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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.

Sincerely Yours,

Barbara Lopez Kunz
Global Chief Executive
DIA

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.

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.
### Saturday, June 22

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 AM-5:00 PM</td>
<td>Exhibitor Registration</td>
</tr>
</tbody>
</table>

**Schedule**

- **9:00 AM**
  - Coffee Break (Exhibit Hall)
  - Educational Tracks
  - Content Hub and Community Rounds (Sails Pavilion)
  - Innovation Theater Presentations (Exhibit Hall)
- **10:30 AM**
  - Lunch Service
- **11:30 AM-1:30 PM**
  - 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 PM-3:15 PM**
  - Educational Tracks
  - Community Rounds (Sails Pavilion)
  - Engage and Exchange Session (Exhibit Hall)
- **3:15 PM-4:15 PM**
  - 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 PM-4:00 PM**
  - Annual Meeting of the Members (DIA Booth #1531)
- **4:15 PM-5:30 PM**
  - Educational Tracks
  - Community Rounds (Sails Pavilion)

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### Sunday, June 23

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 AM-9:00 AM</td>
<td>Registration for Full Day and Morning Preconference Short Courses*</td>
</tr>
<tr>
<td>8:00 AM-6:00 PM</td>
<td>Exhibitor Registration</td>
</tr>
<tr>
<td>12:30-6:00 PM</td>
<td>Registration for Afternoon Preconference Short Courses*, Conference Attendees, and Speakers</td>
</tr>
</tbody>
</table>

**Schedule**

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

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

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### Monday, June 24

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 AM-6:00 PM</td>
<td>Attendee, Speaker, and Exhibitor Registration</td>
</tr>
</tbody>
</table>

**Schedule**

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

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### Tuesday, June 25

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 AM-5:15 PM</td>
<td>Attendee, Speaker, and Exhibitor Registration</td>
</tr>
</tbody>
</table>

**Schedule**

- **7:00-8:00 AM**
  - Coffee and Light Refreshments
- **8:00-9:15 AM**
  - Educational Tracks
- **9:00 AM-5:00 PM**
  - Exhibit Hall Open
- **9:00 AM-4:00 PM**
  - Professional Posters Open (Exhibit Hall)

---

### Thursday, June 27

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 AM-11:00 AM</td>
<td>Attendee and Speaker Registration</td>
</tr>
</tbody>
</table>

**Schedule**

- **8:00-9:00 AM**
  - Coffee and Light Refreshments
- **9:00-10:15 AM**
  - Educational Tracks
- **10:15-10:45 AM**
  - Coffee Break
- **10:45 AM-12:00 PM**
  - FDA Town Hall

---

### Wednesday, June 26

**Registration Hours**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 AM-5:15 PM</td>
<td>Attendee, Speaker, and Exhibitor Registration</td>
</tr>
</tbody>
</table>

**Schedule**

- **7:00-8:00 AM**
  - Coffee and Light Refreshments
- **8:00-9:15 AM**
  - Educational Tracks
  - Community Rounds (Sails Pavilion)
- **9:00 AM-4:00 PM**
  - Exhibit Hall Open
  - Professional Posters Open (Exhibit Hall)
- **9:15-10:30 AM**
  - 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)
- **10:30-11:30 AM**
  - Lunch Service
- **11:30 AM-1:30 PM**
  - 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 PM-3:15 PM**
  - Educational Tracks
  - Engage and Exchange Sessions (Exhibit Hall)
  - Content Hub (Sails Pavilion)
  - Professional Poster Session and Oral Presentations (Exhibit Hall)
- **3:15 PM-4:00 PM**
  - 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 PM-5:30 PM**
  - Educational Tracks

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### Schedule At-A-Glance

- **Location**: San Diego
- **Dates**: June 23-27, 2019
- **Website**: DIAglobal.org/DIA2019
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
- 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
- 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
- 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

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

**Innovation Theaters**
- Traditional workshops or interactive educational format
- Panel discussions or didactic presentations
- 60-75 minutes
- 175+ sessions spanning 13 educational tracks
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Better Together
Advancing Discovery Science for Public Health Impact

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.
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

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 Data Through a Unified Regulatory Platform

AMPLEXOR | Theater 1 | 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
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:

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• 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

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.

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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.

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Social Wall located in Sails Pavilion Lobby
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Jeremy Jokinen, PhD, MS, Senior Director, Decision Sciences, AbbVie, Inc.
Christine Moore, PhD, Global Head and Executive Director, GRACS CMC – Policy, Merck Research Laboratories

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**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.
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:** 7:00 AM–6:30 PM
- **Tuesday:** 7:00 AM–6:00 PM
- **Wednesday:** 7:00 AM–7:00 PM
- **Thursday:** 8:00 AM–12:30 PM

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

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

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

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- 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 DIA 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.

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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 911 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.
**DIA Luncheon Service**

Lunch will be provided in the back of Exhibit Hall C on Monday, 12:00–2:00 PM, and Tuesday-Wednesday, 11:30 AM–1:30 PM. 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 8:00 AM and after 6:00 PM
- Tuesday: Before 8:00 AM and after 5:30 PM
- Wednesday: Before 8:00 AM and after 5:30 PM
- Thursday: Before 9:00 AM and after 12:15 PM

**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: 9:00 AM–6:00 PM
- Monday: 9:00 AM–7:00 PM
- Tuesday: 9:00 AM–6:00 PM
- Wednesday: 9:00 AM–6:00 PM
- Thursday: 9:00 AM–2:00 PM

**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.

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

DIAglobal.org/DIA2019 | #DIA2019
Meeting Highlights: DIAmond Sessions

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 | 8:00–10:00 AM | 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 | 9:00–10:15 AM | 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 | 10:45 AM–12:00 PM | 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.
Meeting Highlights: Global Regulatory Sessions

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

Monday, June 24 | 11:00 AM–12:00 PM | Room 6B
#117 International Regulatory Convergence
This forum will include leadership from international regulatory agencies.

Monday, June 24 | 2:15–3:15 PM | 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 | 2:15–3:15 PM | 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 | 3:30–4:30 PM | 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 | 3:30–4:30 PM | 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 | 8:00–9:15 AM | 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 | 10:30–11:30 AM | 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 | 10:30–11:30 AM | 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 | 10:30–11:30 AM | 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 | 8:00–9:15 AM | 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 | 10:30–11:30 AM | 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 | 10:30–11:30 AM | 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 | 2:00–3:15 PM | 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 | 4:15–5:30 PM | 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 | 9:00–10:15 AM | 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 | 10:45 AM–12:00 PM | 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.
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 | 9:30–10:15 AM
#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 | 12:15–12:45 PM
#122CH Leveraging Extra Value from an Intern Program: Non-Traditional Majors Add Unexpected Value

Wednesday, June 26 | 9:15–9:45 AM
#320CH Considering Consulting? The Good, the Bad, the Ugly, and the Profitable!

Wednesday, June 26 | 2:00–3:15 PM
#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

Student Poster Session
Monday, June 24 | 10:00 AM–6:00 PM
Students from around the world will showcase their research in this year’s Poster Session.
10:30–10:50 AM | 12:30–2:10 PM | 5:10–5:30 PM

Student Oral Presentations
Tuesday, June 26 | 12:15–1:45 PM
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 | 9:00 AM–4:00 PM

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

Oral Presentations
Monday, June 24 | 7:00–7:45 AM | 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.
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) 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 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 healthcare professionals.

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.

## 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 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.

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.

**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.

### 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**

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## DIA 2019 TRACKS AND FEATURED TOPICS

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## CONTENT LEVEL GUIDE

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

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

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

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

Stop by DIA Booth #1531 to learn more and explore all the benefits DIA Membership has to offer!
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.
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**SUNDAY, JUNE 23**

2:30–3:30 PM

**#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)

**Honorary Chair Welcome**

Joanne Waldstreicher, MD
Chief Medical Officer, Johnson & Johnson

**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**

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

**Panelist**

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

**Panelist**

Deven McGraw, JD
General Counsel and Chief Regulatory Officer, Citizen

**Panelist**

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

7:00–7:45 AM

Annual Meeting Orientation

**MONDAY, JUNE 24**

8:00–10:00 AM

**STUDENT POSTER SESSION AND ORAL PRESENTATIONS OPEN | EXHIBIT HALL**

10:10–10:40 AM

**#101 CH**

Modernizing Data Review in Drug Development with R Shiny

Content Hub Sails Pavilion

WORKSHOP

30

Level: ■

10:10–10:55 AM

**#102 EE**

The Female Perspective on the Clinical Trial Patient Experience: A Live Focus Group

Engage and Exchange Area Exhibit Hall

WORKSHOP

45

Level: ●

10:15–10:45 AM

**#103 IT**

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**

ArisGlobal Innovation Theater: Can Blockchain Technology Change Life Sciences?

Theater 2 Exhibit Hall

SESSION

30
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STUDENT POSTER SESSION AND ORAL PRESENTATIONS OPEN | EXHIBIT HALL

1:00–1:30PM

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Meeting Schedule

### Meeting Schedule

- **Basic-level content:** ●
- **Primarily intermediate-level content:** ■
- **Primarily advanced-level content:** ◆

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### 3:30–4:30PM

#### MONDAY, JUNE 24, CONTINUED

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
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### TUESDAY, JUNE 25, CONTINUED

#### 3:15–4:15PM

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<td>#294</td>
<td>09</td>
<td>Update From the US FDA on Progress and Topics of Current Interest in US Biosimilar Policy, Regulation, and Outreach/ Education</td>
<td>Room 6F</td>
<td>SESSION</td>
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<td>Prescription Drug Labeling: New Guidance from the US FDA</td>
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<td>#296</td>
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<td>Informing Development and Authorizations Using Real World Evidence/Artificial Intelligence</td>
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<td>#297</td>
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<td>Integration of Manufacturing Quality Assessment and Pre-Approval Inspections</td>
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<td>#298</td>
<td>11</td>
<td>Clinical Safety Assessment: What’s a Statistician Got to Do with It?</td>
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<td>Public and Regulatory Response To Drug Pricing Concerns</td>
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<td>#299:CH</td>
<td>16</td>
<td>Challenge of Regulatory Starting Material Designation and Its Implication on the Global Markets for the Post Approval Process</td>
<td>Content Hub Sails Pavilion</td>
<td>WORKSHOP</td>
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**Meeting Schedule**

**WEDNESDAY, JUNE 26**

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<td>#301</td>
<td>01</td>
<td>So Much Data, So Little Time: Hot Topics in Benefit-Risk Assessment</td>
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<td>Triple-s (3S) Smart Safety Surveillance</td>
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<td>02</td>
<td>Disruptive Technology Transforming Clinical Trials: The Case for Artificial Intelligence, Blockchain, and Mobile Tech/Wearables</td>
<td>Room 11A</td>
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<td>Demystifying Technology Selection in Mobile Clinical Trials</td>
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<td>03</td>
<td>Methods for Integrating EHR Data into EDC and eSource Databases</td>
<td>Room 1AB</td>
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<td>#307</td>
<td>04</td>
<td>Can Topic-Based Approaches to Document Authoring Help Meet the Demands of Accelerated Marketing Application Timelines?</td>
<td>Room 4</td>
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<td>#308</td>
<td>05</td>
<td>Identifying High-Value Patient Engagement Opportunities: A Collaborative Three-Step Process for Sponsors and Patient Groups</td>
<td>Room 5AB</td>
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<td>Neoantigen-Based Cancer Therapies: Regulatory Challenges and Opportunities</td>
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<td>Project Planning 101: Turning Strategy into Execution</td>
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<td>08</td>
<td>Improving Trial Quality by Better Preparing Site Teams</td>
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<td>#312</td>
<td>08</td>
<td>Translating Academic Research into Product Development: The Importance of Understanding GLPs at an Early Stage (Part 3 of 4)</td>
<td>Room 14A</td>
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<td>#313</td>
<td>09</td>
<td>Model Integrated Evidence as Pivotal Information for Drug Regulatory Decision Making: When, Where, and Why</td>
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<td>Medical Devices: EU Medical Device Regulation, PMDA Updates, and US MDUFA IV – Where Are We Now?</td>
<td>Room 6F</td>
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<td>Measuring and Assessing Product Manufacturing Quality</td>
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<td>Implementation of Innovative and Adaptive Designs in Clinical Trials</td>
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<td>Designing Clinical Trials with the Right Endpoints: Applying ICH-E9(R1) - Getting the Questions Right (GTQR),Estimands and Handling Missing Data</td>
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The content noted on this page was made available to DIA as of April 29, 2019.
### WEDNESDAY, JUNE 26, CONTINUED

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<td>#318</td>
<td>12</td>
<td>Opportunities and Challenges of Collecting Data in a Pre-Approval Access Setting: A Multi-Stakeholder Perspective</td>
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<td>How to Solve the Problem of Access for Rare Diseases</td>
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**9:15–9:45 AM**

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<td>16</td>
<td>Considering Consulting? The Good, the Bad, the Ugly, and the Profitable!</td>
<td>Content Hub Sails Pavilion</td>
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**9:30–10:15 AM**

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<td>15</td>
<td>One Size Does NOT Fit All: Know How to Adapt your Communication Style to be Effective Communicating Up, Down and Peer-to-Peer</td>
<td>Engage and Exchange Area Exhibit Hall</td>
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<td>Round Table Discussion: Real World Data to Real World Evidence</td>
<td>Community Zone Sails Pavilion</td>
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<td>Round Table Discussion: Personalized Healthcare and Clinical Outcomes: How Real World Endpoints Can Improve Approval and Access to Medicine?</td>
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**9:45–10:15 AM**

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<td>#324</td>
<td>18</td>
<td>Salesforce Innovation Theater: Digital R&amp;D: Accelerating Intelligent Innovation With IQVIA’s Orchestrated Clinical Trials Platform, Powered by Salesforce Health Cloud</td>
<td>Theater 1 Exhibit Hall</td>
<td>SESSION</td>
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<td>SAS Institute Inc JMP Innovation Theater: Semi-automation of the Narrative Section of the Clinical Study Report for Oncology Studies</td>
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**10:00–10:30 AM**

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<td>2020 and Beyond, Data Capture Across Systems, Functions, and Modalities</td>
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**10:30–11:30 AM**

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<td>Digital Risk Minimization: The “Next Generation” Risk Management Tools</td>
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<td>Risk-Based Monitoring: Best Practice Today and Technology for Tomorrow</td>
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<td>Global Clinical Trials: Make Them Really Global and Involve Africa</td>
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<td>The Analytics Revolution: Opportunities and Threats for Disrupting Clinical Development Operations</td>
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<td>A Pharma/CRO Partnership in the Design and Execution of Paperless Clinical Trials from eICF to Database Lock</td>
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<td>eSource Adoption: Where We Are - Our Experiences from eSource Implementation</td>
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<td>Pediatric Plans: The Challenges Between Regulations and Reality</td>
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<td>Understanding and Exploring Elements of a Patient-Focused Product Launch</td>
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<td>Highlights of the Patient Engagement Preparedness, Capabilities, Experience, and Impact (PEPCEI) Study</td>
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<td>Exploring the Evolving Requirements for the Clinical Assessment of Abuse and Dependence Potential of CNS-Active Drugs</td>
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<td>Application of Project Management Methodologies and Tools in NonProfit Institutions</td>
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<td>Expanding Use of Interactive Response Technologies in Clinical Trials: Maintaining Data Quality and Reliability</td>
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<td>Hot Topics in Quality and Regulatory Affairs for Combination Products</td>
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<td>Digital Technology Advances Labeling Management and Patient Access</td>
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<td>The Evolving Gene Therapy Regulatory Framework: A Brave New World</td>
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<td>When is Real World Evidence Ready for Prime Time?</td>
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<td>Meaningful Patient-Focused Drug Development for Rare Disease and Personalized Medicine</td>
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<td>Achieving High Performance Through Emotional Intelligence</td>
<td>Room 14A</td>
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11:40 AM–12:25PM

**11:40 AM–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

11:45 AM–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: ■

### #356

**01**

Involving Patients in Medicinal Product Benefit-Risk Communication: How’re We Doing?

Room 6D

SESSION 75

Level: ■

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

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

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

- #376 EE 15 Assessing Medical Adherence in a Clinical Trial Setting: Challenges and Solutions
- #376.1 RT 17 Round Table Discussion: Master Protocols: Applications in Oncology
- #377 RT 17 Round Table Discussion: Pharma and Regulatory Perspectives on Machine Learning Applications in Pharmacovigilance
# Meeting Schedule

## PROFessional poster Session | EXHibit Hall

### 3:15–4:00 PM

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<tr>
<th>Offering Number</th>
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<tr>
<td>#378 CH</td>
<td>16</td>
<td>Measuring “Value” in Value-Based Healthcare: A Health Economics Perspective</td>
<td>Content Hub Sails Pavilion</td>
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<td>#3781 SB</td>
<td>05</td>
<td>On the Soapbox: Good for People and Good for Research - Individuals as Research Partners</td>
<td>Room 16AB</td>
<td>FORUM</td>
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### 4:15–5:30 PM

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<tr>
<td>#379</td>
<td>01</td>
<td>From Trials to Real World: How Safety Protocols Impact REMS</td>
<td>Room 6C</td>
<td>FORUM</td>
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<td>02</td>
<td>Incorporating Patient Input into the Design and Conduct of Clinical Trials</td>
<td>Room 9</td>
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<tr>
<td>#381</td>
<td>02</td>
<td>A New Path Forward for Using Decentralized Clinical Trials</td>
<td>Room 10</td>
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<td>#382</td>
<td>03</td>
<td>Real World Data Quality for Regulatory Decision-Making</td>
<td>Room 1AB</td>
<td>SESSION</td>
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<td>#383</td>
<td>04</td>
<td>Next-Generation Approaches for Developing Narratives</td>
<td>Room 4</td>
<td>SESSION</td>
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<tr>
<td>#384</td>
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<td>Patient Preferences in Decision Making and the PREFERRED Project: Past, Present, and Future</td>
<td>Room 5AB</td>
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<td>#385</td>
<td>06</td>
<td>The Importance of Human Translation for Successful Preclinical Drug Discovery and Cardiac Safety</td>
<td>Room 2</td>
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<td>#386</td>
<td>07</td>
<td>Setting the Stage for Effective Stakeholder Collaboration</td>
<td>Room 15AB</td>
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<td>08</td>
<td>Global Perspective on ICH E8(R1): General Considerations for Clinical Trials</td>
<td>Room 17AB</td>
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<td>#388</td>
<td>09</td>
<td>Convergence of the Regulatory Pathways for Advanced Therapy Medicinal Products</td>
<td>Room 6F</td>
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<td>#390</td>
<td>09</td>
<td>Clinical Trial Innovation: Pathways for Selecting and Developing Novel, Fit-for-Purpose, Technology-Derived Study Endpoints</td>
<td>Room 6E</td>
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<td>09</td>
<td>Real World Evidence and Artificial Intelligence to Inform Post-authorization Studies</td>
<td>Room 16AB</td>
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<td>Breakthrough Therapy and PRIME Expedited Regulatory Pathways: Experience, Analysis, and Reflections from EMA, FDA, and Industry</td>
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<td>Case Studies in Resolving Quality Issues</td>
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<td>11</td>
<td>Demystifying Basic Statistical Concepts for Anyone Involved with Clinical Trials</td>
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<td>#395</td>
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<td>Utilization and Evaluation of Innovative Approaches for Efficient Drug Development</td>
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<td>#396</td>
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<td>Challenges to Access: Bringing Payers to the Table</td>
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<td>#397</td>
<td>13</td>
<td>PowerUp: Stories of Career Transforming Moments</td>
<td>Room 14A</td>
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### Thursday, June 27

#### 8:00–9:00 AM

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<td>17</td>
<td>Round Table Discussion: Digital Risk Minimization: The “Next Generation” Risk Management Tools</td>
<td>Community Zone Sails Pavilion</td>
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#### 8:30–9:00 AM

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<td>#402 CH</td>
<td>16</td>
<td>Manage Risks and Enhance Engagement Through Digital Approaches</td>
<td>Content Hub Sails Pavilion</td>
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## Meeting Schedule

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<td>Successes and Challenges in Pharmacovigilance for Biologics and Biosimilars</td>
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<td>Investigational Medicinal Products: eLabeling Initiative, Supply Forecasting</td>
<td>Room 11A</td>
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<td>Strategies, and Patient-Centric Technology for Medicine Adherence</td>
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<td>eSource and the Sites: Have They Bonded?</td>
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<td>Electronic Submissions Update</td>
<td>Room 1AB</td>
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<td>A Patient Engagement Wrap Up: Lessons Learned from DIA 2019 and Where Do We Go</td>
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<td>FDA Botanicals</td>
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<td>Case Studies From FDA and MHRA: Good Clinical Practices</td>
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<td>Advancing Benefit-Risk Assessment to Support FDA’s Regulatory Review of Human</td>
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<td>Recent CMC Changes in Emerging Regulatory Agencies</td>
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<td>Keeping Up with FDA and EMA Collaborations: Question Time</td>
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### THURSDAY, JUNE 27, CONTINUED

#### 9:00–10:15AM

#### 10:45AM–12:00PM

| #413            | 14           | FDA Town Hall                                                                      | Room 6B     | FORUM          | 75               | Level: ■           | ACPE, CME, IACET, RN      |

### NOTES
POSTER PROGRAM

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 Sulphonic acid (TNBS) Induced Colitis
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

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

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

Track 3 Data and Data Standards

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 4 Medical Affairs and Scientific Communication

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 5 Patient Engagement

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

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

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

Track 7 Project Management and Strategic Planning

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

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 8 R&D Quality and Compliance

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 (CIIRS), 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

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

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<td>W-01</td>
<td>A Real World Investigation of Finasteride and the Risk of Prostate Cancer</td>
<td>Stephan Palm, Trinetx</td>
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<td><strong>ORAL PRESENTATION: 12:00PM</strong></td>
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<tr>
<td>W-02</td>
<td>Improving Cost Effectiveness by Automating the Aggregate Report Scheduling &amp; Distribution</td>
<td>Jennifer Cichone, MS</td>
<td>Otisuka Pharmaceutical Development and Commercialization Inc.</td>
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<td>W-03</td>
<td>Development and Operationalization of a Method for Determining Adverse Drug Reactions from a Clinical Study Safety Data Set</td>
<td>Fred Jerva, PharmD, PhD, RPH</td>
<td>AstraZeneca</td>
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<tr>
<td>W-04</td>
<td>Reducing the Cost of Systematic Risk Assessments of Medical Products by Using a Modular Learning Risk Repository System</td>
<td>Stephen Sun, MD, MPH</td>
<td>Syneos Health</td>
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<tr>
<td>W-05</td>
<td>Design Thinking in Pharmacovigilance</td>
<td>Ruta Mockute, MS</td>
<td>Celgene Corporation</td>
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<td>W-06</td>
<td>Healthcare Professionals' Knowledge and Adherence to the National Guidelines for Management of Pediatric Asthma</td>
<td>Hamad Alyami, PharmD</td>
<td>Najran University, Saudia Arabia</td>
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#### Track 2 Clinical Trials and Clinical Operations

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<td>W-07</td>
<td>A General Framework for Utilizing Real World Data with Clinical Trials</td>
<td>Xiaoyun (Nicole) Li, PhD</td>
<td>Merck &amp; Co., Inc.</td>
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<td>W-08</td>
<td>Using a Continuous Learning Risk Repository System to Drive Efficiencies in Identification of Clinical Protocol Risk Patterns</td>
<td>Thaddeus Urban</td>
<td>Syneos Health</td>
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<tr>
<td>W-09</td>
<td>Exploring Accuracy of Abdominal Pain Reporting with and Without Specific Instruction</td>
<td>Alyssa Peechatka, PhD, MA</td>
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<td>W-10</td>
<td>The Rise of Electronic Patient-Recorded Outcomes in Oncology (ePRO)</td>
<td>Bhavish Lekh, MS</td>
<td>Synteract</td>
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<td>W-11</td>
<td>Advantages of a Peer Mentoring Program in Clinical Operations</td>
<td>Wen Liu, MPH</td>
<td>Merck &amp; Co., Inc.</td>
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<td>W-12</td>
<td>Relationship Between Efficacy and Discontinuation Rates in Clinical Trials of Moderate to Severe Crohn's Disease</td>
<td>Austin Marraza</td>
<td>Pennsylvania State University</td>
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#### Track 3 Medical Affairs and Scientific Communication

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<td>Common Symptom Terminology is Frequently Misunderstood</td>
<td>Rinah Yamamoto, PhD</td>
<td>ERT</td>
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<td>W-15</td>
<td>Patients are Uncomfortable and Unable to be as Honest When Discussing Depression Symptoms During Recorded Interviews</td>
<td>Nadeeka Dias, PhD</td>
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<td>W-16</td>
<td>Patient Understanding of Rescue Medication: Value of Patient Training on Reporting Rescue Medication Use</td>
<td>Kelly Dumas, PhD</td>
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<td>W-17</td>
<td>Subject Training Substantially Improves Understanding of Key Terminology in Gastrointestinal Clinical Trials</td>
<td>Michael Sadler, PhD</td>
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#### Track 4 Medical Affairs and Scientific Communication

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<td>W-18</td>
<td>Putting the Patient at the Center of Medical Information: A Patient-Centric Standard Response Letter Initiative</td>
<td>Chelsea Aiudi, PharmD</td>
<td>TESARO</td>
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<tr>
<td>W-19</td>
<td>Defining Excellence and Best Practices in Medical Information for AMCP Dossier Creation and Compendia Review</td>
<td>Sally Stansbury, PharmD</td>
<td>Takeda</td>
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#### Track 5 Patient Engagement

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<tr>
<td>W-20</td>
<td>Building Patient Trust: Our Journey to “Radical” Transparency in Compassionate Use</td>
<td>Christine Maccracken, BSN, MEd</td>
<td>Janssen</td>
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<tr>
<td>W-21</td>
<td>Meaningful Patient Engagement: From Vision to Reality in the Rare Disease Space</td>
<td>Linda Brennan, MPH</td>
<td>Cystic Fibrosis Foundation</td>
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<tr>
<td>W-22</td>
<td>Tell Me More: Exploring Patient Perspective on the Benefits and Disadvantages of Drugs During Clinical Trials</td>
<td>Alexis Miller, JD</td>
<td>Sanofi</td>
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<td>W-23</td>
<td>Evaluation of Publicly Available Patient Medical Education Videos on Breast Cancer</td>
<td>Min Kyung (Amy) Kim, PharmD</td>
<td>Rutgers University/Ernest Mario School of Pharmacy</td>
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<td>W-24</td>
<td>Awareness of Polycystic Ovarian Syndrome in Pakistan Through Patient Engagement</td>
<td>Sabahat Arif, PharmD</td>
<td>Kellyocg, Pakistan</td>
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<td>W-25</td>
<td>Bring your own Wearable (BYOW): Considerations for Clinical Research</td>
<td>Marie McCarthy, MSc</td>
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#### Track 7 Project Management and Strategic Planning

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<td>W-26</td>
<td>Educational, Gender, and Age Diversity in the Corporate Leadership of Fortune 500 Pharmaceutical Companies</td>
<td>Michael Severo, PharmD</td>
<td>Rutgers University/Ernest Mario School of Pharmacy</td>
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**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

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

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

Track 10 Regulatory CMC and Product Quality

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
Clinda 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
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

INSPIRE AWARDS: AMERICAS

**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

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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

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*
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assists 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
Contact: Muhammad Ahmad, MD MBA
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
Contact: Amy Ripston
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
Contact: Yasmine Benlahrech
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
Contact: Mark Engelhart
Email: mengelhart@acmlab.com
Website: www.acmgloballab.com

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

ACRP
Contact: Jenna Rouse
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
Contact: Genevieve Baley
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
Contact: Steve Bliss
Email: steve.bliss@adamasconsulting.com
Website: www.adamasconsulting.com

ADAMAS Consulting is the leading global provider of Quality Assurance and Quality Management System consulting services. With 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
Contact: Mitch Collins
Email: mitch.collins@adaptive-clinical.com
Website: www.adaptive-clinical.com

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

Advanced Clinical
Contact: Lizzie Evans
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
Contact: Rachel Ruehman
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
Contact: Kathleen Zazzara
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
Website: www.agilexbiolabs.com.au/
Agilex Biolabs offers the leading IRT solution for clinical trials. With the most advanced secure technology, Agilex Biolabs provides customers with a flexible platform to monitor patient progress, statistically powered trials, and operational efficiencies. Agilex Biolabs is part of the global impact of AGILEX, a leader in life sciences solutions for the research and development needs of the biotechnology and pharmaceutical industries.

AiCure
Contact: Ted Kirby
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
Contact: Adriana Major
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
Contact: Amy Rushing
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
Contact: Ray Patnaude
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
Contact: Ellen Diegel
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
Contact: Catherine Moniz
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
Contact: Sherri Hughes-Smith
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
Contact: Nicole Dooley
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
Contact: Courtney Wright
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.
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<td><strong>Andwin Scientific</strong></td>
<td>Booth: 1120  Contact: Andrew Billimore Email: <a href="mailto:abillimore@andwin.com">abillimore@andwin.com</a> Website: <a href="http://www.andwin.com">www.andwin.com</a>  Andwin specializes in clinical research supply chain management to global life science industry, providing a single source for diagnostics &amp; 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.</td>
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<td><strong>Anju Software</strong></td>
<td>Booth: 1805  Contact: Bob Borysko Email: <a href="mailto:bob.borysko@anjusoftware.com">bob.borysko@anjusoftware.com</a> Website: <a href="http://www.anjusoftware.com/">www.anjusoftware.com/</a>  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.</td>
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<td><strong>APCER Life Sciences</strong></td>
<td>Booth: 2522  Contact: Deepika Duggal Email: <a href="mailto:deepika.duggal@apcersls.com">deepika.duggal@apcersls.com</a> Website: <a href="http://www.apcersls.com">www.apcersls.com</a>  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.</td>
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<td>Booth: 705  Contact: Matthew Johnson Email: <a href="mailto:matts@apdm.com">matts@apdm.com</a> 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.</td>
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<td>Booth: 2237  Contact: Joshua Boutwell Email: <a href="mailto:jboutwell@aquilasolutions.us">jboutwell@aquilasolutions.us</a> Website: <a href="http://www.aquilasolutions.us">www.aquilasolutions.us</a>  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.</td>
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<td>Booth: 1504  Contact: Katherine Miller Email: <a href="mailto:katherine.miller@appian.com">katherine.miller@appian.com</a> Website: <a href="http://www.appian.com">www.appian.com</a>  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 <a href="http://www.appian.com">www.appian.com</a>.</td>
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Contact: Young Jack Lee
Email: jacklee@lskglobal.com
Website: www.lskglobal.com
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Contact: Marietta Sarkisyan
Email: marietta.sarkisyan@atlantclinical.com
Website: www.atlantclinical.com
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Email: dniedzielska@augustresearch.com
Website: www.augustresearch.com
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Contact: Dr. Sanjeev Miglani MD
Email: sanjeev.miglani@awinsals.com
Website: www.awinsals.com
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Email: solutions@axiom.cc
Website: www.axiommetrics.com
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Contact: Jim Cavan
Email: rob.goldman@backpackhealth.com
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<td><strong>Beijing Clinical Service Center</strong></td>
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<td>Email: <a href="mailto:richard@clinicalservice.cn">richard@clinicalservice.cn</a></td>
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<td>Contact: James Whittington</td>
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Contact: Anabel Morales
Email: amorales@brandinstitute.com
Website: www.brandinstitute.com
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CISCRP is committed to engaging and building relationships among members of the public, clinical research volunteers, and clinical research professionals.
Clarness
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Website: www.clarness.com/
Clarness’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+ Clarness employees who speak 29 languages, is the key to success. They help sites convert referrals to randomizations.

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

ClinEdge, LLC
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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
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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)
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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
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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
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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
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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  
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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.

Clinitthink Ltd  
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Founded in 2009, Clinitthink 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  
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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  
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Cmed is a technology-led CRO that specializes in oncology, immunology, 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.  
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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  
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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  
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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.

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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  
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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.

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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.
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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
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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
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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.

CROëe Inc.
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CROëe 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
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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.
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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 -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.
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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
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CSSi is a global full-service patient recruitment and retention company that focuses on providing customized services to help sites maximize their enrollment. 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
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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
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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
Contact: James Nichols
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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
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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
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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
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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
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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.

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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.
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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
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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.
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Deep Intelligent Pharma
Contact: Gao Shi
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Deep Intelligent Pharma is a global Life Sciences company with offices in USA, China, India and Singapore. Providing a full range of services, including clinical trial management, medical coding and medical writing. Deep Intelligent Pharma supports clients with a full suite of regulatory services, including clinical trial design, effective data management, and accurate statistical analysis. www.deepintelligentpharma.com

Deloitte
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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 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.
world's second largest market and help Chinese Biotechs expand globally positioned to leverage China's new regulatory framework to access the capability to deliver clinical services at global quality standards. Led by a seasoned team with deep global experience in MNC, dMed is uniquely as a “next generation” CRO committed to building China's best-in-class medical device companies in China and globally. We define ourselves with regulatory authorities, dramatically increase the rate of approval. throughout lifecycle. Our innovative strategies and collaborative interactions development to compilation and management of regulatory submissions we provide a full range of Regulatory services from strategic advice in early 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. Contact: Zibao Zhang 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.
DSG, Inc.  
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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  
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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  
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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.  
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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.  
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EC Innovations is a world-leading translation and localization provider with ISO 13485:2016, ISO 9001:2015, and ISO 17100:2015 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  
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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.

ECC Clinical Solutions  
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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.  
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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  
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EMB is a CRO specializing in the Data Management and Statistical Analysis/Reporting of clinical research data. EMB was formed in 2000 with a dedicated team of senior level associates each with over 15 years of industry experience and a proven track record of success. With experience on more than 40 NDAs, EMB associates streamline the process, effectively represent your results, & support your presentations to the FDA. EMB is associate owned, has had ZERO turnover, and is “Powered by Experience.”
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EMS 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
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ENNOV
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With over 19 years’ experience and more than 150 life sciences clients worldwide, Ennov provides the industry’s most comprehensive, integrated, state-of-the-art analytical technologies with an expansive geographic reach in order to support our clients’ drug development requirements.

ERT
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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
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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.

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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)
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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
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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 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. 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, 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, 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 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. 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 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 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 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 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  
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Food and Drug Administration  
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“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.  
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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  
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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  
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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  
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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  
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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  
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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.

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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  
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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, makes us the firm of choice for life sciences companies.

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Greenphire is the leader in global clinical trial payment solutions. Greenphire’s best-in-class solutions optimize clinical trial performance by providing tools for all cardiac safety tests. 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.
Exhibitor Directory

GxPeople
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GxPeople - Senior QA and QC talent search for the global life sciences industry. GxPeople is a global leader in the provision of 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

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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
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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.

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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
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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

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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.

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Ideagen
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Website: www.ideagen.com
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Imperial Clinical Research Services
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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.
Inference Inc.
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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
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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.

InfuseServe America
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InfuseServe 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.

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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.

Innovaderm Research Inc.
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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.

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Innovocore, 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
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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.

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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.

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Innovocore, 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.

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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.

Insife
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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

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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.

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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.

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Integron

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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.

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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

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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

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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

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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

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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

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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.
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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
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Q2 (Q-square Business Intelligence) is a global Clinical Research Organization, with over 16 years pharmaceutical research and development experience, providing a broad range of services. Our principle is “Quality Work for Quality World”. Janus Clinical Research Institute (Janus) is a Q2 based company in China. Janus possesses the capacity with extraordinary talented people for any large or small projects in clinical research.

Jazz Pharmaceuticals Inc.
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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
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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
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Jsure Health Inc.
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Jsure Health is a global clinical research organization that connects the world’s top clinical research organizations with leading life science companies to improve global health outcomes. Jsure Health provides a unique, cross-border, and flexible model for delivering the highest quality clinical research study execution. Jsure Health delivers the most comprehensive and diverse clinical research services to the biopharmaceutical industry world-wide.

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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
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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.

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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.

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Kinapse is an innovative and enterprising consulting 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.

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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
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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
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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.

LabConnect, LLC
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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
Contact: Mr. Brian Roberts
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.
Contact: Pam Massa
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
Contact: Julie Estrada
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
Contact: Matt Miller
Email: mmiller@litera.com
Website: www.litera.com
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LORENZ Life Sciences Group
Contact: Pam Massa
Email: Pamela.Massa@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
Contact: Jung Min Lee
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.
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Phone: 510-839-5600  
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Machao 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.

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Phone: 973-900-2728  
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Email: jcatley@mdconnectinc.com  
Website: www.mdconnectinc.com/

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Email: tyler@medable.com  
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<tr>
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<th>Contact Person</th>
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<tbody>
<tr>
<td>Medical Vigilance Solutions</td>
<td>2740</td>
<td>Todd Tierney</td>
<td>513-803-6690</td>
<td>[email protected]</td>
<td><a href="http://www.cincinnatichildrens.org/mvs">www.cincinnatichildrens.org/mvs</a></td>
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<td>meu.org.uk</td>
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<td><a href="mailto:nburrows@medixteam.com">nburrows@medixteam.com</a></td>
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<td>763-258-2735</td>
<td>[email protected]</td>
<td>mednetstudy.com</td>
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<td>Medpace Inc.</td>
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<td>Beth Cullen</td>
<td>513-579-9911</td>
<td><a href="mailto:info@medpace.com">info@medpace.com</a></td>
<td><a href="http://www.medpace.com/">www.medpace.com/</a></td>
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<tr>
<td>Medical Vigilance Solutions (MVS)</td>
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<td><a href="mailto:sara.nolan@medpt.com">sara.nolan@medpt.com</a></td>
<td><a href="http://www.medpt.com">www.medpt.com</a></td>
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<td>415-276-9261</td>
<td><a href="mailto:mlomazzi@medrio.com">mlomazzi@medrio.com</a></td>
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<tr>
<td>MedPoint Digital, Inc.</td>
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<td>Rebecca Davis</td>
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<td><a href="mailto:rebecca.davis@mesm.com">rebecca.davis@mesm.com</a></td>
<td><a href="http://www.mesm.com">www.mesm.com</a></td>
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<tr>
<td>Metina PharmConsulting Private Limited</td>
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<td>Hasumati Rahalkar</td>
<td>91-982013613</td>
<td><a href="mailto:hasumati@metinapharmconsulting.com">hasumati@metinapharmconsulting.com</a></td>
<td><a href="http://www.metinapharmconsulting.com">www.metinapharmconsulting.com</a></td>
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<td>Metina PharmConsulting Private Limited</td>
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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).

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<tr>
<td><strong>Ministry of Food and Drug Safety (MFDS)</strong></td>
<td>1640</td>
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<tr>
<td>Contact: Cheol Seung Lee</td>
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<tr>
<td><strong>MonitorForHire.com</strong></td>
<td>2137</td>
<td>610-862-0909</td>
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<tr>
<td>Contact: Scott Freedman</td>
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<td>Email: <a href="mailto:scott.freedman@monitorforhire.com">scott.freedman@monitorforhire.com</a></td>
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<td>Contact: Oliver Pearce</td>
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<td>Email: <a href="mailto:opearce@montrium.com">opearce@montrium.com</a></td>
<td>Website: <a href="http://www.montrium.com/">www.montrium.com/</a></td>
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<td><strong>Muv Inc.</strong></td>
<td>1950</td>
<td>214-223-9153-219</td>
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<tr>
<td>Contact: Jennifer Marley</td>
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<td>Email: <a href="mailto:jmarley@muvpeople.com">jmarley@muvpeople.com</a></td>
<td>Website: <a href="http://www.muvpeople.com">www.muvpeople.com</a></td>
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<td><strong>MyData-TRUST/FGK Representative Service</strong></td>
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<td>Contact: Gautier Sobczak</td>
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<td>Email: <a href="mailto:g.c.sobczak@mydata-trust.com">g.c.sobczak@mydata-trust.com</a></td>
<td>Website: <a href="http://www.mydata-trust.eu">www.mydata-trust.eu</a></td>
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<td>1618</td>
<td>763-444-4747</td>
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<tr>
<td>Contact: Robert Doty</td>
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<td>Email: <a href="mailto:Rdoty@nacsinc.com">Rdoty@nacsinc.com</a></td>
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<tr>
<td><strong>National Association of Veterans’ Research and Education Foundations</strong></td>
<td>734</td>
<td>202-813-6681</td>
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<tr>
<td>Contact: Hawk Tran</td>
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<td>Email: <a href="mailto:htran@navref.org">htran@navref.org</a></td>
<td>Website: <a href="http://www.navref.org">www.navref.org</a></td>
<td>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.</td>
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<tr>
<td><strong>National Disease Research Interchange</strong></td>
<td>712</td>
<td>215-557-7361</td>
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<tr>
<td>Contact: Gene Kopen</td>
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<tr>
<td>Email: <a href="mailto:szakarewsky@ndriresource.org">szakarewsky@ndriresource.org</a></td>
<td>Website: ndriresource.org/</td>
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<td>1147</td>
<td>303-398-1303</td>
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<tr>
<td>Contact: Tom Kaczka</td>
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<tr>
<td>Email: <a href="mailto:kaczkat@njhealth.org">kaczkat@njhealth.org</a></td>
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<td>609-454-7753</td>
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<td>Contact: Mr. Patrick Mullen</td>
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<td>Email: <a href="mailto:patrick.mullen@navitaslifesciences.com">patrick.mullen@navitaslifesciences.com</a></td>
<td>Website: <a href="http://www.navitaslifesciences.com">www.navitaslifesciences.com</a></td>
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<td><strong>NCGS Incorporated</strong></td>
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<td>Contact: David McCrary</td>
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OMI 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, OMI built the first intelligent data cloud for healthcare, enabling more precise information and better decision making for stakeholders across the healthcare ecosystem.

Oracle Health Sciences
Contact: Rachel Weinstein
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 Health 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
Contact: Michael Celata
Email: mcelata@orbiscclinical.com
Website: www.orbiscclinical.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.
The content noted on this page was made available to DIA as of April 21, 2019.

Orbit
Contact: Dan Feith
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, PVAAs, 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
Contact: Thomas Marbury
Email: tmarbury@ocrc.net
Website: www.ocrc.net
OCRC is a cutting edge independent Phase I – IV custom-built 35,000 sq. ft. research site. Designed specifically for Phase 1 clinical trials, OCRC includes 110 in-house volunteer beds, dual lead digital telemetry, CCTV security system, and cardkey access. A special treatment/observation area has 12 hospital beds (6 used for onsite Hemodialysis studies). OCRC specializes in Phase I trials with an emphasis in PK, QTc, SAD/MAD, & BA/BE studies in healthy, hepatic, hemodialysis, renal, and diabetic.

Parexel
Contact: Jo Sudore
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

PharmaOut
Contact: Lynn Sansosti
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
Contact: Larry Shen PhD
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, & AdA&M) • Data Management
PPD
Contact: Laura Mullaney
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
Contact: Francesco Amorosi
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
Contact: Tami Klerr
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
Contact: Robert Loll
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
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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
Contact: Melissa Malski
Email: melissa.malski@precisionformedicine.com
Website: www.precisionformedicine.com
Precision for Medicine supports the discovery, development, clinical trial work, and implementation of biomarkers essential for targeting patients more precisely and effectively. This dynamic new field requires novel services that aren’t currently offered by traditional research organizations. We provide an uncommon array of talent and services to enable our pharmaceutical and life sciences clients to take advantage of new advancements in science and stay ahead of regulatory changes.

Preveil InfoWorks, Inc.
Contact: Mats Olsen
Email: mats.olsen@Preveilinfoworks.com
Website: www.preveilinfoworks.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
Contact: Thomas Campbell
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 Patient Care Platform and Body Guardian family.

PrimeVigilance
Contact: Florence Denance Habek
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 world 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.
Contact: Pramod Sachdeva
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 Pharmacovigilance, Label Management, Clinical Study Management and IND Product Registration, leverage our experience to accelerate your automation journey.
Projects 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.
Contact: Mr. Bill Stewart
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 portfolio management reduces product development and introduction lifecycles by over 30%.

Protocol First
Contact: Joseph Collins
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.
Contact: Wendy Powers
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 • High-skilled project management services • Operational experience in North America and throughout Europe

Proventa International
Contact: Nicholas Williams
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
Contact: Punit Sinha
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
Contact: Amelia Hocine
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
Contact: Suzanne Canfield
Email: suzanne@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.
Contact: Jason Proos
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 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.
Contact: Paul Swidersky
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. QA1 has a staff of auditors with various scientific experience. QA1 also maintains a large GLP archive for storage of documents and specimens.
 QuantifiCare
Contact: Deborah Poole
Email: info.usa@quantifiicare.com
Website: www.quantifiicare.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
Contact: Stephen Boccardo
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
Contact: Charles Martin
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
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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
Contact: Lea Ann McNee
Email: lmcnnee@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
Contact: Ms Fiona Windsor
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
Contact: Jesse Norton
Email: j.norton@reallstaffing.com
Website: www.realstaffing.com

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
Contact: Kathleen Clary
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
Contact: Gaurav Sharma
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
Contact: June Spitz
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.  
Contact: Cameron McGregor  
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, ANDA, etc.; online GCP Training.

Rho, Inc.  
Contact: Karley St. Pierre  
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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  
Contact: Christine Kremzar  
Email: christine.kremzar@rmpds.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  
Contact: Berett Garbus  
Email: berrett.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  
Contact: Ruth Whittington  
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  
Contact: Shalini Modi  
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 Mgmt 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 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 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.  
Contact: Erin Hathaway  
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  
Contact: Walter Teague  
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.
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.

Contact: Alexandra Wolfer
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

Contact: Drinda Benjamin
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

Contact: Urszula Weska
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

Contact: Faiz Kermani
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

Contact: Martina Donohue
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.

snapiT

Contact: Nick Salcedo
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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.

Contact: Briana Mendoza
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. With expertise across healthcare, retail, media, financial services, software, and more, our end-to-end solutions deliver innovation, quality, and speed.

Sonic Clinical Trials

Contact: Carolyn Cheer
Paulette Azar-Tannous, Abraham Roodt
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

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

Southern Star Research is an award-winning Australian CRO. Our expertise in a broad range of indications is supplemented by a Clinical Team who have an average of 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.
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<td>Splash Clinical is an innovative patient recruitment firm that’s pioneered the use of digital &amp; 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 &amp; social media campaigns.</td>
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<td>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 &amp; more GmbH.</td>
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<td><strong>Statistics &amp; Data Corporation (SDC)</strong></td>
<td>1239</td>
<td>Jim Townsend</td>
<td><a href="mailto:data@sdcclinical.com">data@sdcclinical.com</a></td>
<td><a href="http://www.sdcclinical.com">www.sdcclinical.com</a></td>
</tr>
<tr>
<td>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, &amp; 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.</td>
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<tr>
<td><strong>Stefanini</strong></td>
<td>2343</td>
<td>Nikki Bonnell</td>
<td><a href="mailto:Nikki.Bonnell@stefanini.com">Nikki.Bonnell@stefanini.com</a></td>
<td><a href="http://www.stefanini.com">www.stefanini.com</a></td>
</tr>
<tr>
<td>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 &amp; nurses, CRA’s and clinical site personnel.</td>
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</tr>
<tr>
<td><strong>Sterling Institutional Review Board</strong></td>
<td>1850</td>
<td>Kathye Richards</td>
<td><a href="mailto:kathye.richards@sterlingirb.com">kathye.richards@sterlingirb.com</a></td>
<td><a href="http://www.sterlingirb.com">www.sterlingirb.com</a></td>
</tr>
<tr>
<td>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. <a href="http://www.sterlingirb.com">www.sterlingirb.com</a></td>
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</tr>
<tr>
<td><strong>Stiris Research Inc.</strong></td>
<td>1250</td>
<td>Shantal Feltham</td>
<td><a href="mailto:dpalmer@stirisresearch.com">dpalmer@stirisresearch.com</a></td>
<td><a href="http://www.stirisresearch.com">www.stirisresearch.com</a></td>
</tr>
<tr>
<td>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 involved 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.</td>
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<tr>
<td><strong>StudyKik</strong></td>
<td>2442</td>
<td>Matt Miller</td>
<td><a href="mailto:Matt.Miller@studykik.com">Matt.Miller@studykik.com</a></td>
<td><a href="http://www.studykik.com">www.studykik.com</a></td>
</tr>
<tr>
<td>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.</td>
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<tr>
<td><strong>SubjectWell</strong></td>
<td>923</td>
<td>Ivor Clarke</td>
<td><a href="mailto:Ivor.Clarke@subjectwell.com">Ivor.Clarke@subjectwell.com</a></td>
<td><a href="http://www.subjectwell.com">www.subjectwell.com</a></td>
</tr>
<tr>
<td>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.</td>
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</tr>
</tbody>
</table>

**Stefanini**

- **Contact:** Nikki Bonnell
- **Email:** Nikki.Bonnell@stefanini.com
- **Website:** www.stefanini.com

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- **Website:** www.stirisresearch.com

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**SubjectWell**

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Symbio, LLC
Contact: Chad Troller
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
Contact: Nicki Norris
Email: nnorris@symphonycriminalresearch.com
Website: www.symphonycriminalresearch.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.

Syneos Health
Contact: Dana Bobrowski
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
Contact: Alessandra Leanza
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
Contact: Trisha Vonder Reith
Email: trishavonderreith@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.
Contact: Warren Pearlsn
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 diagnostic 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.
Contact: Anais Silva
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
Contact: Javeed Abbas Shaik
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’s global pharmaceutical – information technology focus and techno-functional expertise enables it to provide technology services and consultancy across the drug life cycle.

Telelingua Translations
Contact: Lionel Mellet
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.
Exhibitor Directory

TFDA / Center for Drug Evaluation, Taiwan
Contact: Keng-Che Chou
Email: kchou758@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
Contact: Lance Nickens
Email: lance@tprusaha.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
Contact: Arbi Harootoonian
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.
Contact: Anthony Andrasfay
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, PI designs and executes Phi>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.
Contact: Ilene Brooks
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
Contact: Melynda Geurts
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
Contact: Ryan Simper
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 TFM 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
Contact: Jon Cecchettini
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
Contact: Rick Ward and Karen Olszewski
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
Contact: Evija Kuemmel
Email: evija.kuemmel@trilogycorp.com
Website: www.trilogycorp.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.
Quality oversight. Audit and believe this can be done well. Part 11, Annex 11 and ISO 27001. All activities have experienced Life Science in accordance to 21 CFR Part 820 encompasses ISO 9001, HIPAA, 21 CFR service is ISO 27001:2013 certified. A fully integrated Quality system built support services. Purpose built for the specialized needs of the Life Validated Cloud is the leader in Quality forward GxP hosting cloud and Website: www.ValidatedCloud.com Email: info01@ValidatedCloud.com Contact: Douglas Lantigua Validated Cloud Inc. mission is to support and promote patient safety through effective global professionals make wise therapeutic decisions in their use of medicines. Our and scientific research. Our vision is a world where all patients and health Inspire. Engage. Transform. Uppsala Monitoring Centre (UMC) is an Website: www.who-umc.org Email: info@who-umc.org Contact: Jessica Avasol Uppsala Monitoring Centre 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 & 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 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 through the clinical development & regulatory submission process. We to partnering with biopharmaceutical firms to advance their therapies to mastering the entire process. 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
Contact: Sverre Bengtsson
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.)

Booth: 737
Phone: 46-709611524

Viitai LLC
Contact: Jeff Cao
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...

Booth: 431
Phone: 415-493-9177

VirTrial
Contact: Amanda Rangel
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.

Booth: 2056
Phone: 480-462-2222

Vitalograph, Inc.
Contact: Mark Russell
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.

Booth: 1817
Phone: 913-730-3212

Vitrana
Contact: Sean Pfifer
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.

Booth: 2823
Phone: 973-476-5095

VivaLNK
Contact: Lucia Nguyen
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.

Booth: 2438
Phone: 408-868-2898

WCCT Global
Contact: Talia Hight
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.

Booth: 1445
Phone: 714-252-0700-2001

WCG Clinical Services
Contact: Lauren Ozmore
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.

Booth: 1005
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WebbWrites, LLC
Contact: Laura A. Webb-Murrah
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.

Booth: 1514
Phone: 919-384-8850

Welch Allyn
Contact: Sonja daly
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.
Weloocalize Life Sciences

Contact: Kim Jones
Email: kim.jones@welocalize.com
Website: lifesciences.welocalize.com/

Weloocalize 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. Weloocalize Life Sciences holds ISO 9001, ISO 13485, and ISO 17100 certifications.

Whitsell Innovations, Inc.

Contact: Natalie Becker
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

Contact: Lauren Ozmore
Email: lozmore@wircgclinical.com
Website: www.wircgclinical.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

Contact: Robin Wickham
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

Contact: Eriel Fauser
Email: eriel.fauser@wuxiapptec.com
Website: www.wuxiclinical.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.

Contact: Cathy Hlinka
Email: cathy.hlinka@xcclinical.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.

Contact: Adam Blackburn
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

Contact: Ifthi Kalanther
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

Contact: Julie Beal
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

Contact: Julie Chappel
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.
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
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