Outsourcing in Clinical in Trials Southeast

Embassy Suites Raleigh-Durham Research Triangle, Cary, NC

March 28th – March 29th, 2023
www.arena-international.com/octsoutheast

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'The must attend clinical outsourcing event in the Southeast region where industry professional can encounter a platform to explore new solutions to common issues within their clinical trial'

The conference has an incredible speaker line-up this year with presidents and directors of regional biopharma organisations and tech innovators. Along with a varied agenda with topics suitable for all size companies. Key topics to be presented and discussed include exploring the shift to technological advancements including innovative trends such as: exploring advanced genomic technology, decentralized trials, remote monitoring and blockchain. Along with current trends such as diversity, equality, & inclusion and health literacy, patient centricity and recruitment, regulatory standpoints and more.

2023 Speakers

- **Michael Karg,** Sr. Director, Clinical Operations, **Precision Biosciences**
- **Matthew Barnes**, Director Portfolio Management, **Virpax Pharmaceuticals**
- **Ed Addison**, Co Founder, **Cloud Pharmaceuticals**
- **Linda Davidson-Ray,** Director, Diversity, Equity, Inclusion**, DCRI**
- **Lauren Neighbours**, PhD, RAC, Senior Vice President, Product Development and Regulatory Affairs, **Checkpoint Therapeutics, Inc**
- **Deborah Covington**, Global Director Clinical Outsources Management, **Grifols**
- **DeAnn Hyder,** Associate Director, Clinical Data Management and Programming, **Kronos Bio**
- **Jesse Kooker**, Head of Program Leadership & Alliance Management, **Dermavant Sciences**
- **Liz Presson,** Founder & Chief Strategist, **PursuitOf**
- **Nicole Leedom ,** Vice President, Head of Clinical Operations**, Spring Works Therapeutics**
- **Megan Liles,** Vice President Clinical Operations, **ProKidney**
- **David Dworaczyk**, CEO, **Bryn Pharma**
- **Charlene Knape,** Vice President, Clinical Affairs, **NecteroMedical Inc**
- **Barb Geiger**, Sr VP Clinical Operations, **Mana Therapeutics**
- **Roger Nolan,** President, **BioKier**
- **Jamie Kime, Vice President, Clinical Operations & Procurement, Locus Biosciences**
- **Behtash Bahador,** Director, Health Literacy**, CISCRP**
- **Michael Hickey**, Director of Clinical Program Management, **Bio-Path Holdings**
- **Om Dhingra**, Vice-Chair and Co-Founder, **Marius Pharmaceuticals**

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DAY ONE – TUESDAY MARCH 28TH 2022

8:00	Registration & Refreshments
8:55	Chairman's Opening Remarks **Robert Loll**, SVP, Business Development & Strategic Planning, **Praxis**
9:00	**Measure, Map, Mobilize: Recruitment plans that ensure diversity** • The urgency of now: movements in patient and community outreach and how the entire industry needs to adapt • Setting and measuring goals for diversity that include, not target, patients and communities • Mapping goals to study designs, advisory groups, thought leaders, technologies, and protocols that ensure success • Mobilizing with tactics and strategies that work for partners and participants and meet goals **Linda Davidson-Ray**, Director, Diversity, Equity, Inclusion, **DCRI**
9:30	**Trends in outsourcing among small/emerging biopharma** • Key needs of small/emerging biopharma • Recent trends in outsourcing models in this space • What is the role of CROs in value creation for biotech **Brandon Early,** Vice President, Project Delivery**, ICON Biotech**
10:00	**Exploring the rising use of AI in every phase of drug development, from discovery through to commercialization.** • Preclinical: target discovery, drug design, hit to lead optimization • Enrollment of trials and how AI can boost the process. • Addressing patient biomarkers to smooth out the trial process. • Using AI to enhance and streamline protocol design. • Enhancing health and safety measures by using sophisticated AI driven techniques. • Drug repurposing, finding alternative uses for already approved drugs. **Ed Addison**, Co Founder, **Cloud Pharmaceuticals**
10:30	Morning Refreshments & Networking
11:00	**Leveraging CRO Site Relationships to Drive your Study Forward** • Early engagement to get an early pulse on opportunities and challenges • The role of strategic sites to meet important milestones • Ongoing feedback to make needed adjustments and ensure on-time, quality data **Steve Chriscoe,** Vice President, Project Management – United States**, Worldwide Clinical Trials**
11:30	**Navigating operational challenges for Cell & Gene Therapy trials**

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Sales Enquiry
Nicholas McCudden
Head of Sponsorship Sales
T: +44 (0)207 9472755
E: NicholasMcCudden@arena-international.com

Speaker Enquiry
Douglas Webber
Conference Producer
E: Douglad.Webber@arena-international.com

Marketing Enquiry
Haida Amirzadah
Marketing Manager
E: Haida.Amirzadah@arena-international.com

	• Expanding on the real challenges that arise when designing and running a cell & gene therapy trial. • Which technologies were essential in creating a smooth and easy to run trial. • Things to keep in mind when organising the supply chain of a cell and gene therapy trial. **Michael Karg,** Sr. Director, Clinical Operations, **Precision Biosciences**
12:00	**State of the Global Biotech Landscape: *Where the opportunities lie*** - State of Global Clinical Trials Landscape - Lasting COVID Impact - Biotech Economic Landscape - APAC as a Focus for Clinical Development **Steve Brandao**, Regional Director Business Development, **Novotech**
12:30	Lunch
1:30	**Identifying the approaches and challenges to improving diversity in clinical research** • Identifying the approaches and challenges to improving diversity in clinical research • How patient and community partnership is key to improving diversity • Fostering collaboration to build public and community trust and engagement • How regulatory and cross-disciplinary guidance can guide your efforts • Review concrete examples of diversity initiatives and projects **Behtash Bahador,** Director, Health Literacy**, CISCRP**
2:00	**Hybrid trials using DCT technology and processes; focus on patients and the sites** • Highlighting the complexity that Hybrid/DCT brings whilst moving away from the common brick-and-mortar sites. • Discussing the rise in regulator concerns in areas such as investigator oversight, and participant's safety when face to face contact is limited. • How we tend to focus too much on technology when it's actually the processes for the patients and the sites that matter even more. • Major points to consider in designing hybrid/DCT trials; building blocks and practical examples to best prepare you to meet the needs of regulators whilst keeping the patient and sites front of mind. **Sverre Bengtsson**, Co-Founder, Sr. VP Strategic Relations**, Viedoc**
2:30	**How a strong Sponsor / Clinical Site collaboration can improve clinical trial performance** • Highlighting the role in the team that the clinical site plays and how to work with the site during the planning phase. • How a sponsor's study can stand out at a clinical site. • Site centricity vs patient centricity, how patient care can actually be impacted by a lack of foresight. • Focus points moving forwards, how both CRO's and sponsors can work with a site to improve the quality of a trial. **Jamie Kime,** Vice President, Clinical Operations & Procurement**, Locus Biosciences**

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3:00	**Data-Driven Operations and Oversight with elluminate** • Operational analytics including enrolment, protocol compliance and safety • Risk-based analyses and insights with elluminate RBQM • Operational knowledge for data-driven development with elluminate CTMS • Centralized issue management across roles in operations, data and medical review • Sample tracking, data forecasting and financial performance indicators **Dawn Kaminski**, VP, BD Operations, **eClinical Solutions**
3:15	Afternoon Networking & Refreshments
3:45	**The Intersection of Data Privacy and Improving Diversity in Clinical Trials** • Balancing global and US requirements • Challenges and solutions • Practical approach of a start up biotech navigating both needs **DeAnn Hyder,** Associate Director, Clinical Data Management and Programming, **Kronos Bio**
4:15	**Case Study: Virtual drug development from concept through to FDA approval with one full-time employee: challenges and learnings.** • Fund raising from a concept without initial clinical data. • Conducting drug development virtually with only one employee. • Interactions with the FDA • Progression throughout the different clinical phases through to approval as a small team of consultants. **Om Dhingra**, Vice-Chair and Co-Founder, **Marius Pharmaceuticals** **James Bernstein**: President, Live Oak®, **Pharmaceutical Consulting, Inc.**
4:45	Chairman's Closing Remarks & Drinks Reception Sponsored by KPS Life  

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DAY TWO – WEDNESDAY 29TH MARCH 2023

8:00	*Registration and Refreshments*
9:00	***Panel:* Movements in patient engagement, what we as an industry need to change to promote trust.** • Collaboration is key when it comes to promoting the reputation of the industry. • Key focus areas to work on to improve how we are keeping patients engaged in trials. • Tackling patient education, understanding is the real key to engagement. • Working alongside technology, do patients receive a higher quality or do they feel frustrated working with screens. • Involving the site and patient perspective, what are their thoughts on movements within the industry. **Matthew Barnes**, Director Portfolio Management, **Virpax Pharmaceuticals** **Nicole Leedom ,** Vice President, Head of Clinical Operations**, Spring Works Therapeutics** **Lani Hashimoto,** Associate Director, Patient Engagement Management, **Novartis**
9:30	**Innovative Processes To Better Address Todays Trial Dynamics** **What you will learn** i. **Supply Chain Efficiency** 1. Why do extra work and spend more money than necessary? ii. **Payment Process Efficiency** 1. Leverage an existing workflow process sites use everyday. iii. **Understanding The Total Value A Vendor Can Provide** 1. Select a vendor that can demonstrate their total value (and make you look good in the eyes of your company) **Tom Gottschalk,** Senior Director, Clinical Business Development, **TrialCard™**

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10:00	***Panel:* What are our current biggest industry challenges at the moment in small biotech and how are we dealing with them?** • Dealing with staffing shortages across the industry and how it affects the smaller firms. • Timescale issues that affect everything from supply to patient engagement, what we as a smaller team can do to make this easier. • Managing slow turnaround from the FDA and how it impacts trials. • Working with CRO's as a small biotech, how to keep the costs down when the budgets remain small. **Roger Nolan,** President, **BioKier** **Lauren Neighbours**, PhD, RAC, Senior Vice President, Product Development and Regulatory Affairs, **Checkpoint Therapeutics, Inc.**
10:30	**Innovative Training Strategies** • Explore the future-state of performance-based training • Discuss how to interpret and apply learning results to optimize and de-risk your study • Discover how simulation-based training improves study performance **David Hadden**, President & Founder, **Pro-ficiency**
11:00	*Morning Refreshments & Networking*
11:30	**Looking into relationship management with vendors small scale and large from a small start-up perspective:** • Establishing the foundations is a key start to a good relationship with your vendors • Managing your communication with a vendor, from conferences like this to regular meet ups. • When and where to work on protocols with your vendors as a small company, can you ask too much? **Michael Hickey**, Director of Clinical Program Management, **Bio-Path Holdings**
12:00	**Why expert partners & staff matter in IRT** • Are you moonlighting in IRT? • What does experience look like & who has it • Case study • Why internal experts matter • Platform or Purpose Built **Craig Mooney,** VP Scientific E-Tech Enabled Services, **Calyx**
12:30	**Case Study: Running a successful cell therapy trial in a non-oncology indication, the key takeaways and most successful methods.** • An in depth discussion of a successful trial run with a novel autologous cellular therapy. • Sharing insight into the positive steps taken to help with recruitment, engagement and enrolment. • A focus on the real pain points of a logistically complex trial and what surprising obstacles we came across. **Megan Liles.** Vice President Clinical Operations, **ProKidney**

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1:00	*Networking Lunch & Prize Draw*
2:00	**Funding, how to get the most funding as a startup and to enhance your current funding.** • Covering the biggest challenges you will face with a start-up • Looking into the milestones you need to cross on your funding journey. • How to manage fund raising for a novel product and promote it to the right people. **David Dworaczyk**, CEO, **Bryn Pharma**
2:30	**Running a trial outside of the US, how to secure FDA approval for your drug** • Discussing the current advantages and pitfalls with hosting trials outside of the US. • Planning a path from the start to ensure you get the right dataset from your trials that will be approved. • Dealing with differing standards of care in other countries. • A case study of how we approved a drug with the FDA with 100% non US patients. **Lauren Neighbours**, PhD, RAC, Senior Vice President, Product Development and Regulatory Affairs, **Checkpoint Therapeutics, Inc.**
3:00	**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 30 minutes, and delegates may attend up to 2 roundtables
RT1	**A critical discussion of novel technology that is out there, how do bring something from concept through to clinical trials.** **Charlene Knape,** Vice President, Clinical Affairs, **NecteroMedical Inc**
RT2	**Addressing the latest budgeting challenges we are facing and sharing cost saving techniques.** **Megan Liles,** Vice President Clinical Operations, **ProKidney**
RT3	**Working alongside CROs, tips and strategies for relationship management.**
4:00	*Close of Conference*

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