Outsourcing In Clinical Trials East Coast 2023

King of Prussia, PA, USA

23rd – 24th May 2023

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Discover effective strategies for outsourcing clinical trial operations to ensure trials run smoothly and within budget.

Join us for a two-day event filled with case studies, panel discussion and face to face networking opportunities around clinical operations, technology and innovation, and data management.

2023 Speakers

Experience high-level discussions and talks from industry leaders

2023 Speakers Include…

Craig Lipset, Advisor and Founder, **Clinical Innovation Partners**
Rosalie Filling, Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals**
Peter O'Neill, Sr. Director, Clinical Operations, **Incyte**
John Gregg, Chairman and CEO at **BalinBac Therapeutics, Inc.**
Dr. Harsha Karur Rajasimha, President, **IndoUSRare**
Jill McNair, Chief Growth Officer, **CISCRP**
Narayan Lebaka, Senior Director of clinical data management, **Inspirna (formerly known as Rgenix)**
Rick O'Hara, Director of R&D Business Operations, **Endo Pharmaceuticals**
Anthony Fuller, Global Head of Sourcing, **Mitsubishi Tanabe Pharma Development America**
Ram Raju, Senior Vice President and Community Health Investment Officer, **Northwell Health**
Frank Leu, CEO, **BioPharMatrix**
Carrie Lewis, Executive Director, Clinical Program Optimization, **Endo Pharmaceuticals**
Adam Barrows, Executive Director - Solid Tumour TA Head, **Bristol Myers Squibb**
Kathleen Cohen, Head of Clinical Operations, **Marinus Pharma**
Ella Balasa, Patient Advocate, speaker, published writer, and health engagement consultant
Kelly Ragins, Global Head of Portfolio Delivery Office, **Novartis**
Anka G. Ehrhardt, Director, Cell-Based Sciences, AR&D, **Merck**
Venkat Sethuraman, Head of Global Biometrics and Data Sciences, **Bristol Myers Squibb**
Adam Kinsey, Associate Vice President, Global Clinical Trial Operations (GCTO), Head of GCTO North America, **Merck**
Susan Maloney, Former Associate Vice President, Head Clinical Operations, **PhaseBio**

Join our new OCT community on LinkedIn
#OCTEastCoast | @ArenaIntPharma

Linda Blount, President, **Rare Disease Diversity Coalition**
Jenifer Waldrop, Executive Director, **Rare Disease Diversity Coalition**
Evan Tzanis, Chief Operating Officer and Executive Vice President, Head of R&D**, Neuraptive Therapeutics**
Dominique Duchesne, Director, Clinical Operations Lead, **Bristol Myers Squibb**
Kevin Shipe, Director, Head of Strategic Sourcing and Study Start-up, **INOVIO Pharmaceuticals**
Jen Horonjeff, CEO, **Savvy Cooperative**
Jenny Wakefield, Senior Director- Quality Development Operations, **Incyte**
Sherin Abdel-Meguid, President, **Shifa Biomedical Corporation**
Candice Estes, Clinical Trial Manager, Clinical Operations, **Incyte**
Hassan Kadhim, Senior Director, Head of Clinical Trial Business Capabilities, **Bristol Myers Squibb**
Terry Katz, Sr Director, Biostatistics and Data Management Planning and Functional Excellence, **Daiichi Sankyo, Inc.**
Travis Caudill, Vice President Feasibility, Site Identification & Clinical Informatics. Feasibility & Site Identification Integration Workstream Lead, **ICON**
Sverre Bengtsson, Co-Founder, Senior Vice President Strategic Relations, **Viedoc**
Keith Kennedy, Principal and Team Lead, Patient Cloud, **Medidata**
Ellen Weiss, Vice President, In-Home Solutions, Decentralized Clinical Trials, **PCM Trials**
Dr. YuFeng Li, Executive Director, Clinical Development, **Qilu Pharmaceuticals**

DAY ONE – TUESDAY 23rd MAY 2023

7:30	**Registration and refreshments**
8:20	**Chairperson's opening remarks: Peter O'Neill,** Sr. Director, Clinical Operations, **Incyte**

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8:30	**Keynote** **We Are All At-Risk of Being Obsolete: Earning Our Place in the Future of Clinical Research** Clinical research is a crucial part of delivering a healthy society, and no stakeholder involved in the process today has a "right" to be here tomorrow. There are futures where every entity in research is at risk of being made obsolete. How can we best avoid complacence and ensure we are all earning the right to be at this table? **Craig Lipset,** *Advisor and Founder,* ***Clinical Innovation Partners***	
9:00	**Session Reserved for NOVOTECH**	
9:30	**Artificial Intelligence & the future of clinical trials:** ***the potential of AI to help with study planning*** • Identify and assess the possibilities for AI in your clinical trial • Understanding the technologies behind AI such as machine learning, deep learning, neural networks, and algorithms • Social and ethical implications of Artificial Intelligence • A contextual understanding of AI, its history, and evolution, helping you to make relevant predictions for its future trajectory. • Looking at how to successfully implement AI into your clinical trial **Venkat Sethuraman,** *Head of Global Biometrics and Data Sciences,* ***Bristol Myers Squibb***	
10:00	**Session Reserved for MEDIDATA**	
10:30	**Morning Refreshments & Networking**	
	OUTSOURCING & CLINICAL OPERATIONS	**CLINICAL INNOVATION & TECHNOLOGY**
	Chair: **Rosalie Filling,** Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals**	*Chair:* **Peter O'Neill,** Sr. Director, Clinical Operations, **Incyte**

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11:00	**Strengthening patient relationships authentically to enhance the therapeutic development process** **Abstract:** *Gain a comprehensive understanding of a patient's journey to advocacy highlighting important pillars of successful patient engagement directly from a patient advocate's experiences. Understanding and recognizing the barriers, burdens, knowledge gaps, and needs of patients allows for strengthened patient relationships and optimizes long term gains in patient engagement strategies* • Treating the patient as more than a consumer builds the foundation for patient relationships • Recognizing and mitigating the barriers patient trial participation and retention • Understanding the value of incorporating the patient voice from the inception and design of research and trials through drug development • Improving health literacy and ensuring transparency builds trust • Maintaining patient relationships through a feedback loop of dissemination of trial results and co-creation in design strengthens future research **Ella Balasa,** *Patient Advocate, speaker, published writer, and health engagement consultant*	**Data Management in Oncology; the importance of using suitable technology in your clinical trial, leading to a manageable data structure** • Challenges: How we collect data – number of data forms and adverse effects in oncology • Using the right technology • Understanding the importance of data • Looking at how to manage your data structure **Narayan Lebaka,** *Senior Director of clinical data management,* ***Inspirna (formerly known as Rgenix)***
11:30	**The Last Millimeter is Everything: Essential Guide for Home Visits** • Home visits have evolved since their inception in 2003 • Services possible in 2023 – an overview of what is possible today • Sourcing the right professionals for visits is essential to success **Ellen Weiss,** *Vice President, In-Home Solutions, Decentralized Clinical Trials,* ***PCM Trials***	**Advancements in AI: turning big data into actionable intel for optimal site identification** Despite advancing technologies, trials still struggle to meet patient enrolment goals. Slow enrollment directly impacts schedule and budget, with each day of delay carrying cripplingly high costs. Successful, timely patient recruitment is directly linked to effective site selection. Conversely, selecting the wrong site can negatively impact recruitment or result in total failure to enroll patients. Join us to learn how advancements in AI can help the pharma industry identify the best sites for their clinical trials through the harnessing of big data. Topics include: • Transitioning from data overload to data driven decision-making

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		• The role of Artificial Intelligence in optimizing site identification and selection • Expected and unexpected downstream benefits of an AI-enabled site selection strategy **Travis Caudill,** *Vice President Feasibility, Site Identification & Clinical Informatics* *Feasibility & Site Identification Integration Workstream Lead,* **ICON**
12:00	**Panel: Reversing the Conversation: What the clinical trial industry really wants from its service providers** *We've all had to sit through several pitches from vendor companies telling us what they can do for us, but now it's time to reverse the conversation! Hear from the trial industry as they discuss the services, they would like to see from their solution providers, including:* • What they like to see in an outsourced partner organization • What they would like a partner to know about them / how they work • What things do they need a partner to do and what they don't need! • What things can be best done in house? **Moderator: Rosalie Filling,** Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals** **Panellists:** **Kathleen Cohen,** *Head of Clinical Operations,* ***Marinus Pharma*** **Adam Kinsey,** *Associate Vice President, Global Clinical Trial Operations (GCTO), Head of GCTO North America,* ***Merck*** **Novotech**	**FIRESIDE CHAT** **Are We Committed to "Not Going Back"?** *The rapid introduction of new approaches to sustain clinical trials during the COVID-19 pandemic drove substantial early enthusiasm that there was "no going back"* *But with the convergence of the end of the pandemic along with a challenging economic environment, can we sustain this promise? How do we mitigate the risk of sliding backward and losing the positive changes introduced during the last two years?* • Discuss the factors bringing new challenges to the adoption of innovative approaches in clinical trials • Explore how some organizations may be "over the crest" in change and adoption while others may "slide back" • Consider strategies to sustain forward momentum and progress despite new organizational challenges **Craig Lipset,** *Advisor and Founder,* ***Clinical Innovation Partners*** **Hassan Kadhim,** *Senior Director, Head of Clinical Trial Business Capabilities,* ***Bristol Myers Squibb***
12:45	*Session Reserved for* ***Worldwide Clinical Trials***	*Session Reserved for* ***YPrime***
1:15	**Lunch and networking**	

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2:15	**Protecting our planet: Sustainable drug development**  • Understanding the environmental and social impacts of clinical trials • Collaborating with supplier ecosystems to drive sustainability goals • Sustainability by design: innovation and changing behaviours **Anthony Fuller,** *Global Head of Sourcing*, ***Mitsubishi Tanabe Pharma Development America***	**Leveraging study participants' Real-World Data to enable researchers to confirm the representativeness of the baseline;** *A patient enrols in a trial, is administered test drug, and has an outcome. Post-treatment results are compared to pre-treatment to claim a change from baseline. That is the classic method to establish a drug effect, whether it's a positive treatment outcome or an adverse effect. But, this absolute dependence on the single baseline measurement may be unsubstantiated.* • Looking at the reliability of baseline values • Leveraging real world data for that participant from their Electronic Medical Record **Terry Katz,** Sr Director, Biostatistics and Data Management Planning and Functional Excellence, **Daiichi Sankyo, Inc.**
2:45	***Session Reserved for Paraxel***	***Reserved for Session Sponsor*** **Running Up That Hill: Accelerate Cycle Times & Reach Patients Faster with elluminate** *Operational oversight within outsourced models has become increasingly complex for teams who are tasked with managing trials amid a rapidly changing landscape of partners, technologies, and global regulations. Data proliferation along with dwindling resources has made it a top priority for clinical development teams to look to technology to improve cycle times and the overall experiences of data managers, medical monitors, and clinical operations leaders.* *This presentation will highlight how the elluminate Clinical Data Cloud and Biometrics Services can reshape your data architecture by automating data flows to keep up with the pace of data evolution and speed time to insights.* *Learn how elluminate and eClinical's Biometrics Services deliver:* • Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety

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		• Improved study oversight with a holistic view of risk across all data sources • 50 out-of-the-box visualizations to support supports cross-study analysis for deeper insights with self-service access to clinical and operational analytics • Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles **Dawn Kaminski,** *Vice President, BD Operations,* ***eClinical Solutions***
3:15	**Encouraging public health literacy, patient education and engagement;** *informing and empowering patients and the public as partners in clinical research.* • Focusing on nurturing our established relationships, building new ones, and on identifying and developing new opportunities. • Discussing how to serve patient communities and clinical research stakeholders throughout the world with the highest quality educational and advocacy services ***Jill McNair, Chief Growth Officer, CISCRP***	**Exploration of AI training, accuracy, and the precision of outputs in the validation of clinical data** **Rakesh Maniar,** *Head of eClinical Technologies, Global Data Management & Standards,* ***Merck & Co***
3:45	**Afternoon refreshments and networking**	

4:15	**How CRO's can help sponsors be the sponsor of choice, a partnership with CRO's population of sites and conducting clinical trials** • Removing the bias for sites to engage with CROs in the same way as sponsors • The ability to leverage a CRO's global reach for clinical trial site footprint **Adam Barrows,** *Executive Director - Solid Tumour TA Head,* ***Bristol Myers Squibb***	***Featured New Technology Presentation:*** **Administration of Respiratory Therapeutics with a Device and Fixed Dose Drug Combination Using Portable Medical Vaporizers** • First usage of Portable Therapeutic Vaporizers as a new delivery modality for prescription drugs arising out of technologies originally developed as electronic nicotine delivery systems (ENDS) • Advantages in safety and efficacy of delivering respiratory drug regimens directly to sinus, throat and lung tissue in gas vapor form • Likely regulation of a new therapeutic delivery modality • Clinical trial challenges for therapeutic vape device and drug systems ***John Gregg,*** *Chairman and CEO at* ***BalinBac Therapeutics, Inc.***
4:45	***Session Reserved for TrialCard***	**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, Senior Vice President Strategic Relations,* ***Viedoc***

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5:15	PANEL: **Addressing the issues with Decentralised Clinical Trials and how we may work collaboratively to overcome them; *addressing the pitfalls & challenges*** *There are varied viewpoints on the success of DCT's, we are therefore using this panel as a platform to discuss issues raised within processes* • Are timelines actually increasing? *Taking into consideration site staff turnover and knowledge base* • It is said DCT's will enhance patient recruitment, is this the truth in practice? *Looking into patient's ability to par-take and keep to trial timelines considering factors beyond our control* • Site Perspective; their involvement with sponsors and the differences with their involvement of the trial **Moderator: Peter O'Neill,** *Senior Director, Clinical Operations,* ***Incyte*** **Panelists:** **Anka G. Ehrhardt**, *Director, Cell-Based Sciences, AR&D,* ***Merck*** **Dominique Duchesne,** *Former Director, Clinical Operations Lead,* ***Bristol Myers Squibb*** **Susan Maloney,** *Former Associate Vice President, Head Clinical Operations,* ***PhaseBio*** ***Keith Kennedy,*** *Principal and Team Lead, Patient Cloud,* ***Medidata*** **Candice Estes,** *Clinical Trial Manager, Clinical Operations,* ***Incyte***
5:45	**Chairperson's closing remarks followed by Drinks Reception**

END OF DAY 1 AND NETWORKING DRINKS

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DAY TWO – WEDNESDAY 24TH MAY 2023

8:15	**Registration and refreshments**	
	Outsourcing & Clinical Operations ***Chair:*** **Rosalie Filling,** Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals**	**Clinical Innovation & Technology** ***Chair:*** **Peter O'Neill,** *Sr. Director, Clinical Operations,* ***Incyte***
08:45	**What does it really take to achieve global IDEA in clinical trials?** • Inclusion, Diversity, Equity, and Access • Major barriers to achieving IDEA for sponsors and investigator teams • Recent regulatory guidelines • Strategies for achieving IDEA in clinical trials **Dr. Harsha Karur Rajasimha,** *President,* ***IndoUSRare***	**Digital and telehealth; remote monitoring in clinical trials** • Integrating apps and wearables into your clinical study: what additional benefits can this bring? • Combining remote monitoring with risk-based monitoring to deliver a successful decentralised trial • How consumer-wearables can provide enhanced access to clinical trials • Compiling data from wearables to contribute toward clinical trials • Overcoming common issues around using data collected remotely **Jen Horonjeff,** CEO, **Savvy Cooperative**
09:15	***Session Reserved for Clario***	***Session Reserved for Saama Technologies***
09:45	**Interactive Session** **The Elephant in the room – what is holding you back from developing key relationships when managing your trials? Are you in your own way?** How do you relate and interact with: • Your Study Team • Your Vendors • Your Manager • Yourself	**Blockchain – Exploring the Implications for the Future In this session Frank Leu, CEO at BioPharMatrix explores where he sees Blockchain going in the future, its implications and whether we should all be investing in it.** • What is blockchain? • How can it be adapted in the Clinical Trial? • Why do we need to reach a consensus platform as soon as possible? Who gets to decide this, will it be FDA or the Pharma industry? • What would be its cost impact on drug development?

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	• Are you willing to face others' perceptions of you? This will be a brief presentation followed by an Open discussion on some barriers to communication that Clinical Operations professional experience. **Jenny Wakefield,** *Senior Director- Quality Development Operations,* ***Incyte***	• Why does the C-suite need to engage in blockchain use immediately? **Frank Leu,** CEO, **BioPharMatrix**
10:30	**Morning refreshments and networking**	
	OUTSOURCING & CLINICAL OPERATIONS	**CLINICAL INNOVATION & TECHNOLOGY**
	Chair: **Rosalie Filling,** Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals**	*Chair:* **William Newton,** Senior Healthcare Reporter, **GlobalData Healthcare**
11:00	**Population Health & Diversity in Clinical Trials** • Highlighting the importance of inclusion • Focusing on the opportunities within Decentralised Clinical Trials to encourage enhanced enrolment of minority and diverse populations into research • Understanding why we struggle to recruit a varied patient population; how improving our recruitment can improve our study results • Looking into the best step forward **Ram Raju,** *Senior Vice President and Community Health Investment Officer,* ***Northwell Health***	**Leveraging global trial footprint to accelerate clinical development** *Clinical trial conduct is facing multiple challenges from budget pressure, patient recruitment difficulties, to regulatory uncertainties. At the beginning of each development program, companies need to plan for global trial capabilities by utilizing multiple geographic locations for clinical trials to accelerate the development process. This approach allows for larger and more diverse patient populations to be enrolled, leading to faster completion of trials and ultimately getting treatments to market faster. A global trial footprint also enables the collection of data in different regions and across different populations, providing valuable insights into* the *efficacy and safety of treatments. By leveraging a global trial footprint, biotech and pharmaceutical companies can overcome barriers to clinical development and bring life-saving treatments to patients more quickly.* **Dr. YuFeng Li,** *Executive Director, Clinical Development* ***Qilu Pharmaceuticals***
11:30	***Session Reserved for WCG***	**Leveraging predictive analytics to improve patient retention, data quality, and enrollment outcomes in clinical trials** *Clinical trial data complexity has tripled in the past decade, leading to fragmented data, insights, and stakeholder collaboration. These data complexities pose significant inefficiencies in the research and drug development process and are exacerbated as clinical operations teams become leaner and cost-constrained.*

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		In this presentation, you will gain insight to real world case studies that use Lokavant to radically improve clinical trial outcomes, as well as overall successes for leaner study teams. **Rohit Nambisan,** *CEO & Co-Founder,* **Lokavant**
12:00	**PANEL DISCUSSION** **What are the different outsourcing relationships and how do you manage them?** • What are the categories and the driving needs for 2023? • How has this changed over the years? • Key strategies that sponsor companies have – how has this changed? • Did the pandemic effect these strategies? **Moderator: Rosalie Filling,** Vice President, Clinical Operations & Biometrics, **Endo Pharmaceuticals** **Panelists:** **Kevin Shipe, Director,** *Head of Strategic Sourcing and Study Start-up,* ***INOVIO Pharmaceuticals*** **Adam Barrows,** *Executive Director - Solid Tumour TA Head,* ***Bristol Myers Squibb*** **Sherin Abdel-Meguid,** *President,* ***Shifa Biomedical Corporation***	**PANEL DISCUSSION** **Focusing on today's Innovation & Technological Advancements** • Are we making the most of Technology & Innovation in the Clinical Trial space? • How are these tools being utilised? • What's next? **Moderator: William Newton,** *Senior Healthcare Reporter,* ***GlobalData Healthcare*** **Panelists:** **Peter O'Neill,** Sr. Director, Clinical Operations, **Incyte** **Frank Leu,** CEO, **BioPharMatrix** **Rakesh Maniar,** *Head of eClinical Technologies, Global Data Management & Standards,* ***Merck & Co***
12:45	**Lunch and Networking**	
1:45	**Collaborating across Functions to Improve the Forecasting, Budgeting, and Accruals Process** *This fireside chat will focus on the accrual/forecasting process for Clinical trial budgets. Specifically, the processes for working with vendors to obtain current accruals and forecasts. We will also discuss coordination with the internal functions at the Sponsor to ascertain the most accurate and current timelines, enrollment rates, screen failure and drop out rates. Aligning all expectations with both the operations teams as well as Finance and Senior Management.* **Carrie Lewis,** Executive Director, Clinical Program Optimization, ***Endo Pharmaceuticals*** **Rick O'Hara,** Director of R&D Business Operations, ***Endo Pharmaceuticals***	
2:15	**PANEL** **Diversity & Inclusion in Clinical Trials** • Increasing diversity in clinical trials; overcoming critical barriers	

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	• Focusing on the application of diverse populations • Action for increasing diversity • Regulatory Updates Moderator: **Linda Blount**, President, **Rare Disease Diversity Coalition** Panelists: **Jenifer Waldrop**, Executive Director, **Rare Disease Diversity Coalition** **Dr. Harsha Karur Rajasimha,** *President,* ***IndoUSRare*** **Jen Horonjeff,** CEO, **Savvy Cooperative** **Ram Raju**, Senior Vice President and Community Health Investment Officer, **Northwell Health**
3:00	**Afternoon refreshments and Apple prize draw**
3:30	**ROUNDTABLE SESSIONS** *During the roundtable discussion session, the conference hall will be divided into zones. Delegates can choose which zone they would like to join. Each zone will be led by a table moderator and will focus on a different challenge within the industry. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	Roundtable 1 **Strategies for Country and Site Selection** **Kelly Ragins,** *Global Head of Portfolio Delivery Office,* ***Novartis***
	Roundtable 2 **Implementing effective vendor management tools and communication strategies to avoid the failure of clinical trials** **Kathleen Cohen,** *Head of Clinical Operations,* ***Marinus Pharma***
	Roundtable 3 **Top Tips in Effective Budget Management, Forecasting and Contracting: Ensuring Your Resources Are Allocated Correctly** **Kevin Shipe, Director,** *Head of Strategic Sourcing and Study Start-up,* ***INOVIO Pharmaceuticals***
	Roundtable 4 **Decentralised Clinical Trials; a discussion on transforming clinical trial development** **Candice Estes,** *Clinical Trial Manager, Clinical Operations,* ***Incyte***
	Roundtable 5 ***Session Reserved for Event Sponsor***

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4:30	Chairman's closing remarks

END OF DAY TWO

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