OUTSOURCING IN CLINICAL TRIALS TEXAS

September 11th-12th 2019 - Houston, Texas

VALUE FROM ATTENDING

The OCT conference series is the leading Outsourcing and Clinical Operations event for the clinical trials community in 15 locations worldwide and we have been delivering the conference for more than 10 years. Selecting the right partners, managing your relationships with your solution providers and other stakeholders are all key factors in reducing the overall cost of your clinical trial. Our content-driven conference will offer delegates the opportunity to develop practical strategies they can implement to refine their outsourcing strategy and overall running of clinical trials. Bringing our OCT global series to Texas for the first time, we are inviting decision makers from both small, medium and large pharma and medical device companies to help advance your clinical trial within timelines and budget whilst keeping each patient the priority.

2019 CONFIRMED SPEAKERS

Heather Giles**, CSO & CEO, **Vapogenix
Adina Pelusio**, Vice President, Medical and Clinical Operations, **Turnstone Biologics
Jane M. Jacob**, Vice President, Research and Clinical Affairs, **Orthofix
Stan Watowich**, Founder, **Ridgeline Therapeutics
Allan Miranda,** Head JLABS, Canada, **Johnson & Johnson Innovation
Jason Jones**, VP North America, Clinical & Scientific Affairs, **LivaNova
Shanna Jackson**, Director, Clinical Operations, **Immatics US
Jane Hart**, Vice President, Global Clinical Affairs, **Acelity
Patrick Moran**, Founding Board Member, **Texas Cannabis Industry Association
Alicia Kae Miller**, Director, Patient Engagement, **Aeglea BioTherapeutics, Inc.
Tara Burt**, Associate Director, Clinical Affairs, **Procyrion
Anastasia Gutierrez**, Director, Clinical Operations, **Bellicum Pharmaceuticals
Sofia Achaval Wied**, Executive Director of Development, **Tvardi Therapeutics
Whitnie Strauss**, President, **Association for Creatine Deficiencies
Catherine Barker**, Site Education Manager, **Turnstone Biologics
Gowri Sukumar**, Director CMC & Regulatory Affairs, **Iterion Therapeutics
Morgan Farrar Brown**, Associate Director of Clinical Partnerships, **TMC
Yan Wang**, Clinical Study Coordinator, Department of Leukemia, **MD Anderson Cancer Center
Anthony Tate,** Director, Clinical Operations, **Acelity
Dr Ike Ogbaa**, US Medical Affairs Lead, **Sanofi

Atul Varadhachary, *Managing Partner,* ***Fannin Innovation Studio***

Outsourcing in Clinical Trials Texas
Day One- September 11th 2019, Houston

Registration: 8:15- 8:50
Chair Opening Remarks: 8:50
Jane M. Jacob, Vice President, Research and Clinical Affairs, Orthofix

9:00 ***Evaluating recruitment and engagement strategies to develop a successful rare disease drug development model***

- Highlighting the key challenges associated with rare disease trials especially considering the lack of available therapies
- Outlining your CRO selection process including how to evaluate their level of experience
- Pinpointing best practices for rare disease patient recruitment and engagement in order to prevent study start-up delays
- Recognising the need for effective site and investigator engagement

Shanna Jackson, *Director, Clinical Operations,* ***Immatics US***

9:30

Building a Scalable Delivery Ecosystem - Creating Real Value for Sponsors

- Sponsors need CROs that can offer more than simply CRO staff.
- Pharm-Olam is proactively and purposely building site networks and relationships with appropriate vendors and local partners to support their three Centers of Excellence
- Learn how this approach is adding value to study start-up and study execution thus providing more value to Sponsors

Donna Campbell*, Clinical Research/Global Operations,* ***Pharm-Olam***

10:00 ***Patient Perspectives Panel Discussion: A Stakeholder Conversation***

Recognizing the intrinsic value of patient advocacy groups (PAGs) to help boost patient engagement in all phases of the drug development process. This session will be followed by 10mins Q&A.

- Exploring the role and importance of PAGs in healthcare
- Pinpointing the struggle of patient engagement when there is not a disease-specific patient advocacy group
- Establishing inclusive stakeholder relationships and best practices for expanding partnerships
- Stakeholder educational opportunities
- 10mins audience Q&A

Panellists: ***Alicia Kae Miller****, Director, Patient Engagement,* ***Aeglea BioTherapeutics, Inc.; Whitnie Strauss****, President,* ***Association for Creatine Deficiencies***

10:45 **Morning Refreshments & Networking**

11:15 ***Understanding Initial IND***

This session will explore the process once the initial IND is submitted to the FDA. Understanding the rational for imposing the clinical trial hold is critical for the sponsor to avoid or mitigate this risk.

- Overview of the basic steps to the process for the initial 30 days after an initial IND is submitted to the FDA
- Understanding the types of clinical hold
- Rational for imposing a clinical Trail hold for phase I by the FDA
- Identification and options for resolution of the clinical hold
- Analyzing the options for the sponsor's response to clinical hold
- Discussing best practices for the dialogue between the Sponsor and the FDA during the initial submission phase

Gowri Sukumar**, Director CMC & Regulatory Affairs, **Iterion Therapeutics

11:45 **Importance of early patient involvement in clinical trial design**

Patient-centricity gets a lot of buzz, but what are the benefits of involving patients in the planning of a clinical trial? This presentation looks at:

- Where in the process to get patient input—from protocol reviews to endpoint selection to assessments
- How patient input can benefit enrollment, compliance, and outcomes
- What tactics can be used to elicit meaningful input

Samantha Hoopes**, PhD, RAC, Research Scientist, **Rho

12:15 ***Revealing Strategies to Work With CRO Partners to Ensure the A-Team for Your Trial***

- Specifying the individuals you agreed to work with during the contract stage to avoid losing valued team members
- Harnessing methods for maximizing CRO engagement once you have the right team
- Implementing best practices for establishing good communication between internal teams and vendors
- Promoting frequent face-to-face meetings and reporting metrics to promote open communication

Anastasia Gutierrez**, Director, Clinical Operations, **Bellicum Pharmaceuticals

12:45 **Lunch & Networking**

1:45 ***Clinical trials in MD Anderson – from a site's point of view***

- Overview of clinical trials in MD Anderson
- Introducing values a quality site would bring to sponsored trials
- Discussing what sponsors could consider to facilitate clinical research and patient care

Yan Wang**, Clinical Study Coordinator, Department of Leukemia, **MD Anderson Cancer Center

2:15 ***Accelerating Clinical Trials in Asia-Pacific***

- Australia's scientific talent, excellent medical infrastructure and lucrative R&D cash refund scheme makes it a preferred destination for early phase clinical trials.
- Patient availability makes Asia a key region to accelerate later phase development, at lower costs.
- The partnership between regional specialists, an alternative to large global CRO to manage complex global trial

Alex Ireland,** Business Development Manager, **Novotech

2:45

PANEL DISCUSSION

Comparing international with local medical device trials to develop strategies for overcoming barriers

'The globe is getting smaller so more needs to be done internationally'

- Pinpointing the importance of international sites generating greater outreach in order to recruit suitable patients
- Recognising the benefit of having a local contact for abroad sites to maximise local knowledge and regulations
- Appreciating good relationships with international site coordinators to solve issues quickly despite time zone differences
- Exploring the motivation to conduct more device trials in China to take advantage of the largest population in the world

Moderator: ***Anthony Tate,*** *Director, Clinical Operations,* ***Acelity***

Panellists: ***Jane M. Jacob****, Vice President, Research and Clinical Affairs,* ***Orthofix, Inc;***
Jane Hart*, Vice President, Global Clinical Affairs****, Acelity***

3:15 ***CASE STUDY: Uncovering strategies for planning and executing a clinical trial in Australia, drawing on experience from a small company's perspective***

- Addressing the pros, cons and planning stages associated with implementing a clinical study in Australia
- Exploring the importance of trust with your vendor to ensure you can rely on them to successfully run your trial abroad
- Pinpointing practical methods involved with planning and executing clinical trials in Australia
- Discussing what small companies should consider when contemplating running a study in Australia

Heather Giles*, CSO & CEO,* ***Vapogenix***

3:45 **Afternoon Refreshments & Networking**

4:15 ***ONSTAGE INTERVIEW***

A Data-Driven World: Unlocking how to properly utilize Real World Evidence/Data to improve study design and execution

- Identifying how RWE is used to locate patients for faster recruitment
- Delving into electronic medical health records to identify patient numbers before you set out study parameters
- Navigating RWE to gain metrics on how many patients sites bring in to improve site selection processes
- Exploring competitive intelligence and landscape assessments to identify investigators with the capacity for your study
- Highlighting the use of RWE for protocol modelling and regulatory submission
- Building regulatory, clinical and healthcare economics strategies- involving cross functional teams

Tara Burt, *Associate Director, Clinical Affairs,* ***Procyrion***

4:45 ***CASE STUDY: Discovering the operational challenges and successes of our recent CBD clinical trial to identify lessons learned and explore the future of CBD clinical studies***

- Developing the in-house infrastructure to conduct scientifically valid research and avoid the pitfalls of attempting to outsource pioneering work, especially related to cannabis

- Understanding the unique challenges qualified participating families face and structuring/conducting your trial in an empathetic manner that helps ensure completion
- Recognizing the value of both analytical & observational data for teeing-up future studies and establishing the protocols to gather all, including 'blind' 3rd parties
- Creating a trial template that can be both replicated and evolved to help establish the foundation for future cannabis clinical studies

Patrick Moran, *Founding Board Member,* ***Texas Cannabis Industry Association***

5:15 ***Discussing a model for early stage companies to bring their innovations in therapeutics, medical device or consumer health from concept to fruition***

- Appreciating that innovation is just as likely to come from outside the walls of a large healthcare company as it is from within
- Exploring why many innovative ideas fail at the early stage
- Discussing a model for early stage companies to bring their innovations in therapeutics, medical device or consumer health from concept to fruition

Allan Miranda*, Head JLABS, Canada****, Johnson & Johnson Innovation***

5:45 **Chairman's Closing Remarks & Close of Day One**

Outsourcing in Clinical Trials Texas
Day Two- September 12th 2019, Houston

Registration: 8:15- 8:50
Chair Opening Remarks: 8:50
Jane M. Jacob, Vice President, Research and Clinical Affairs, Orthofix

9:00 **KEYNOTE**
Key considerations for executing rapid study start-up with multiple vendors

- Developing an internal strategy for vendor management during start-up to meet deliverables and ensure correct specification
- Promoting strong vendor communication plans with weekly calls and regular face-to-face meetings
- Considering the advantage of having an experienced clinician review your protocol pre-start-up to ensure it will be well-received by sites
- Outlining the main reasons for start-up delay to put structured agreements in place so this can be avoided

Jason G. Jones*, VP North America, Clinical & Scientific Affairs,* ***LivaNova***

9:30 **PANEL DISCUSSION**

Striking a balance between outsourcing and utilizing in-house resources to improve trial efficiency: Which model offers the most value to the sponsor?

- Determining how best to evaluate your internal capabilities to decide what to keep in-house to make the most of your resources
- Highlighting the challenges of hybrid vs fully outsourcing models to identify the most suitable method for achieving your development goals

- Evaluating the risk of either outsourcing model to determine who is ultimately responsible for the various aspects of the trial
- Defining big vs small company perspectives to understand the key factors that should be considered in the final decision

Panellists: ***Stan Watowich****, Founder,* ***Ridgeline Therapeutics;***
Shanna Jackson*, Director, Clinical Operations,* ***Immatics US;***
Atul Varadhachary, *Managing Partner,* ***Fannin Innovation Studio***

10:00 ***Discussing challenges associated with patient screening and recruitment to reduce timeline delays in orthopedic medical device trials***

- Outlining the role of patient screening in medical device trials to ensure the most suitable patients are selected
- Screening patients appropriately so that qualified and quality patients are enrolled
- Identifying challenges with informed consent in medical device trials to ensure compliance with the protocol
- Identifying the logistical challenges of doing trials to reduce the burden on both the patients and the site

Jane M. Jacob*, Vice President, Research and Clinical Affairs,* ***Orthofix, Inc***

10:30 **Morning Refreshments & Networking**

11:15 ***TMC Innovation: Accelerating life science startups in Texas***

- To discuss the different programs embedded within TMC Innovation: TMC Biodesign, TMCx, TMCx+, TMC Corporate Partners
- TMCx's individualized approach for startups attempting to navigate major healthcare systems
- How to measure success? A startup perspective

Morgan Farrar Brown*, Associate Director of Clinical Partnerships,* ***TMC***

11:45 ***15min Spotlight on CPRIT: Investment, Ecosystem Development and Opportunities***

Cindy WalkerPeach*, Chief Product Development Officer,* ***Cancer Prevention & Research Institute of Texas***

12:00 ***Strategies for engaging and ensuring protocol compliance amongst multiple stakeholders on site***

Cancer therapies are utilizing complex biologics but clinical sites remain uneasy with the preparation, administration, or handling of these products and the patients receiving them. This session will explore how designing and outsourcing education to clinical sites as a strategic plan between the Sponsor and the CRO can help to increase patient enrolment and site interest.

- Identifying stakeholders
- Designing a comprehensive education plan
- When and what activities can be outsourced, but which activities should remain in-house
- Benefits and budget impacts

Adina Pelusio*, Vice President, Medical and Clinical Operations,* ***Turnstone Biologics &***
Catherine Barker*, Site Education Manager,* ***Turnstone Biologics***

12:30 **Lunch & Networking**

1:45 ***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 runs for 30 minutes and delegates have an opportunity to take part on 2 roundtables.

RT 1- **MDR Debate- Discussing the best strategies for developing a post-market plan & clinical follow up for you device to ensure acceptance**

Anthony Tate, *Director, Clinical Operations,* ***Acelity*** & ***Jane Hart****, Vice President, Global Clinical Affairs****, Acelity***

RT 2- **Establishing strategies for vendor management and oversight to strengthen collaboration**

Sofia Achaval Wied*, Executive Director of Development ,* ***Tvardi Therapeutics***

RT 3- **CPRIT roundtable- Discussing how to meet the challenges of company funding**

Cindy WalkerPeach*, Chief Product Development Officer,* ***Cancer Prevention & Research Institute of Texas***

RT 4- **Demystifying Medical Affairs; the big pharma secret to maximizing the value proposition of your product**

Dr Ike Ogbaa*, US Medical Affairs Lead,* ***Sanofi***

2:45 **Close of Day Two**