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 Abbadessa,** VP, Head, Oncology Early Development, **Sanofi**
- **Hyun Kim,** Vice President, Clinical Development, **AOBiome Therapeutics**
- **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**
- **Baljeet Kaur, U.S. Customs and Border Protection**
- **Isaac Rodriguez-Chavez,** Former Senior VP-Scientific and Clinical Affairs and former FDA officer, **Independent Consultant**
- **Eric Elbel,** Senior Manager, Supply Chain Logistics, **AVROBIO**
- **James Krupa**, Director, Clinical Supply Team Lead, Operations, **Takeda**
- **Matthew L. Plaud,** Former 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**
- **Henk Dieteren,** Clinical Supply Chain Solutions Consultant**, Suvoda**
- **Antoine Remiot,** Director Solutions Engineering**, Clinical Supply Optimization, N-SIDE**
- **Maxime Derep**, Clinical Supply Optimization Senior Solutions Engineer , **N-SIDE**

Join our new CTS community on LinkedIn
#CTSNewEngland | @ArenaIntPharma

- **Henk Dieteren,** Clinical Supply Chain Consultant, **Suvoda**
- **Tom Gottschalk,** Vice President, Clinical Business Development**, TrialCard™**

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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: State of the Biopharmaceutical Industry** • 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**
9:30	**Managing stockout risk without impacting patients and recruitment** - How to identify, locate and quantify risks - To identify the main causes of risk in your clinical supply chain - Innovative ideas to solve risks without slowing down recruitment - How proactivity and collaboration in the clinical supply environment can alleviate stressful mid-trial situations. **Henk Dieteren,** Clinical Supply Chain Solutions Consultant, **Suvoda** **Antoine Remiot,** Director Solutions Engineering, Clinical Supply Optimization**, N-SIDE** **Maxime Derep,** Clinical Supply Optimization Senior Solutions Engineer **, 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 Rodriguez-Chavez**, Former Senior VP-Scientific and Clinical Affairs and former FDA officer **Melissa Morandi,** Vice President, Head of Global Quality, **Sumitomo Pharma Oncology**
11:45	**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**
12:15	**Lunch and networking**
2:00	**Case study in clinical supply chain innovation by TrialCard** Tom Gottschalk will be joining us to share insights into cutting edge innovation for clinical supply chains and an update on TrialCard's latest technological developments **Tom Gottschalk,** Vice President – Clinical Business Development, **TrialCard™**
2:30	**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

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	Giovanni Abbadessa, VP- Head of Oncology Early Development**, Sanofi**
3:00	**Afternoon refreshments and networking**
3:30	**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**
4:00	**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**
4:30	**Chairperson's closing remarks** **Amanda Murphy**, Director of Product Management, **GlobalData**
END OF DAY 1 AND NETWORKING DRINKS	

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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 '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 clinical supply chains. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.
	ROUND TABLE 1: Q&A Session with U.S. Customs and Border Protection – Here to help with any questions you may have 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** **Baljeet Kaur, U.S. Customs and Border Protection**
	ROUND TABLE 2: IRTs and just-in-time packaging, labelling, and shipment strategies for efficient CTS life cycle **Hyun Kim,** Vice President, Clinical Development, **AOBiome Therapeutics**
	ROUND TABLE 3: Innovation in integrating supply models, decentralized clinical trials and technology **Isaac Rodriguez-Chavez,** Former Senior VP-Scientific and Clinical Affairs and Former FDA officer
	ROUND TABLE 4: Best Practice for Comparator Labelling **David Adams,** Associate Director-Global Clinical Supply Chain, **Takeda** **Bharti Kansara,** Associate Director -Global Clinical Supply**, Takeda**
	ROUND TABLE 5: Best practices for clinical supply planning: brainstorming and sharing experiences **Antoine Remiot,** Director Solutions Engineering, Clinical Supply Optimization**, N-SIDE** **Maxime Derep,** Clinical Supply Optimization Senior Solutions Engineer **, N-SIDE**
10:30	**Morning refreshments and networking**

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11:00	**Lessons learnt: Strategy for Generation of Stability Data to Demonstrate and Justify Longest Expiration Period of IMPs** • Maximize expiration period of IMPs • Understand the meaning of the stability data generated as well as what is not reported or discussed • 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 how preparation is everything 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 time- sensitive/temperature dependent shipments, at U.S. ports of entry • Highlighting the key takeaways for ensuring a smooth inspection as we look to the future **Sean Smith, Biological Threat Exclusion Coordinator, U.S. Customs and Border Protection** **Baljeet Kaur, U.S. Customs and Border Protection**
12:00	**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 management techniques and 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**
12:30	**Lunch and networking**
2:30	**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

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	• Planning effective process improvement **Kaitlin Bova,** Manager- Research Quality and Development, **Moderna**
END OF CONFERENCE	**Chairperson's closing remarks** **Amanda Murphy,** Director of Product Management, **GlobalData**

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