OUTSOURCING IN CLINICAL TRIALS MIDWEST 2017
CHICAGO, 12TH- 13TH SEPTEMBER 2017

SPONSORS INCLUDE

Advanced Clinical

Confirmed 2017 Speakers Include

Elizabeth Hanson, Clinical Scientist **– Takeda Development Center Americas Inc.**

Theodore Danoff, Senior VP Clinical and Medical Affairs & Chief Medical Officer **- Clarus Therapeutics**

Kelly Cain, Senior Director Global Clinical Data Solutions **– Medtronic Core Clinical Solutions**

Bruce Riser, CEO **- BLR Bio**

Jim Kremidas, Executive Director **- Association for Clinical Research Professionals**

Alexandra Massoud, Director, Clinical Affairs **- Exact Sciences**

Tonya Thurman, RAC, Director, Clinical Affairs & Clinical Relations **- Cook Medical**

Nancy Sacco, Vice President, Global Clinical Operations - **Revance Therapeutics**

Minji Bae, Assistant Director, Clinical Vendor Management **- Abbvie**

Barbara Kaesdorf, Associate Director Clinical Affairs **- Abbott**

B. Woun Seo, Associate Director of Medical Affairs **- Pinnacle Biologics**

Jeff Wagner, Advisor, Clinical Development Information and Optimization - **TransCelerate/Eli Lilly**

Kara Cassady, Associate Director, Clinical Operations – **Medline**

Joseph F. Gotowko, Assistant Director, R&D Quality Systems – **Abbvie**

Kenneth David Fernandez Prada, Senior R&D Engineer **- Depuy-Synthes Joint Reconstruction (J&J)**

Amber Meriwether, Senior Manager, Medical Affairs Lead, Contracts & Outsourcing, Medical and Development- **Astellas Pharma Global Development, Inc.**

Edward P Cohen, Professor Microbiology and Immunology**- University of Illinois College of Medicine**

FURTHER INFORMATION

For program enquiries please contact:
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	Outsourcing in Clinical Trials Midwest | Chicago, Illinois **Day 1 | 12th Sept, 2017**
07:45	**Registration and Refreshments**
08:25	**Chairman's Opening Remarks**
08:30	**Discussing the impact the 21st Century Cures Act will have on the US Pharma industry and operating models to plan ahead during political uncertainty** • Key features of the 21st Century Cures Act, particularly changes in the use of Real World Evidence and Summary Data for indication approvals • The impact of the January 2017 "One-in-Two-Out" Executive Order calling for two regulations to be eliminated for every new one issued on the rollout of the 21st Century Cures Act 20 minute spotlight presentation session followed by 10 minutes of Q&A. *Confirmed speaker*: **Amber Meriwether**, JD, MA, Senior Manager, Medical Affairs Lead, Contracts & Outsourcing, Medical and Development - **Astellas Pharma Global Development, Inc.**
09:00	**Trends in Industry Responsiveness to New Innovations for Clinical Trials** • Results from Advanced Clinical's 2017 Industry Innovation Survey, which covers reactions to new innovations in clinical research from industry-wide survey responders • Forecast of future trends in clinical trial technology use based on survey results • Strategies for operationalizing new tools and tech **Julie Ross**, President - **Advanced Clinical**
	Patient Recruitment and CRO Selection
09:30	**Striking the balance between outsourcing and using in-house resources to improve efficiency in your trial: Which model offers the most value to sponsors?** • Evaluating your internal expertise to decide which processes to outsource ensuring you make the most of in-house capabilities • Advantages and challenges of hybrid vs full outsourcing models to identify which is more suitable for your company • Ensuring you are attracting successful suppliers who will provide clinical and regulatory experts to work with you • Evaluating the risk of either outsourcing model to understand who is ultimately responsible for different aspects of the trial **Barbara Kaesdorf**, Associate Director Clinical Affairs- **Abbott**

10:00	**Exploring your clinical trial imports and exports to ensure a smooth transition through US Customs** • Demystifying the import/export regulations to increase uniformity of practices across ports of entry ensuring a timely resolution of nationwide trade compliance issues • Pinpointing the goals and achievements of the centre to date to prevent a holdup at Customs of your clinical supplies • Utilizing the Centers' recent expansion to include processing for the entire industry to appreciate the effect on your clinical supply • Reviewing key strategies for ensuring your drugs make it through customs in a safe and timely manner **Nancy L. Anderson,** Pharmaceuticals, Health and Chemicals CEE, **United States Customs and Border Protection (US CBP)**
10:30	**Morning Refreshments & Networking**
11:00	**Patient recruitment: Discussing the strict inclusion/exclusion criteria to ensure successful enrolment and exploring the internet and social media as patient recruitment engagement tools** • Designing a recruitment strategy appropriate to age and demographic of patients you aim to recruit • Identifying methods to ensure the best predictions possible in cutting edge trials and to update the enrolment plan as you go to ensure right patient population • Reviewing the sites experience prior to enrolment plans to understand how they will execute this trial and eliminate recruitment hurdles early • Addressing the barriers of privacy and intimacy of sharing trial participation info on social media **Nancy Sacco**, Vice President, Global Clinical Operations - **Revance Therapeutics**
11:30	CASE STUDY **Selecting CROs who cater for start-ups to establish the best approaches for clinical trials from a small biotech/medical device perspective** • Outlining a successful CRO selection process to examine what size CRO is best for your company and trial • Addressing best practices to reduce the impact of having limited internal resources to improve study efficiency • Using real life examples examine the benefit of working with a comprehensive CRO who understands your budget restrictions and implications of regulatory work • Exploring the opportunities available with niche types of CROs to examine what services you have the option to outsource to cater to a start-up budget • Pinpointing strategies for working with CROs with a strong clinical background who can help you get in front of sites to encourage a high level of patient engagement **Bruce Riser**, CEO - **BLR Bio**

12:00	**PANEL DISCUSSION** **Debating the pros and cons of working with a big vs small CRO to ensure the right fit for your clinical trial** • Discussing strategies to find a CRO that has a different approach when pitching to a smaller biotech or med device company who have different levels of resources and infrastructure • Debating the challenges when looking for a CRO in the right therapeutic area and deciding on the specific trial design in the first meeting • Discussing contracts to review study managers and monitors to ensure the right investigators are working on your study • Exploring methods with vendors to establish needs and priorities to ensure correct prioritization and the right level of attention required *Confirmed Panellists:* **Nancy Sacco,** Vice President, Global Clinical Operations **- Revance Therapeutics** **Kelly Cain**, Global Clinical Data Management Director – **Medtronic** **Bruce Riser**, CEO - **BLR Bio**
12:30	**Lunch & Networking**
14:00	**ACRP session: Exploring the human aspect of driving implementation of new initiatives in the clinical trial industry** • Assessing the importance of considering implications of change in the industry • Discussing the need for new training for site personnel for future clinical trials • Identifying the competency standards for clinical research personnel **Jim Kremidas,** Executive Director, **Association for Clinical Research Professionals**
14:30	**Maximising the use of wearable technologies in clinical trials to be more time and cost efficient in the long run** • Learning about new wearable technologies available and how they can be incorporated into clinical trials • Identifying challenges with moving over to wearables whilst ensuring patient and data safety is maintained at the highest level • Understanding compliance requirements and FDA standards in relation to wearables • Using real life case study examples to explore pilot tests done on low risk trials to test out new technologies and improve the running of your trials • Exploring home monitoring technologies used to collect patient data in a more time effective manner **Kenneth David Fernandez Prada**, Senior R&D Engineer - **Depuy-Synthes Joint Reconstruction (Johnson and Johnson)**

15:00	**Afternoon Refreshments & Networking**
15:30	**Demystifying Risk Based Monitoring (RBM) approaches and CRO collaboration for smaller sponsor companies** • Emphasizing the importance of a CRO with RBM experience for a smaller sponsor company • Risk-Based Monitoring incorporates standard practice • Understanding RBM pricing during RFPs, bid defences and contract negotiations • Appreciating the importance of introducing remote monitoring correctly to ensure your data is safe and easily accessible across the team **Alexandra Massoud**, Director, Clinical Affairs - **Exact Sciences**
16:00	**Analysing strategies to minimize the consequences of site personnel turnovers to help reach study timelines and attain quality data** • Site selection counts for more than identifying qualified investigators • Leveraging the expertise of the sites and your relationship with the most qualified investigator • Consider your investigator as an extension of your in-house team to keep your clinical trial top-of-mind • Ensuring key leaders are identified during study start-up to maintain accountability **Tonya Thurman**, RAC, Director, Clinical Affairs & Clinical Relations - **Cook Medical**
16:30	**Chairman's Closing Remarks**
16:35	**Drinks Reception**

	Outsourcing in Clinical Trials Midwest | Chicago, Illinois **Day 2 | 13th Sept 2017**
8:15	**Registration & Refreshments**
08:50	**Chairman's Opening Remarks**
	Strengthening Vendor Relationships And Exploring Global Trial Opportunities
9:00	**CASE STUDY: Overcoming hurdles presented when outsourcing clinical trials off-shore** • Establishing operations prior to study work transition to offshore provider • Ensuring the correct criteria is selected to help pinpoint a knowledgeable provider with a global presence and experience with the regulatory bodies • Providing effective tools/plan with all parties to overcome language barriers, time zone difference and ensure your clinical trial stays on track

	• Implementing governance to oversee vendor performance **Minji Bae**, Assistant Director, Clinical Vendor Management – **Abbvie**
9:30	**Assessing medical device companies outsourcing challenges to allow for smooth vendor selection process and trial success** • Exploring the advantages of outsourcing to CROs with medical device expertise to help achieve trial success • Examining whether the high prices and lack of expertise associated with pharma vendors are a worthy investment • Establishing thorough tests to ensure your investigator has the level of expertise required and is fully committed to your trial • Determining the correct balance between micro management and a ' hands on' approach to maintain CRO trust and reduce delays **Kara Cassady**, Associate Director Clinical Operations- **Medline**
10:00	**Morning Refreshments & Networking**
10:30	**Exploring the benefit of the TransCelerate Shared Investigator Platform (SIP) initiative** • Outlining the SIP initiative • Identifying the benefits of SIP and understand how it can improve communication with sites • Update on the status of SIP **Jeff Wagner** (Advisor, Clinical Development Information and Optimization at TransCelerate/Eli Lilly) will give a 20 minute presentation, introducing to the SIP initiative. This will be followed by a 10 minute Q&A to open up the discussion to the audience. **Jeff Wagner**, Advisor, Clinical Development Information and Optimization - **TransCelerate/Eli Lilly**
	Looking Ahead To The Future Of Clinical Trials
11:00	INTERACTIVE SESSION: **Exploring a novel idea for a future CRO selection tool to overcome the many challenges associated with CRO selection** • Addressing the current challenges associated with vendor selection • Asking the audience for their experiences with vendor selection/CROs • Exploring the idea of an online CRO review tool to aid the biopharma industry with CRO selection (asking the audience for their thoughts) • Identifying how best to use this CRO tool • Conclusion: what you will take away from this session and how to implement it into your current processes

	Theodore Danoff, MD, PhD, Senior VP Clinical and Medical Affairs, Chief Medical Officer - **Clarus Therapeutics**
11:30	**Exploring the role of Medical Affairs and how cohesive work with Clinical Operations can lead to successful execution of clinical trials** • The role of medical affairs in a successful investigator initiated study program • The use of the field based medical affairs group within the initiation of clinical trials • Impacting clinical trial recruitment with direct medical affair involvement • Insuring appropriate compliance between medical affairs within a clinical trial program **B. Woun Seo,** Associate Director of Medical Affairs - **Pinnacle Biologics**
12:00	**Lunch & Networking**
13:30	**Speaker Hosted Roundtables** Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way to build your personal network and learn from the experience and expertise of others. Each roundtable session lasts for **45 minutes**, and delegates may attend up to **2 Roundtables**
RT 1	**Immunotherapy, Steps Required to Obtain FDA Approval for Cancer Therapy** **Edward Cohen,** Professor Microbiology and Immunology **- University of Illinois College of Medicine**
RT 2	**Exploring how companies are addressing the QRM in ICH E6 Addendum- with regards to outsourcing and working with CROs** **Joseph F. Gotowko**, Assistant Director, R&D Quality Systems – **Abbvie**
RT 3	**Outsourcing challenges in emerging markets and best practices** **Minji Bae**, Assistant Director, Clinical Vendor Management – **Abbvie**
RT 4	**Comparatively exploring commercial VS clinical supply chain; lessons learnt for trial supply** **Shan Rahman**, Director, Global Project Management - **Takeda Pharmaceuticals**
RT 5	**Discussing partner relationships to join the emerging market before embarking on a clinical trial: exploring US FDA vs cFDA; the recent cFDA regulatory changes; having a partner in China;**

	exploring the option of co-developing a new drug with a partner in China **Ruth Wu-Wong**, CSO - **Vidasym**
15:00	**Chairman's summation and close of conference**