Clinical Trial Supply New England

The Westin Waltham Boston

April 5th – 6th, 2023
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'Optimizing supply strategies to streamline operations and create an efficient, cost-effective clinical trial process'

2023 will gather the key stakeholders in the clinical trials community, including the New England Institute for Clinical Research, U.S. Customs and Border Protection, Takeda, Sanofi, Moderna and many more. With interactive session formats, fresh content and networking, the event will provide attendees with an unparalleled opportunity for collaboration between players across the whole industry.

2023 Speakers

- **Amanda Murphy,** Director of Product Management, **GlobalData**
- **Giovanni Abbaessa,** VP, Head, Oncology Early Development, **Sanofi**
- **Hyun Kim,** Vice President, Clinical Development, **AOBiome Therapeutics**
- **Angelo Termine,** CEO and Director, **New England Institute for Clinical Research**
- **Kaitlin Bova,** Manager, Research Quality and Development, **Moderna**
- **James Sherley,** President and CEO, **Asymmetrex® LLC**
- **Susan Marlin,** President and CEO, **Clinical Trials Ontario**
- **Tomasz Adamusiak,** Chief Scientist, Clinical Insights and Innovation Cell, **Mitre**
- **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda**
- **Fred Moreau,** Director of Central Ancillary Supplies, **Takeda**
- **Tyler Wilson**, Global Clinical Supply Chain Fellow**, Takeda**
- **John Gregg,** Chairman and CEO, **BalinBac Therapeutics inc.**
- **David Adams,** Associate Director, Global Clinical Supply Chain, **Takeda**
- **Sean Smith,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**
- **Isaac Rodrigues-Chavez,** Former Senior VP-Scientific and Clinical Affairs and FDA officer, **independent consultant**
- **David Sokoloff,** Sr. Director Global Logistics and Materials Management, **Novavax**
- **Frank Leu,** CEO, **Novapeutics**
- **Eric Elbel,** Senior Manager, Supply Chain Logistics, **AVROBIO**
- **James Krupa**, Director, Clinical Supply Team Lead, Operations, **Takeda**
- **Matthew L. Plaud,** President and COO**, Sotio Biotech inc.**
- **Bharti Kansara,** Associate Director, Global Clinical Supply Chain,**Takeda**
- **Melissa Morandi,** Vice President, Head of Global Quality, **Sumitomo Pharma Oncology**

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DAY ONE – WEDNESDAY, APRIL 5TH, 2023

8:15	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Amanda Murphy,** Director of Product Management, **GlobalData**
9:00	**OPENING KEYNOTE: Ensuring that quality patients are enrolled and retained using AI to help generate quality data and reduce wastage of time sensitive products** • Mitigating huge financial loss as an incentive to using AI in the initial stages of clinical trial, finding eligible participants via simplification of data entry criteria, analysis of hospital records and social media, direct communications with clinicians and patients • Improving patient experience through AI by facilitating access to information and contact points whilst reducing dropout rate via identification of non-compliance or prediction of adverse events • Addressing issues with data management and inherent bias in datasets when implementing AI to help streamline cohort selection resulting in increased trial efficacy potential **Angelo Termine,** CEO, **New England Institute for Clinical Trials**
9:30	**Reserved for N-side ,**
10:00	**Using Real World Data and Evidence to Accelerate Clinical Trials** • Augmenting clinical trials with observational data gathered via hybrid trials, pragmatic trials, routine clinical practice and late phase trials to accelerate clinical validation and get new drugs to patients quicker • Deriving real world data from a range of sources including: electronic health records, product and disease registries, wearable devices, genomic data sets, medical claims registries and social determinants of health • Expanding patient population assessed beyond the formal clinical trial to ensure demographics or geographics are not overlooked when assessing efficacy of a trial drug **Thomasz Adamusiak,** Chief Scientist, Clinical Insights and Innovation Cell, **Mitre**
10:30	**Morning refreshments and networking**

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11:00	**PANEL DISCUSSION: Looking at ethical and practical benefits of direct-to-patient models in clinical trials and the resulting challenges and expectations of the supply chain** • Patient centricity: advances in technology enabling seamless data capture and reinforcing logistics networks to orchestrate decentralized supply chains • DTP and real-world evidence: providing invaluable patient feedback and real-life contextual understanding of treatment efficacy leading to improved care and deeper understanding of patients on an individual, case-by-case level • Protecting patient confidentiality in direct to patient trials: adhering to data protection regulations by implementing strategies such as AI and smart packaging to avoid delays and improve patient retention **Moderator: John Gregg**, CEO, **BalinBac Therapeutics** **Isaac Rodrigues-Chavez**, Former Senior VP-Scientific and Clinical Affairs and FDA officer **Melissa Morandi,** Vice President, Head of Global Quality, **Sumitomo Pharma Oncology**
11:45	**Reserved for Event Sponsor**
12:15	**An emerging clinical trials supply industry for therapeutic tissue stem cells** • Exploring how trials cell and gene therapy will bring about new innovations and solutions that will ripple into other clinical supply chains, translating into huge advances • Overcoming operational complexity issues and increasing possibility with the help of lower barriers to market, technological developments and analysis of real-world data • Addressing issues surrounding the shortage of manufacturing capacity and talent, logistical issues, data protection and a fragmented market landscape **James Sherley**, CEO, **Asymmetrex®LLC**
12:45	**Lunch and networking**
2:00	**GlobalData research** • Gaining insight and understanding into themes that are shaping biopharmaceutical industry, both today and into the future • Hearing about key emerging technologies and disrupters • Reviewing industry, regulatory and macro-economic factors affecting pharma in 2023 **Amanda Murphy**, Director of Product Management, **GlobalData**
2:30	**Reserved for Trial Card**

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3:00	**Strategies for growing a pipeline, accelerating decision making, set up the organization, in order to improve drug development** • Strategic design of pipeline growth • Methods to accelerate decision-making in Ph1-2 trials • Team culture by organizational design **Giovanni Abbaessa,** VP- Head of Oncology Early Development**, Sanofi**
3:30	**Afternoon refreshments and networking**
4:00	**The Improving Clinical Trials Environment in Canada** • Harnessing many unique assets that span demographic diversity, to academic leadership, clinical expertise, government commitment and public-private collaboration, sustaining Canada's role as a medical research and health innovation hub. • Raising numerous interesting and difficult policy questions related to how Canadian and US pharma companies must collaborate and ready the system to address the "extraordinary" needs of rare patients including novel clinical innovation strategies, new regulatory and funding mechanisms, infrastructure accommodation and knowledge sharing across boundaries and through centres of excellence. • Focusing on the future of clinical innovation as a means to cultivate supportive conditions for improved care for rare patients in Canada. Using scientific knowledge to improve patient impact and system receptivity. **Susan Marlin,** CEO, **Clinical Trials Ontario**
4:30	**Navigating Ancillary Management Challenges through Collaboration and Centralized Teams** • Discussing important considerations for ensuring compatibility of your IMP with common infusion materials. • Discussing the importance of strong relationships with CMC, Clinical, and CROs in assessing product compatibility. • Developing a plan for ancillary supply needs. • Sharing tips for establishing a centralized ancillary supply team in your organization to better serve the needs of studies. **Paul Larochelle,** Director, Global Clinical Supply Chain, **Takeda** **Tyler Wilson,** Global Clinical Supply Chain Fellow**, Takeda** **Fred Moreau,** Director of Central Ancillary Supplies**, Takeda**
5:00	**Chairperson's closing remarks** **Amanda Murphy**, Director of Product Management, **GlobalData**

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END OF DAY 1 AND NETWORKING DRINKS	

DAY TWO – THURSDAY, APRIL 6TH 2023

8:15	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Amanda Murphy,** Director of Product Management, **GlobalData**
9:00 	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** During the roundtable discussion session, the conference hall will be divided into four 'zone which zone they would like to join. Each zone will be led by a table moderator and will foc within clinical supply chains. After 45 minutes, delegates will have the opportunity to swap and each roundtable will run twice.
	ROUNDTABLE 1: Q&A Session with U.S. Customs and Border Protection – Here to help with a about how to import or export biological materials to or from the U.S. **Sean Smith,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**
	ROUNDTABLE 2: IRTs and just-in-time packaging, labelling, and shipment strategies for effici **Hyun Kim,** Vice President, Clinical Development, **AOBiome Therapeutics**
	ROUNDTABLE 3: Effectively strategizing cold chain logistics operations **David Sokoloff,** Sr. Director Global Logistics and Materials Management, **Novavax**

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	ROUNDTABLE 4: Innovation in integrating supply models, decentralized clinical trials and tec **Isaac Rodrigues-Chavez,** Former Senior VP-Scientific and Clinical Affairs and FDA officer, **indep**
	ROUNDTABLE 5: Best Practice for Best practice for Comparator Labelling **David Adams,** Associate Director, Global Clinical Supply Chain , **Takeda** **Bharti Kansara,** Associate Director, Global Clinical Supply Chain,**Takeda**
10:30	**Morning refreshments and networking**
11:00	**Lessons learnt: Strategy for Generation of Stability Data to Demonstrate and Justify Longest** • Maximize expiration period of IMPs • Understand the meaning of the stability data generated as well as what is not reported • Maximize storage conditions (e.g., flexibility of storage at 30°C as opposed to 25°C) • Understand what data must be generated to support Temperature Excursions of IMPs • Leverage the ICH Guidelines – Topic 'Q' for Quality **James Krupa**, Director, Clinical Supply Team Lead, Operations, **Takeda**
11:30	**KEYNOTE** **Q&A Discussion: Explore importing and exporting requirements for biological materials and in the modern world** • Important steps to take to help expedite the clearance of biological materials. • Case studies of inspections: when it really goes wrong and how to tackle it • Discover resources and contacts available to help facilitate your imports, especially tim dependent shipments, at U.S. ports of entry • Highlighting the key takeaways for ensuring a smooth inspection as we look to the futur **Sean Smith,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**

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12:00	**Lunch and networking**
1:15	**PANEL DISCUSSION:** **Maintaining optimal performance conditions of temperature sensitive products whilst ensur regulations to ensure success of trials and ultimately their commercialization** • Addressing issues regarding transporting and storing vaccines, biospecimens and tempera avoid compliance issues and wastage whilst ensuring product integrity and ultimately, con trial success. • Exploring the potential benefits to supply quality of real-time data monitoring and alerts to corrective response, while automatically documenting supply chain temperature data for • Implementing holistic supply chain management in supply chain risk reduction. Enabling re facilitating cooperation between technology, logistics and manufacturing **Moderator: Amanda Murphy,** Director of Product Management, **GlobalData** **David Sokoloff,** Sr. Director Global Logistics and Materials Management, **Novavax** **Eric Elbel,** Senior Manager, Supply Chain Logistics, **AVROBIO** **Matthew L. Plaud,** President and COO, **Sotio Biotech inc.**
1:45	**Building a strong foundation for proactive quality improvement** • Understanding basics of issue management & root cause analysis • Trending issue management data to identify key areas for improvement • Planning effective process improvement **Kaitlin Bova,** Manager- Research Quality and Development, **Moderna**
2:15	Future Technologies that could Power Drug Development **Frank Leu,** CEO, **Novapeutics**

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2:45	**Management of the Cold Chain and Best Practices in the Shipping Process** •Answering the question on how end users and solution providers can improve their mana implement newer practices for them cold chain operations • Detailing what are best practices in the supply chain • How to effectively manage cold chain operations • Discuss and elaborate on proper shipping management and regulations for products **Eric Elbel, Senior Manager, Supply Chain Logistics, AVROBIO**
3:15	**Chairperson's closing remarks** **Amanda Murphy,** Director of Product Management, **GlobalData**
END OF CONFERENCE	**Chairperson's closing remarks** **Amanda Murphy,** Director of Product Management, **GlobalData**

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