OUTSOURCING IN CLINICAL TRIALS SOUTHEAST

March 13th-14th, 2018 I Durham, North Carolina, USA

2018 Speaking Faculty

Nicole Leedom, Director Clinical Operations, **SpringWorks Therapeutics**
William Gluck, Ph.D., Program Director, Clinical Trials Research Associate & Medical Product Safety/Pharmacovigilance Programs, **Durham Technical Community College**
Blake Jensen, Director/Head, Quality and Compliance, **Precision BioSciences**
Shailesh Chavan, Vice President of Clinical Research, Medical Affairs & Drug Safety, **Biotest Pharmaceuticals**
Malcolm Thomas, Chief Executive Officer, **Agile Sciences Inc**
Ashley H Johns, MSHS, Director of Clinical Operations, **inRegen**
Jennifer Shi, Director Clinical Operations, **Atox Bio**
Deborah Covington, Associate Director of Global Clinical Outsourcing Planning and Contracts**, Grifols**
Kenneth Batchelor, Chief Executive Officer, **NovaTarg Therapeutics**
Erica Elefant, Associate Director, Clinical Program Management**, Avid Radiopharmaceuticals**
Karthi Natarajan, Director, Clinical Affairs, **Mayne Pharmaceuticals**
Michael McDonald, Data Delivery Lead, **UCB**
Katrina Ruth, Senior Manager, Clinical Affairs, **Medtronic**
Heather Smith, Director Clinical Operations**, QOL Medical, LLC**
Om Dhingra, Chief Executive Officer, **Marius Pharmaceuticals**
Dave Mathews, Clinical Project Director**, Merz North America**
Tawana Wester, Manager, Clinical Affairs and CQA, **Bioventus**
Elizabeth Burton, Project Manager, **Precision BioSciences**
Greg Hottell, Director, Supply Chain Group Lead Target to Patient Supply Chain - Clinical Interface, **GSK**
Jim Joffrion, VP of Clinical Operations, **Aeglea BioTherapeutics**
Jessica Meyer, Director of Outsourcing & Contracts, **United Therapeutics**

	Outsourcing Clinical Trials Southeast **Day One - 13th March 2018**
07:45	**Registration and refreshments**
08:20	**Chair's opening remarks – Katrina Ruth**, Senior Manager, Clinical Affairs, **Medtronic**
08:30	**Strategically adopting novel approaches to your patient recruitment; harnessing the power of social media and e-technology to keep patients engaged** • Assessing cost and benefits associated with the adoption of a social media strategy to determine whether this is right for your company • Exploring social media as a viable alternative to traditional sources of patient recruitment asses its validity for your trial • Incorporating e-consent and electronic diaries into your trial reporting mechanism to improve data collection and minimize the need for so many patients • Harnessing social media as a tool to build relationships between sponsors, site physicians and patients as a mechanism to improve retention • Consider ways through which you can build these capabilities internally to avoid increasing costs **Tawana Wester**, Manager, Clinical Affairs and CQA, **Bioventus**
9:00	**Session reserved for SyntheractHCR**
09:30	**Encouraging greater patient centric trials which can improve trial results by ensuring higher levels of retention and engagement whilst targeting patients smartly** • Understanding the value and promise of patient centricity in clinical trials • Exploring methods through which patients can be involved in the design process of trials from the initial phases to ensure your drug is serving their needs whilst delivering results • Selecting vendors who are patient centric in their approach so that your trial design is effectively implemented by your partners and adhered to as per protocol outline • Harnessing new technologies to maximize the relationship between investigator and patient to improve reporting and reduce dropout rates Greg Hottell, **Director, Supply Chain Group Lead Target to Patient Supply Chain - Clinical Interface,** GSK
10:00	**Morning refreshments and networking**
10:45	**Uncovering ways through which you can manage your vendors without duplicating tasks, affecting trial integrity and increasing inhouse responsibilities** • Highlighting key challenges faced by small-pharma and biotech when managing vendors to design strategies for best practice • Reviewing vendor management strategies to avoid task duplication whilst ensuring your vendor is delivering as promised • Exploring ways through which communication between partners can be improved to ensure that

	deliverables are presented on time and delays are avoided • Debating whether full or functional outsourcing is the best model to reduce oversight and remain within budget • Comparing niche vendors vs one-stop-shop CRO's and which are easiest to manage for your trial type and company size **Jennifer Shi**, Director Clinical Operations, **Atox Bio**
11:15	**Session reserved for PSI**
11:45	**Encouraging teambuilding between in-house and partner teams to improve trust between parties and minimize resource misuse** • Promoting greater communication cadence between trial sponsors and CRO teams to ensure both parties are aligned and minimize miscommunication • Exploring ways through which CRO team members can be brought into the sponsor company to create a cohesive unit which will further the success of your trial • Uncovering best practice techniques to guarantee commitment from partners for a trials success to ensure quality is maintained throughout study duration • Considering whether a complete or partial outsourcing model is the best to achieve this cohesion and stay within your budget **Nicole Leedom**, Director Clinical Operations, **SpringWorks Therapeutics**
12:15	**Lunch and networking**
13:30	**Why does my service provider never give me what I want? Exploring how both sponsors and vendors can improve their relationships to ensure a trials success** • Examining miscommunication between sponsor and partner teams as the cause of delivery failures and suggest improvements to avoid this • Modifying relationships with vendors to invest them in the clinical trial process and equate your success with theirs • Outlining differences between small and large pharma when partnering with vendors to highlight that one size does not fit all • Appreciating that sponsors disruption of vendor timelines compromises their trials success and exploring how this can be prevented • Presenting strategies to improve different vendor oversight given the differences between bioanalytical labs, CMO's and CRO's to avoid task duplication **Michael McDonald,** Data Delivery Lead, **UCB**
14:00	**Improving staff recruitment; discussing how industry and academia can work together to ensure adequate training for future clinical trial staff to ensure trials are not compromised**

	• Uncovering what difficulties lay in ensuring the establishment of a competent workforce and how this can be effectively addressed by academic institutions • Establishing partnerships between academia and industry to ensure educational courses are equipping new staff with adequate competencies for future roles • Exploring ways through which placement programs can be implemented within local companies to improve student training and knowhow of lab procedures • Creating program which assist both device and trial teams to train staff given increasing pressures to recruit because of more companies investing in RTP **William Gluck, Ph.D**., Program Director, Clinical Trials Research Associate & Medical Product Safety/Pharmacovigilance Programs, **Durham Technical Community College**
14:30	**Panel discussion: approaching funding opportunities strategically; which funding options are available for small-midsize pharma and biotech to boost your pipeline** • Exploring various funding opportunities available for sponsor companies and what is required to be able gain access to these • Designing a cohesive business strategy to showcase your trials feasibility and improve your success at acquiring external investment • Assessing whether alternative models to VC funding could be employed to offer new avenues of growth and investment for your company • Investigating deluded funding opportunities to increase your current resources and stretch your budget • Presenting which funding opportunities are available in RTP maximize your budget and increase your revenue stream options **Kenneth Batchelor –** Chief Executive Officer – **NovaTarg Therapeutics** **Malcolm Thomas –** Chief Executive Officer – **Agile Sciences Inc**
15:00	**Afternoon refreshments and networking**
15:30	**Workshop: unpacking readily available technologies in the clinical trial arena to explore their usefulness in your studies** *This interactive workshop will provide an opportunity for the audience to share thoughts and insights into the usefulness of technology in their clinical operational systems whilst exploring the cost implications of on boarding this* • Exploring which technologies are currently available for sponsors in the clinical trial space and how they can be integrated into your trial design • Uncovering what infrastructure capabilities are required for sponsors to adopt clinical technologies into their current processes • Highlighting technological investments as a mechanism to cut overall costs in your trials by minimizing IP waste, improving overall drug monitoring and expediting expiry date processes • Ascertain the value technology brings and whether there is a need for incorporating these into your clinical trials • Considering security risks that arise from the adoption of apps and wearable technologies into your trials and how do you guarantee data is not compromised

	Shailesh Chavan – Vice President of Clinical Research, Medical Affairs & Drug Safety – **Biotest Pharmaceuticals**
16:15	**Encouraging greater patient centric trials which can improve trial results by ensuring higher levels of retention and engagement whilst targeting patients smartly** • Exploring methods through which patients can be involved in the design process of trials from the initial phases to ensure your drug is serving their needs whilst delivering results • Selecting vendors who are patient centric in their approach so that your trial design is effectively implemented by your partners and adhered to as per protocol outline • Assessing sites and vendors adherence to the 21st Century Cures Act requirements to guarantee their compliance and increase focus on patient's individual needs • Appreciating common complaints by patients regarding trials designs and how these can be addressed to minimize disengagement and delay your trials success • Harnessing new technologies to maximize the relationship between investigator and patient to improve reporting and reduce dropout rates **Heather Smith,** Director Clinical Operations**, QOL Medical, LLC**
16:45	**Assessing whether your CRO is equipped to carry out direct-to-patient (DtP) trials to guarantee that data integrity is not compromised** • Determining if a DtP model is right for your study, company and budget • Assessing partners responsibility in ensuring nurses and CRA's are adequately trained to collect and report trial results from patients to guarantee data integrity • Improving communication between CRO's and home-health care providers to ensure all parties objectives are aligned and effectively monitored • Exploring current trial kits and labels designs to certify these can be utilised by patients at home without compromising trial results • Examining current regulations and their impact on the viability of making DtP a reality **Erica Elefant,** Associate Director, Clinical Program Management**, Avid Radiopharmaceuticals**
17:15	**Chair's summary and close of day one – Katrina Ruth**, Senior Manager, Clinical Affairs, **Medtronic**

Outsourcing in Clinical Trials Southeast 2018

MARCH, 13TH – 14TH 2018, DURHAM, NORTH CAROLINA

The leading clinical outsourcing roadshow for the biotech, pharma & medical device industries

	Outsourcing Clinical Trials Southeast **Day Two - 14th March 2018**
08:15	**Registration and refreshments**
08:50	**Chair's opening remarks – Katrina Ruth**, Senior Manager, Clinical Affairs, **Medtronic**
09.00	**Uncovering what is driving outsourcing; how and why are traditionally in-house capabilities being externalized or centralized** • Investigating what major components of the supply chain are being outsourced across the industry to assess if there is an industry trend • Outlining what structural arrangements those who do not outsource have in place to enable them to carry this out and what others can learn from this • Exploring what underlying causes are driving industry towards a further reliance on Contract Research Organizations • Examining ways through which increased oversight because of greater levels of outsourcing can be streamlined given regulatory expectations to monitor vendor compliance • Assessing the implications that greater outsourcing will have upon sponsor-vendor relationships **Katrina Ruth**, Senior Manager, Clinical Affairs, **Medtronic**
09:30	**Integrating communication strategies across in-house and outsourcing teams to maximize efficiency and minimize trial overrun** • Ensuring in-house supply and operations teams share up-to date information so timelines are adhered to effectively with external partners • Modifying relationships with vendors to invest them in the clinical trial process and equate your success with theirs • Sharing successful communication strategies to ensure data is distributed effectively and improve industry's ability to react to unforeseen changes • Promoting better communication between supply trial teams to ensure sufficient drug is delivered to trial sites • Designing systems which enable all parties involved to be notified of changes which affect the supply chain and enable these to react best **Deborah Covington,** Associate Director of Global Clinical Outsourcing Planning and Contracts**, Grifols** **Om Dhingra,** Chief Executive Officer, **Marius Pharmaceuticals**
10:00	**Creating opportunities for dynamic change to maintain competitiveness and flexibility; building on the agility and success of small pharma** • Maximizing biotech's flexibility to quickly respond and applying this when unforeseen changes arise in your supply chain • Exploiting the fluid organizational structure of small biotech's to prevent organizational silos developing which add administrative burdens to your clinical trials • Exploring how small biotech's can improve their supply chain by mimicking the standardized supply process employed by large pharma

	• Determining how the accountability structure of large pharma can provide a platform for biotech's to grow and expand • Capitalizing on the rapid changes of technology to ensure your clinical trial processes remain ahead of the curve **Malcolm Thomas –** Chief Operating Officer – **Agile Sciences Inc**
10.30	**Morning refreshments and networking**
11:00	**Two-way discussion: Niche vendors or full-service providers? Which is the best in delivering quality and helping you stay on budget** • Outlining your internal outsourcing capabilities to determine which vendor is within budget • Debating how growing market consolidation of CRO's as being sponsor driven and its effect on outsourcing quality • Discussing whether functionally outsourcing to a niche vendor is best for your current trial over full service outsourcing • Reviewing the complexity of managing multiple partners over establishing a prefered alliance provider to reduce oversight requirements • Determining which vendor is more flexible in its ability to align itself with your internal structures and deliver results on time and in budget **Ashley H Johns, MSHS**, Director of Clinical Operations, **inRegen** **Karthi Natarajan**, Director, Clinical Affairs, **Mayne Pharmaceuticals**
11:30	**Determining which size vendor is the best for biotech and small-mid-size pharma companies to meet study requirements whilst staying within budget** • Considering budgetary differences between small and mid-size pharma and biotech versus large pharma when selecting partners to ensure you choose the correct vendor • Determining which outsourcing model is the right for your company based on your budget and trial • Appreciating how small biotech companies often work working to tight budget and timelines and determining how CRO's can tailor their services to match this • Exploring whether a full service CRO or a niche vendor is best for your study given your trial requirements **Ashley H Johns, MSHS**, Director of Clinical Operations, **inRegen**
12:00	**Lunch and networking**
13:00	**Debate: Challenging the responsibility of trial sponsors when vendors don't deliver; how to improve your vendor management** • Discussing differences between small and large pharma to ensure vendors are aware of your company needs • Measuring effectiveness of outlining expectations at the start of a partnership to solidify sponsor-vendor relationships • Determining the impact of greater transparency from vendors in spending and resource allocation to

	ensure budgetary control • Debating drawbacks and advantages when partnering with small and large vendors to determine what size vendor is right for you • Assessing best approach to continue your trial after a sponsor-vendor relationship disintegration **Deborah Covington,** Associate Director of Global Clinical Outsourcing Planning and Contracts**, Grifols** **Om Dhingra,** Chief Executive Officer, **Marius Pharmaceuticals** **Dave Matthews,** Clinical Project Director**, Merz North America**
13:30	**Panel discussion: to outsource or not to outsource, this is the question? Examining the arguments behind keeping capabilities in house versus contracting out** • Considering why companies are preferring to keep certain competences in-house and determine if this an industry trend • Pinpointing how keeping capabilities in-house improves communication management and reduces delays in turn around • Examining whether outsourcing trial components is cheaper than keeping these in-house if you are required to contract extra staff to manage your partners • Appreciating that CRO's experience can assist small pharma and biotech in bridging knowledge gaps and offload pressure on small teams • Assessing whether a hybrid outsourcing model is the most effective one to stay within budget **Blake Jensen**, Director/Head, Quality and Compliance, **Precision BioSciences** **Jennifer Shi**, Director Clinical Operations, **Atox Bio**
14:00	**Afternoon refreshments and networking**
15:00	**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
Roundtable 1	Navigating a changing ecosystem; how current political uncertainty affects your ability to conduct clinical trials and what can be done to address this **Elizabeth Burton,** Project Manager, **Precision BioSciences**
Roundtable 2	Continuing the conversation on niche versus full-service provider, which is best at delivering? **Jennifer Shi**, Director Clinical Operations, **Atox Bio**
Roundtable 3	Discussing ways through which expectations can be clearly outlined prior to study start up to avoid downstream conflicts

	Jessica Meyer, Director of Outsourcing & Contracts, **United Therapeutics**
Roundtable 4	Reviewing the partner selection process; key tips to select long-lasting partnerships **Nicole Leedom**, Director Clinical Operations, **SpringWorks Therapeutics**
Roundtable 5	Strategies used to vet vendors; how can you ensure your partner is trustworthy? **Erica Elefant,** Associate Director, Clinical Program Management**, Avid Radiopharmaceuticals**
16:30	**Chair's summary and close of conference – Katrina Ruth**, Senior Manager, Clinical Affairs, **Medtronic**