division **Booth: 1017**
Contact: Walter Teague
Phone: 919-531-7395
Email: walter.teague@jmp.com
Website: www.jmp.com

JMP® is the SAS® software designed for dynamic data visualization on the desktop. JMP Clinical shortens the drug development process by streamlining safety reviews of clinical trials data. It helps clinicians and biostatisticians migrate into the modern review environment using CDISC data. Intuitive dashboards create a visual framework for rigorous statistical analysis.

Scientia Clinical Research
Booth: 807
Contact: Franziska Loehrer
Phone: 61-419-385-369
Email: franziska.loehrer@scientiaclinicalresearch.com.au
Website: scientiaclinicalresearch.com.au

We are a state-of-the-art clinical trials facility focused on early stage clinical research studies in healthy volunteers as well as patients across a wide range of therapeutic disciplines, including oncology and haematology. We are co-located within a major research precinct including Prince of Wales Hospital, Nelune Comprehensive Cancer Centre, Lowy Cancer Centre and the University of NSW. We have the services and facilities to partner with you from study design through to study close-out.

Self Care Catalysts Inc.
Booth: 2301
Contact: Alexandra Wolfer
Phone: 647-795-8210
Email: alexandra@selfcarecatalysts.com
Website: www.selfcarecatalysts.com/

Self Care Catalysts Inc. is a health solutions company powered by patient intelligence and analytics. SCC offers a mobile and desktop platform that collects RWE and allows researchers and providers to utilize the data in real time for clinical decision making and hypothesis testing. The Real World Evidence Platform by SCC is a unique approach to patient-centered care that connects patients, caregivers, and providers while empowering the patient to engage in self-care practices.

Senseonics
Booth: 2604
Contact: Drinda Benjamin
Phone: 240-624-2603
Website: www.senseonics.com

We are a medical technology company focused on the design, development and commercialization of glucose monitoring systems to improve the lives of people with diabetes by enhancing their ability to manage their disease with relative ease and accuracy. Our first generation continuous glucose monitoring, or CGM, system is a reliable, long-term, implantable CGM system that we have designed to continually and accurately measure glucose levels in people with diabetes for a period of up to 90 days.

SeproTec Multilingual Solutions
Booth: 621
Contact: Urszula Weska
Phone: 512-823-0332
Email: marketing@seprotec.com
Website: seprotec.com/

SeproTec, a Multilingual Service Provider with 30 years of experience, provides translation, interpreting and IP solutions for pharmaceutical and medical device companies, clinical research and healthcare organizations. Ranked among the Top 30 LSC's, SeproTec uses the most advanced translation management technology available today to maximize productivity and quality, and our dedicated customer-specific teams work with over 325 employees and 7,500 freelancers 24/7 to guarantee satisfaction.

SFL Regulatory Affairs & Scientific Communication
Booth: 2648
Contact: Faiz Kermani
Phone: 41-613-667-168
Website: www.sfl-services.com

SFL combines expertise in Regulatory Affairs, Public Affairs, Legal Services and Medical Communication and thus can offer a wide range of services related to practically all lifecycle stages of your product. Depending on the complexity of a project, we offer single services or a customized service package drawing from our broad expertise. SFL also provides specialized training courses where participants can benefit from the team's cross-functional expertise.

Shimmer Research
Booth: 533
Contact: Martina Donohue
Phone: 353-1-6875760
Email: mdonohue@shimmersensing.com
Website: www.shimmersensing.com

Shimmer is a leading wearable technologies services and sensor manufacturing company based in Dublin, Ireland. In addition to standard products, Shimmer provides customized sensor development services, volume manufacturing, and complete wearable sensor solutions of any complexity. Shimmer's technology and services have been employed by thousands of researchers at more than 900 leading companies, universities, and research institutes in more than 75 countries. Shimmer is ISO 13485:2016 certified

snaploT
Booth: 2610
Contact: Nick Salcedo
Phone: 858-829-7895
Email: nicholas.salcedo@snapiot.com
Website: snapiot.com

Bringing the innovation of tomorrow into clinical trials today. snapClinical is the industry's only self-service enabled platform that allows rapid implementation of digital clinical trials for any protocol, deployment, mobile device, and assessment/instrument and connected health monitoring device. The platform requires no software coding to easily transform study protocols into powerful digital patient-centric engagement solutions that maximize the power and benefit of mobile technology.

Softserve Inc.
Booth: 2455
Contact: Briana Mendoza
Phone: 512-516-8880
Email: info@softserveinc.com
Website: www.softserveinc.com

SoftServe is a digital authority that advises and provides at the cutting-edge of technology. We reveal, transform, accelerate, and optimize the way enterprises and software companies do business. And with expertise across healthcare, retail, media, financial services, software, and more, our end-to-end solutions deliver innovation, quality, and speed.

Sonic Clinical Trials
Booth: 904
Contact: Carolyn Cheer,
Paullette Azar-Tannous, Abraham Roodt
Phone: 61-2-9855-6000
Email: enquiries@sonicclinicaltrials.com
Website: www.sonicclinicaltrials.com.au

Sonic Clinical Trials provides global central laboratory services. In Australia, SCT provides site management services within the GP setting, facilitating access to Australia's largest network of GP sites (10M patient consultations annually by over 2,000 physicians). Sonic Services include: Laboratory Testing, Project Management, Sample Management, Kit Production, Collection Services as well as GP-based Patient Recruitment and Study Feasibility.

Southern Star Research
Booth: 805
Contact: David Lloyd
Phone: 61-2-9011-6266
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 14 years direct clinical research experience. With a willingness to provide every Client with exceptional customer service and a history of success in clinical trials from Phase I to IV, Southern Star Research has the capability and the drive to support your R&D objectives in Australia.

Sparta Systems **Booth: 1837**
Email: insidesales@spartasystems.com Phone: 609-807-5100
Website: www.spartasystems.com

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta. Learn why at www.spartasystems.com

Spencer Health Solutions Inc. **Booth: 518**
Contact: Gayle McCracken Phone: 919-208-9176
Email: gmccracken@spencerhealthsolutions.com
Website: helloimspencer.com

Splash Clinical, LLC **Booth: 837**
Contact: Lauri Badura Phone: 414-443-3280
Email: lbadura@splashclinical.com
Website: splashclinical.com/

Splash Clinical is an innovative patient recruitment firm that's pioneered the use of digital & social media to recruit patients for clinical trials. The company was founded to help solve patient enrollment by leveraging the power of social media, data analytics and mobile technologies. We work with Sponsor's and CRO's from across the globe, supporting 5,000+ study sites in 19 countries. Splash Clinical has proven successful completions of more than 300 digital & social media campaigns.

spmd Safety Strategies for Health Inc. **Booth: 2451**
Contact: Annelie MacDonald Phone: 978-969-2393
Email: annelie.macdonald@spmd-safety.com
Website: spmd-safety.com/

spmd – safety strategies for health Inc. (spmd) is a contract pharmacovigilance service provider working with various pharmaceutical companies from all over the world. We are a new company with German roots in the USA with plenty of entrepreneurial spirit. We collaborate on a daily basis with our well-established pharmacovigilance partner enterprise in Germany, spm_ - safety projects & more GmbH.

Spotline **Booth: 811**
Contact: Don LaMure Phone: 40-876-816-64

Statistics & Data Corporation (SDC) **Booth: 1239**
Contact: Jim Townsend Phone: 480-632-5468
Email: data@sdcclinical.com
Website: www.sdcclinical.com

SDC delivers top-tier clinical trial services to pharma, biologic, and device/diagnostic companies. We are committed to providing experienced teams who will take ownership of your needs and are positively engaged in your projects. With strategic scientific consulting and clinical data services (biostatistics, data management/EDC, & IRT/IWRS) expertise at our core, our services are scalable via strategic partnerships to provide full service clinical trial solutions that are The Right Fit For You.

Stefanini **Booth: 2343**
Contact: Nikki Bonnell Phone: 248-263-3440
Email: Nikki.Bonnell@stefanini.com
Website: www.stefanini.com

Stefanini Digital Health Services is a branch of Stefanini - a global 25k people, $1.7 Bn revenue company - focusing on digital/eHealth technology services for the Life Sciences industry with +20 years of experience. Stefanini provides multilingual (34 languages) helpdesk and global hardware deployment services for global eHealth end-users, including patients, doctors & nurses, CRA's and clinical site personnel.

Sterling Institutional Review Board **Booth: 1850**
Contact: Kathye Richards Phone: 770-690-9491
Email: kathye.richards@sterlingirb.com
Website: www.sterlingirb.com

For more than 28 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. **Booth: 1250**
Contact: Shantal Feltham Phone: 519-652-5327
Email: dpalmer@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.

StudyKik **Booth: 2442**
Contact: Matt Miller Phone: 949-235-9286
Email: Matt.Miller@studykik.com
Website: www.studykik.com

StudyKIK utilizes social media to provide patient recruiting solutions for clinical trial sites, clinical research organizations, and pharmaceutical companies. The Company is a first mover in the patient recruitment space, using social media to address recruiting and retention of patients in the $40bn+ clinical trial industry. StudyKIK serves over 1,600 research sites with a growing database of over 2,000,000 patients from its social media communities.

SubjectWell **Booth: 923**
Contact: Ivor Clarke Phone: 888-634-1166
Email: ivor@subjectwell.com
Website: www.subjectwell.com

SubjectWell is the risk-free clinical trials marketplace that only charges for patients who randomize. While the typical approach to recruitment is study specific, SubjectWell runs broad-based education campaigns, highlighting the benefits of clinical trials in general, engaging the public when they are not thinking about their condition. This unique approach combined with telephone-based pre-screening delivers highly qualified referrals and allows them to only charge for those who randomize.

Symbio, LLC
Booth: 1412
Contact: Chad Troller
Phone: 631-403-5123
Email: ctroller@symbioresearch.com
Website: www.symbioresearch.com

Symbio is a full-service CRO. Since 2002, we have been successfully managing Proof of Concept and Phase I-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
Booth: 2216
Contact: Nicki Norris
Phone: 847-215-1358
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 in-home and alternate-site care on six continents. Sponsor benefits include accelerated recruitment, enhanced retention, improved compliance, increased site productivity and increased patient satisfaction. A Certified Women Owned Business Enterprise.

synchrogenix
A CERTARA COMPANY

Synchrogenix, a Certara Company
Booth: 1117
Contact: Lauren Sobocinski
Phone: 302-892-4800
Email: lauren.sobocinski@synchrogenix.com
Website: www.synchrogenix.com

For life science companies worldwide seeking the highest quality-oriented partner, Synchrogenix is the added-value provider of customized regulatory solutions with a proven record of success. With over 90% repeat business and 33 years of experience, our expert operations, consulting, and communications teams, along with our reliable technology, ensure successful submissions, enable clients to communicate with confidence, and guide partners through the global regulatory maze.

Syneos Health
Booth: 1721
Contact: Dana Bobrowski
Phone: 919-876-9300
Email: conferences@syneoshealth.com
Website: www.syneoshealth.com/

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Created through the merger of two industry leading companies – INC Research and inVentiv Health – we bring together approximately 24,000 clinical and commercial minds with the ability to support customers in more than 110 countries. To learn more about how we are shortening the distance from lab to life® visit syneoshealth.com.

Synova Health
Booth: 1602
Contact: Alessandra Leanza
Phone: 55-19992243421
Email: paula.meneghetti@caeplab.com.br
Website: synovahealth.com

Synova is a Full Service Contract Research Organization based out of Brazil, stemming from the country's population pool of 210 million. We are the largest CRO in Latin America, born out of the Brazilian Bioequivalence Center CAEP. Our well established databases, expansive networks in Technical, Scientific and Regulatory realms remain key to Brazil's Clinical Trial Potential. Our global team of professionals are driven to facilitate and expedite the process of worldwide drug development.

Synteract
Booth: 1931
Contact: Trisha Vonder Reith
Phone: 760-268-8028
Email: trisha.vonderreith@synteract.com
Website: www.synteract.com

Synteract is an innovative CRO supporting biotech and pharma companies across all phases of drug development to help bring new medicines to market. Synteract has conducted nearly 4,000 studies in more than 60 countries, working with more than 26,000 investigative sites and nearly 750,000 patients. It has contributed to more than 240 product approvals. Synteract offers a notable depth of therapeutic expertise in oncology, dermatology, neuro degenerative, as well as pediatrics and rare and orphan.

Target Health Inc.
Booth: 2305
Contact: Warren Pearlson
Phone: 212-681-2100
Email: wpearlson@targethealth.com
Website: www.targethealth.com

Target Health Inc., is full service, technology driven CRO, with staff dedicated to all aspects of drug, device and diagfnostic development including Regulatory Affairs (represent over 50 companies at the FDA), Strategic Planning, Clinical Research, Biostatistics, Data Management & Medical Writing. All of our software is web based, 21 CFR part 11 compliant. THI has received the first FDA approval for a product using our eSource software, Target eCTR(eSource; Electronic Clinical Trial Record)

Technical Resources International, Inc.
Booth: 1717
Contact: Anais Silva
Phone: 301-897-1724
Email: asilva@tech-res.com
Website: www.tech-res.com

As a CRO+, TRI possesses all the essential resources to offer first-class functional and full-service outsourcing services: quality operational, strategic, technical, and regulatory solutions, long-standing clinical trial expertise, and deep therapeutic knowledge. TRI supports patient recruitment through its health communication services including design and implementation of recruitment and outreach campaigns and scientific event planning services.

Techsol Corporation
Booth: 2108
Contact: Javeed Abbas Shaik
Phone: 609-373-2921
Email: javeed.abbas@techsolcorp.com
Website: www.techsolcorp.com

Techsol Corporation is a leading global technology service organization, providing pharmaceutical industry focused services in the areas of Medical Information, Drug Safety, Signal Detection and Management, Clinical Development and Pharmaceutical Sales Management. Techsol' global pharmaceutical – information technology focus and techno-functional expertise enables it to provide technology services and consultancy across the drug life cycle.

Telelingua Translations
Booth: 1447
Contact: Lionel Mellet
Phone: 914-833-3305
Email: lmellet@telelingua.us
Website: www.telelingua.com

Telelingua performs clinical research and clinical trial translations across all stages of the product development and registration process, including clinical research, phases 0 - IV, surveys, drug testing, regulatory approval dossiers, registration submission and review, production and marketing.

TFDA / Center for Drug Evaluation, Taiwan

Booth: 1740

Contact: Keng-Che Chou
Phone: 886-2-81706000
Email: kcchou758@cde.org.tw
Website: www.cde.org.tw

Taiwan Food and Drug Administration is the regulator of medical product registration in Taiwan, and Center for Drug Evaluation was established to assist in technical dossier review. Taiwan has one of fastest regulatory submissions processes in the Asia and hosts more than 100 clinical research sites, providing high quality medical care and clinical data. Taiwan adopts and recognizes all ICH guidelines, which are applied to NDA, BSE, IND review process and GMP inspection.

The Patient Recruiting Agency

Booth: 2437

Contact: Lance Nickens
Phone: 512-789-7788
Email: lance@tprausa.com
Website: www.patientrecruiting.com/

A full-service global patient recruiting/retention company for Investigators, CROs & Sponsors. Since 1999, TPRA has completed over 3,500 campaigns for over 150 indications. IN-HOUSE services: Branding Content development Production & fulfillment of site kit materials Media production and placement (Online/TV/radio/print, etc) Mobile-friendly pre-screening website development Call pre-screening Text messaging RADIUS365™ online response, referral delivery and retention tracking, managing & reporting systems

Therapak, LLC

Booth: 2317

Contact: Arbi Harootoonian
Phone: 909-267-2000
Email: info@therapak.com
Website: www.therapak.com/

Therapak is the global leader in providing 3rd party kit assembly & distribution services to pharmaceutical & laboratory organizations. Therapak's menu of services include assembly of lab convenience kits for collection of samples, temperature sensitive shipping systems, requisition & label printing and ancillary & equipment supply distribution direct to sites on a global basis. Therapak is a cGMP compliant organization with facilities in the US, UK & CZ and is a fully owned subsidiary of VWR.

Therapeutics Inc.

Booth: 1143

Contact: Anthony Andrasfay
Phone: 858-571-1800
Email: tandrasfay@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 Ph1-4 multicenter trials in acne, psoriasis, dermatitis, rosacea, alopecia, tissue fillers, inflammation, & all pediatric/ adult derm categories. Guiding strategy, CMC, nonclin + clinical development, regulatory, trial management, DM+statistics, & life cycle management: concept, design, project planning/management.

ThoughtSphere Inc.

Booth: 1050

Contact: Ilene Brooks
Phone: 408-898-9828
Email: ilene.brooks@thoughtsphere.com
Website: www.thoughtsphere.com/

ThoughtSphere has one mission – help life science companies use data science to develop and deliver treatments to patients faster and smarter. Driven by AI and ML, ThoughtSphere Cloud is the only source-system agnostic data and analytics platform built for clinical trials resulting in faster start-up and reduced costs. The data-driven platform enables risk-based monitoring at granular levels, integrated site budgeting with quality triggered payments, and clinical data review and reconciliation.

Total Clinical Trial Management

Booth: 2055

Contact: Melynda Geurts
Phone: 214-855-1222
Email: mgeurts@totalcro.com
Website: www.totalcro.com

Total Clinical Trials Management (TCTM), is a full-service 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 dermatology, aesthetics, ophthalmology, respiratory and cosmetics, generic studies.

TransPerfect

Booths: 1731 & 1838

Contact: Ryan Simper
Phone: 919-361-9200
Email: rsimper@transperfect.com
Website: www.trialinteractive.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.

Trial By Fire Solutions

Booth: 910

Contact: Jon Cecchettini
Phone: 888-871-1965
Email: contact@simpletrials.com
Website: www.simpletrials.com

SimpleTrials is an on-demand Clinical Trial Management System (CTMS) from Trial By Fire Solutions. With plans starting at $99 per month, SimpleTrials is a cost effective subscription based system, built to support sponsors, sites & CROs in the life science industry. Features include study-based management of sites/teams & contacts, startup tracking, documents & eTMF, screening & enrollment, contracts & payments, monitoring and visit reports, as well as insights from dashboards & custom reports.

Trifecta

Booth: 1137

Contact: Rick Ward and Karen Olszewski
Phone: 317-955-7890
Email: sales@trifectaclinical.com
Website: www.trifectaclinical.com

Trifecta is the global leader in clinical trial training, safety letter delivery and site communication. As a clinical technology solutions provider, Trifecta produces more than 350 live, on-demand, and web-based Investigator meetings each year in 87 countries. Trifecta's 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 for more trial with far less error.

Trilogy Writing & Consulting

Booth: 2251

Contact: Evija Kuemmel
Phone: 49-691-382-5282-2
Email: evija.kuemmel@trilogywriting.com
Website: trilogywriting.com

At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients' teams. We proactively plan, coordinate and write clinical documents to meet timelines, with a readability that reduces the time for review and approval. Our goal is to help teams streamline their documentation process and make sure their documents communicate clearly and effectively.

UBC — **Booth: 1649**
Contact: Brein Crumlich
Phone: 215-591-2880
Email: brein.crumlich@ubc.com
Website: www.ubc.com

UBC leads the market in providing integrated, comprehensive clinical, safety, and patient support services. Our experts are committed to working in unison with pharmaceutical and biotech organizations to effectively navigate the product lifecycle and make medicine and medical products safer and more accessible. By powering unsurpassed expertise and experience with proprietary software, UBC stands out in the generation of real-world evidence of product safety, value, and effectiveness.

Uber — **Booth: 2618**
Contact: Kate Stewart
Phone: 408-839-7060
Email: kate.stewart@uber.com
Website: www.uberhealth.com/

Uber Health is a HIPAA-compliant solution that enables healthcare organizations to coordinate reliable, comfortable rides for patients, caregivers and staff. Through a web dashboard, healthcare partners are able to schedule rides on behalf of others going to and from the care they need. It is easy to use, cost effective and taps into the on-demand Uber experience and scale you know for healthcare rides. Stop by and speak with the Uber Health team to learn more about partnering together.

uMotif — **Booth: 2545**
Contact: Rob Nichols
Phone: 44-772-089-1283
Email: rob@umotif.com
Website: www.umotif.com/

uMotif is the modern data capture that patients love to use. Our validated digital platform deploys globally to capture data that gives researchers smarter insights in clinical and commercial phases. We take a patient-centric approach, and have built a platform that engages participants to submit high volumes of data during studies. Our platform has captured over 65 million data points from over 20,000 patients in a range of studies and clinical deployments in 21 clinical conditions.

Uppsala Monitoring Centre — **Booth: 838**
Contact: Jessica Avasol
Phone: 46-186-560-60
Email: info@who-umc.org
Website: www.who-umc.org

Inspire. Engage. Transform. Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practice.

Validated Cloud Inc. — **Booth: 840**
Contact: Douglas Lantigua
Phone: 617-849-8650
Email: info01@ValidatedCloud.com
Website: www.ValidatedCloud.com

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.

Veeva Systems, Inc. — **Booth: 2031**
Contact: Lauren Offers
Phone: 925-452-6500
Email: contact@veeva.com
Website: www.veeva.com

Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 675 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America.

Verantos — **Booth: 2400**
Contact: Jeff Strada
Phone: 678-521-6003
Email: contact@Verantos.com
Website: verantos.com/

Verantos is a real world evidence company specializing in advanced regulatory-grade studies for biotech and pharmaceutical companies. Verantos' mission is to advance biopharma capabilities to accelerate cost-effective innovation in drug development and address unmet medical needs in patients with either rare or common diseases. Verantos uses advanced real world data including electronic health records to evaluate health outcomes to produce reliable evidence for regulators, payers and providers.

Verified Clinical Trials — **Booth: 1014**
Contact: Mitchell Efros
Phone: 516-469-3196
Email: DrEfros@verifiedclinicaltrials.com
Website: www.verifiedclinicaltrials.com

Verified Clinical Trials is the largest global research subject clinical trials database registry designed to prevent dual enrollment & several key protocol violations critical to a trials success. VCT uses a hybrid biometric and IDmetric research subject authentication process. VCT will improve safety & data quality in clinical trials. This will reduce adverse events and placebo rates. VCT is utilized by the majority of phase 1 units as well as across multiple phase 2 & 3 clinical trials.

Veristat — **Booth: 1713**
Contact: JoAnn Eckhoff
Phone: 508-429-7340
Email: marketing@veristat.com
Website: www.veristat.com/

Veristat is a smart, effective and impactful CRO CRO that is committed to partnering with biopharmaceutical firms to advance their therapies through the clinical development & regulatory submission process. We provide strategic decision-making, the operational efficiencies to manage and monitor international trials, the biometrics expertise to collect, analyze & report clinical trial data to regulatory agencies, and the therapeutic and medical proficiency to mastermind the entire process.

Versiti — **Booth: 2044**
Contact: Carrie Kapczynski
Phone: 414-937-6095
Email: ckapczynski@versiti.org
Website: www.bcw.edu/diagnostics

The BloodCenter of Wisconsin is a world-renowned organization with medical and scientific expertise in diagnostics and cellular therapies. We support preclinical and phase I-IV trials, including: specialty laboratory testing, custom assay development, specimen collections, sample storage and electronic data transfer. BCW is a part of Versiti, an affiliation of successful healthcare organizations whose vision is to become the national leader in transfusion medicine and blood disorder research.

Viedoc
Booth: 737
Contact: Sverre Bengtsson
Phone: 46-709611524
Email: sverre@viedoc.com
Website: viedoc.com

Viedoc is the most intuitive and easy to use EDC system with powerful built-in features, Viedoc is easy to learn (certification takes less than 3 days) and study set up take 1/2 the time of other systems. Viedoc is highly scalable and allows clinical trial sponsors and investigative sites to easily and securely collect, validate, transmit and analyze clinical study data. Viedoc meets all regulatory benchmarks and compliance standards - including the GCP (good clinical practice.)

Viitai LLC
Booth: 431
Contact: Jeff Cao
Phone: 415-493-9177
Email: jcao@viitai.com
Website: www.viitai.com

Viitai is a leading software company developing applications exclusively for life science organizations. Most of our customers elected to use multiple applications because they like the quality, efficiency, compliance, friendly UI, and customer care. Welcome to our booth 431 to have a chat or see a demo. Applications: Biostatistical Programming Studio, Biodigital Library, Nonclinical Study Tracker, eTMF, Site Training management, Regulatory Submission & Correspondence tracker, Medical Writing...

VirTrial
Booth: 2056
Contact: Amanda Rangel
Phone: 480-462-2222
Email: amandarangel@virtrial.com
Website: virtrial.com

VirTrial is a technology company using a proven telehealth platform to transform the clinical trial industry. The platform offers a patient management program that combines video, text and email, allowing pharmaceutical companies and CROs to create patient-centric trials by replacing some study visits with virtual visits, creating a hybrid model. The VirTrial app is supported on any device (Android, Apple, iPad, computer), can be used by any site and is hosted in a secure environment.

Vitalograph, Inc.
Booth: 1817
Contact: Mark Russell
Phone: 913-730-3212
Email: mark.russell@vitalograph.com
Website: www.vitalograph.com

Vitalograph has been a market leader in the design and manufacture of respiratory devices for over half a century. Our innovation enables us to respond effectively to the growing need for centralized cardio-respiratory data in clinical trials. Our dedicated clinical trials team has grown into a multi-national organization providing centralized Spirometry, home spirometry, e-diary questionnaires, centralized ECG, Holter monitoring and full lung function testing services.

Vitrana
Booth: 2823
Contact: Sean Pfifer
Phone: 973-476-5095
Email: sean.pfifer@vitrana.com
Website: www.vitrana.com

Vitrana has a vision to drive major advances in the quality, efficiency and cost of clinical research, development and patient care through Vitrana's integrated healthcare and life sciences IT platform. Clinical research, development and patient care can be significantly improved through the adoption of key technology innovations in information management, focusing both on bottom line costs and on top line growth, leveraging information assets for improved insights and service quality.

VivaLNK
Booth: 2438
Contact: Lucia Nguyen
Phone: 408-868-2898
Email: info@vivalnk.com
Website: www.VivaLNK.com

VivaLNK is a provider of connected healthcare devices for wellness, patient care, and telemedicine. The company's portfolio includes wearable medical grade devices and data analytics applications that continuously monitor the health and well-being of individuals. Our vision is to improve the quality and accessibility of healthcare worldwide by combining technology, data, and analytics into an integrated solution.

WCCT Global
Booth: 1445
Contact: Talia Hight
Phone: 714-252-0700-2001
Email: talia.hight@wcct.com
Website: www.wcct.com

WCCT is a multisite, full-service early phase contract research organization (CRO) for pharmaceutical, biotechnology and medical device industries. We are specialized global regulatory and clinical development professionals who offer an innovative, agile and collaborative approach to every program we deliver.

WCG Clinical Services
Booth: 1005
Contact: Lauren Ozmore
Phone: 239-249-2364
Email: lozmore@wcgclinical.com
Website: www.wcgclinical.com

The pioneer of independent ethical review, WCG continues to drive ingenuity in the clinical research space. Today, WCG's solutions are built upon the foundation of ethical review, but have grown to include a suite of complementary services and technologies that expand the capabilities of the modern research professional. WCG delivers transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

WebbWrites, LLC
Booth: 1514
Contact: Laura A. Webb-Murrah
Phone: 919-384-8850
Email: webb@webbwrites.com
Website: www.webbwrites.com

WebbWrites has extensive experience in regulatory document preparation, ability to provide a full range of statistical services, and provision of superior products due to continuity of personnel, flexibility to work onsite with clients, unsurpassed customer service, & capacity to meet aggressive timelines. We have prepared over 95 submissions in our 21 years of existence.

Welch Allyn
Booth: 1936
Contact: Sonja daly
Phone: 414-354-1600
Email: sonja.daly@welchallyn.com
Website: www.welchallyn.com

Welch Allyn Cardiology, powered by Mortara, is a recognized technology leader in the world of ECG. VERITAS is the leading algorithm used in clinical trials requiring digital ECG and the preferred solution used by all leading central ECG laboratories. VERITAS is the same algorithm used in the FDA ECG Warehouse. Diagnostic cardiology products includes electrocardiographs, stress exercise and Holter systems, data warehousing solutions, automated BP solutions, and cardiology monitoring systems.

Welocalize Life Sciences
Booth: 1041
Contact: Kim Jones
Phone: 301-668-0330
Email: kim.jones@welocalize.com
Website: lifesciences.welocalize.com/

Welocalize Life Sciences is an industry leader with proven translation, interpretation and localization expertise for clinical research, pharmaceutical, biotechnology, medical device and healthcare companies. Established in 1997, we operate out of 21 global offices and provide language solutions in 175 languages. Welocalize Life Sciences holds ISO 9001, ISO 13485, and ISO 17100 certifications.

Whitsell Innovations, Inc.
Booth: 1140
Contact: Natalie Becker
Phone: 919-636-5839
Email: info@whitsellinnovations.com
Website: www.whitsellinnovations.com

At Whitsell Innovations our singular focus is perfect medical, scientific, and regulatory writing. Since 2006, we have served our clients' preclinical through post-marketing needs with writing, editing, review, and electronic submissions across therapeutics areas. When you require CSRs, manuscripts, PADERs, narratives, DMFs, development reports, IBs, or full submissions, our US-based writers are ready. We speak science and we love what we do.

WIRB-Copernicus IRB Group
Booth: 1105
Contact: Lauren Ozmore
Phone: 239-249-2364
Email: lozmore@wcgclinical.com
Website: www.wcgclinical.com

WIRB-Copernicus IRB Group is the world's most trusted provider of regulatory and ethical review services for human research. The pioneer of independent ethical review in 1968, WIRB-Copernicus IRB Group delivers transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

Woodley Equipment Company
Booth: 2131
Contact: Robin Wickham
Phone: 800-471-9200
Email: enquiries@woodleyequipment.com
Website: www.woodleyequipment.com/

Woodley Equipment Company is a leading global supplier of medical and laboratory equipment solutions to the Clinical Trials Industry. With rental and purchase options available, a unique range of tailored services, and the ability to source, supply and maintain equipment, we deliver a value for money equipment solution, every time.

WuXi Clinical
Booth: 1416
Contact: Eriel Fauser
Phone: 512-343-1092
Email: eriel.fauser@wuxiapptec.com
Website: www.wuxiclilnical.com

WuXi Clinical is a global CRO providing comprehensive Phase I-IV clinical development services for pharmaceuticals, biologics, and medical devices. With expertise spanning all major therapeutic areas, we deliver the unique blend of an experienced team, combined with the creativity, responsiveness, and the customer centric-focus of a highly nimble organization.

XClinical Services America Inc.
Booth: 1955
Contact: Cathy Hlinka
Phone: 201-340-2749
Email: cathy.hlinka@xclinical.com
Website: www.xclinical.com

Xclinical offers a complete integrated Trial Management Software suite, MARVIN and supporting services. Built on the same platform the MARVIN suite includes a CDISC-certified (EDC) system with numerous modules (CDM), (CTM), (IWRS), (WebPRO), etc. Accessible from any browser, MARVIN supports all global languages. The xclinical suite provides an intuitive interface and easy-to-use tools enabling the conduct of clinical trials to be straightforward and cost-effective.

YPrime Inc.
Booth: 1851
Contact: Adam Blackburn
Phone: 844-299-9204
Email: contactus@yprime.com
Website: www.yprime.com

Technology that enables and automates the research process is equally as important as the underlying science in the success of clinical trials. Sponsors and CROs know they can rely on YPrime for IRT, eCOA and a host of clinical data services to simplify increasingly difficult work. YPrime's forward-looking software solutions give you both the tools you need and the data when you want it.

Zifo
Booth: 2350
Contact: Ifthi Kalanther
Phone: 203-826-8897
Email: Ifthi@zifornd.com
Website: www.zifornd.com

Zifo RnD Solutions, headquartered in Chennai, India, is a Specialized Research Data Management service provider and provides best in class R&D solutions and services that drive efficiency across both sponsors and product companies without increasing the regulatory and business risks. Zifo has expertise in Clinical Data Solutions, Discovery & Lab Informatics, Computer System Validation and Consulting Services for the regulated environments.

Zigzag Associates Ltd
Booth: 2016
Contact: Julie Beal
Phone: 44-1235-854033
Email: info@zigzagassociates.com
Website: www.zigzagassociates.com/

Zigzag Associates Ltd aims to provide straightforward, reliable and flexible Quality Assurance (QA) and auditing services conducted on a global basis. Whether you require ad hoc support or a team to partner with on audit programs, we have the people, the expertise and the experience to provide the assistance you need. Our team has audited in 80 countries across all major continents. We provide a range of tailor-made QA services, with particular strengths in PV and GCP, to meet your requirements.

ZS
Booth: 1300
Contact: Julie Chappel
Phone: 630-816-0181
Email: jachappel@gmail.com
Website: www.zs.com/solutions/research-and-development-excellence

ZS is a professional services firm that works side by side with companies to help develop and deliver products that drive customer value and company results. We leverage our deep industry expertise, leading-edge analytics, technology and strategy to create solutions that work in the real world. With more than 35 years of experience and 6,000-plus ZSers in 23 offices worldwide, we are passionately committed to helping companies and their customers thrive. To learn more, visit www.zs.com.

Quorum Kinetiq

ADVARRA®

altogether EVEN better

Visit Booth 2105 & Get a Free Gift

The Greatest Institutional Reach of Any Central IRB

Compare your preferred institutions to our list & receive a free gift

When Advarra acquired Quorum and Kinetiq, we solidified the #1 name in fully integrated research compliance solutions. We accelerate innovation and support faster study startup with:

- The greatest institutional access in the industry–over 3,100+ sites
- Unprecedented regulatory expertise
- Global compliance and strategic consulting solutions

DON'T MISS OUR SESSIONS ON TUESDAY, JUNE 25:

Mitchell Parrish, JD, RAC, CIP

Improving Clinical Trial Risk Management: How to Leverage the IRB's Designated Purpose
10:30-11:30AM

James Riddle, MCSE, CIP, CPIA, CRQM

Conversation with the Participant: Layperson Summaries and Return of Results
4:15-5:30PM

ADVARRA.COM

Patients are at the center of everything we do.

At UBC, our primary focus is on the patient. We take a customized approach when partnering with pharmaceutical and biotech clients to generate real world evidence, monitor patient safety, and satisfy regulatory requirements.

Because patients are at the center of everything you do, choose a provider with decades of late stage and global safety experience combined with cutting-edge technology.

Together, we will successfully traverse your product's pre- and post-marketing landscape, so that your patients and their care teams can rest assured they are receiving a safe and effective therapy.

Find out how UBC takes a patient-focused approach to each project.

Learn more at ubc.com

UBC®

dMed
缔脉

A Next Generation
Full Service Clinical CRO

- **Trusted Clinical and Regulatory Path to China**
- **World Class Hub for Global Biometrics, Pharmacovigilance and Medical Writing Services**

350 Professionals Delivering 200 Trials
at Global Standards Today

Visit us at Booth #530

Shanghai • Beijing • Wuhan
San Francisco • New York • Washington DC

Tel: 908-500-6881
Website: www.dmedglobal.com
Linked-in: https://www.linkedin.com/company/dmedglobal