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 across the globe 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 and for one year only we are going to bring together decision makers from both small, medium and large pharmaceutical and medical device companies to help advance your clinical trial within timelines and budget whilst keeping each patient the priority.

PREVIOUS SPEAKERS IN THIS SERIES

***Ashley Johns**, VP of Clinical Operations, InRegen*
***Dave Kurisko**, Associate Director, Clinical Portfolio and Vendor Management, BD*
***Liz Mascherino**, Director Clinical Operations, Altavant Sciences*
***Lian Cunningham**, VP Clinical Affairs & Regulatory Affairs, BAROnova*
***Deborah Covington**, Associate Director, Global Clinical Outsourcing Planning & Contracts, Grifols*
***Rosalie Filling**, Vice President, Clinical Operations, Endo Pharmaceuticals*
***Pam Duffy,** Director, Digital & Technology, Pfizer*
***Angela Hee,** Head of Clinical Operations, Hengrui Therapeutics, Inc.*
***Emmanuel Fombu**, Global Commercial Strategy and Digital Innovation, Johnson & Johnson*
***Todd Leathers**, Executive Director, Clinical Operations, Incyte*
***Kathryn Lunga**, Director, Clinical Operations, Insmed*
***Monica Salamea**, Director and Head of Clinical Operations, Trevena*
***Ketty Belizaire**, Director, Global Clinical Operations, Mylan*
***Marcia Wachna**, VP, Clinical Affairs, Empirical Spine*

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

Registration: 8:15- 8:50
Chair Opening Remarks: 8:50

9:00 – 9:30 **KEYNOTE**

Uncovering the challenges with outsourcing from a business perspective: What strategy can we use to start comparing apples to apples? (LEIANNE, NOVARTIS)

- Kick starting the process of building a business case to compare apples to apples and drive an effective outsourcing model
- Delving into your portfolio overview to identify if your demands were met in terms of deliverables
- Weighing up your internal resources to discover the impact of using a specific outsourcing model
- Recognising the benefits of working with finance partners and procurement to understand the total cost of vendors by analysing data sources

9:30 – 10:00 **Session Reserved for Pharm-Olam**

10:00 – 10:30 **PATIENT ENGAGMENT PANEL**

Recognizing the benefits of building a patient community through advocacy groups and boost patient engagement in your study

- Pinpointing the struggle without a stand-alone patient advocacy group especially in rare diseases
- Identifying key patient advocacy groups and best practices for reaching out to KOLs
- Supporting and encouraging patients to set up stand-alone advocacy groups to develop relationships with local physicians and regulators
- Importance of identifying a thought leader who can pass information down to patients in an appropriate manner
- Encouraging advocacy groups to hold regular advisory board meetings with a focus on a specific disease

10:30 – 11:00 **Morning Refreshments & Networking**

11:00 – 11:30 ***Revealing Strategies to Work With Appropriate CRAs 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

11:30 – 12:00 **PANEL DISCUSSION**

Exploring creative ways to encourage TA experts and niche CROs to bring their business to Texas

- Discussing how major institutions can work together to attract new trials and TA experts to Houston
- Overcoming the hurdles of resourcing for TA experts in Texas to identify the right skill set for your study
- Being creative with how to make Houston attractive to the right set of people- how can we stand out against the East and West coasts?
- Examining what novel, innovative CROs Texas has to offer for nimble delivery
- Establishing what Venture Capital firms look for when investing in life sciences and determine how we can make Houston more attractive to them

12:00 – 12:30 ***Discussing challenges associated with patient screening and recruitment to reduce timeline delays in Oncology trials***

- Outlining the role of patient screening in oncology trials to ensure the most suitable patients are selected
- Addressing the implications of multiple screening processes to reduce unnecessary costs and patient burden
- Identifying challenges with informed consent in oncology trials to ensure compliance
- Adopting the process of returning pre-screening data to physicians to enable quick identification for suitable trials in the future

12:30 – 1:30 **Lunch & Networking**

1:30 – 2:00 ***FIRESIDE CHAT***

Debunking the AI Hype- Why are machine learning and AI techniques getting so much traction in the life science industry?

- Recognising the ability of AI to keep track of the data we don't analyse- identifying rare disease patients in a huge database
- Harnessing the power of AI to identify the most suitable sites using electronic health records and enrolment metrics
- Can AI only be beneficial for large Parma due to large amounts of data stored?
- Considering what processes can be automated through technology and AI to reduce monotonous tasks and human error

2:00 – 2:30 ***With the emergence of digital health how can we maximize the use of wearable technologies to improve patient monitoring***

- Being aware of wearable technologies available and how they can be incorporated into your study
- Exploring home monitoring technologies to collect patient data in a more timely manner
- Overcoming challenges when shifting to wearables whilst ensuring patient safety
- Considering the infrastructure required for wearable tech when running a large global trial in multiple locations

2:30 – 3:00 ***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 rare disease 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

3:00 – 3:30 **Afternoon Refreshments & Networking**

3:30 – 4:00 ***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

4:00 – 4:30 ***Debating how ICH E6 will impact vendor oversight: How can the sponsor take further ownership and accountability?***

- Overcoming the common misconception of being hands off with your vendor- identifying strategic touch points to take accountability for your trial
- Changing sponsor processes to ensure more robust monitoring whilst keeping an open relationship with vendors
- Deciding on the level of governance depending on critical data and level of risk
- Discussing best ways to measure performance between the sponsor and CRO with a risk based approach

4:30 – 5:00 ***Eliminating variability in your trial by improving data entry and allowing you to critically deliver a quality product***

- Innovative ways to control variability by developing reliable automations such as AI
- Exploring simple innovations and automations which you can readily pull together with current skill set
- Examining automation using excel based tools to check database specification and can be easily integrated into your study
- Identifying data tools which can be flexible to fit our business needs- what areas of flexibility do you have in your study design?

5:00 – 5:30 **Chairman's Closing Remarks & Close of Day One**

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

Registration: 8:15- 8:50

9:00 – 9:30 **SPOTLIGHT SESSION**

Sharing success stories: Optimizing early phase trials to speed promising drug candidates to Phase II

- Best practices for designing successful early phase protocols to minimize your need for protocol amendments during the trial
- Performing a gap analysis to discover what external support and resources are needed for your trial
- Highlighting lessons learned from previous early phase studies to implement best practices moving forward
- Pinpointing what data is necessary to progress to Phase II to avoid wasted resources

9:30 – 10:00 **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

10:00 – 10:30 ***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***

Session reserved for Patrick Moron, Texas Cannabis Industry Association

10:30 – 11:15 **Morning Refreshments & Networking**

11:15 – 11:45 **PANEL DISCUSSION**

Finding a suitable medical device supplier: How do we band together to create an attractive environment encouraging vendors to run more device trials?

- Overcoming the challenge of finding appropriate device-specific suppliers and building capability with a true partner
- Considering strategies to attract vendors when the pharma industry offers more financial benefit
- Collaborating with your partner to identify CRAs with a MedTech background creating a top level clinical team
- Working closely with your vendor to ensure full understanding of the technology and design of your device trial

11:45 – 12:15 ***Exploring best practices when considering how to raise funds for early stage clinical trials***

- Providing an overview of common funding methods to understand challenges and benefits of each
- Addressing the specific challenges of financing clinical trials from the perspective of a small company
- Learning what needs to be done during the study design phase to make your trial stand out and achieve the funding required
- Exploring the benefits of partnering with local innovation centers to ensure vested interest in your product's development

12:15 – 12:45 ***Patient Recruitment Strategies: Investigating how to efficiently locate and onboard suitable patients based on specific criteria***

- Developing relationships with local physicians to develop effective referral pathways for patients
- Creating pathways for patients to find relevant clinical trials themselves reducing the pressure internally
- Engaging patients in the protocol design phase to identify the best enrolment strategy
- Adopting the use of social media to increase interest in a defined patient population and accelerate recruitment

12:45 – 2:00 **Lunch & Networking**

2:00 – 3:30 ***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 runs for 45 minutes and delegates have an opportunity to take part on 2 roundtables.

RT 1- *Debating whether traditional face-to-face meetings are the gold standard or if virtual investigator meetings have proven online is better*

RT 2- *Uncovering specific minorities within patient pools and how we can ensure they aren't being excluded from trials*

RT 3- *Establishing strategies for vendor management and oversight to strengthen collaboration*

RT 4- *Leveraging technologies in early phase development to accelerate trial timelines*

RT 5- *Exploring the motivation to move device trials to China/Asia*

3:30 **Chairman's Closing Remarks & Close of Day One**

EXTRA SESSIONS:

CRO SELECTION-

Developing strategies for finding the right CRO partner to conduct your early clinical study

- Highlighting different approaches to finding niche CROs to ensure you are getting the attention and help you need
- Identifying the best outsourcing model during early clinical development to discover whether functional or full outsourcing will be the best fit for your study
- Reviewing the positives and negatives of partnering with small CROs during early clinical development to determine which is the best partnership fit for your company
- Highlighting the importance of balancing time, cost and quality with possible vendors to ensure a accurate assessment of RFPs

IND APPLICATION-

Leveraging the knowledge of your partners to provide expert guidance on your IND application to outline what your trials needs to be successful

- Pinpointing the advantages of a pre-IND meeting to develop a checklist of what to consider with your IND application
- Best practices to ensure you provide the FDA with clear data and explanations for results, plus ensuring these results match your protocol
- Designing the IND document in a way that is easy to review and understand with FDA reviewers in mind
- Recognising how the right CRO can be a valuable asset for IND submission by drawing on their expertise to produce higher quality work

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

RARE DISEASE TOPIC-

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

ONCOLOGY TOPIC-

Identifying the importance of selecting the right investigator for your early phase Oncology trial

- Finding and engaging with Phase I units with Oncology specific expertise
- Developing training plans for clinicians that are therapeutic experts but are inexperienced in conducting clinical trials
- Presenting the benefits of working with a CRO specialized in Oncology to find qualified sites and investigators