Clinical Trial Supply West Coast

Hyatt Regency San Francisco Airport, Burlingame, CA, USA

9th-10th May 2023
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'Developing best practices and incorporating novel technologies to meet the demands of a more complex, international clinical trial supply chain'

Clinical Trial Supply West Coast is a strategic event targeted at those who have clinical, technological and regulatory responsibility for the supply of clinical trials. The key outcome of this meeting will be to leverage supply chain delivery to overcome current operational challenges in clinical trials.

Year on year this conference brings together the leading thought leaders from both big and small pharma/biotech to debate discuss and learn best practice from one another in an intimate and relaxed setting. Learning and networking are key outcomes of this meeting.

2023 Speakers

- **Dan Solis,** Assistant Commissioner for Import Operations, **U.S. Food and Drug Administration**
- **Brandy Porter**, Assistant Center Director, Enforcement Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise, **U.S. Customs & Border Protection**
- **Gina Reneau**, Biological Threat Exclusion Coordinator, **U.S. Customs & Border Protection**
- **Matt Burns,** Director Global Trade Compliance, **Gilead Sciences Inc**
- **Anwar Mahmood,** Director Clinical Technology Solutions, **EXELIXIS**
- **Aviral Srivastava,** Senior Director Digital Transformation, **EXELIXIS**
- **Yuyi Shen,** VP Technical Operations, **Abcuro**
- **Umar Hayat,** VP, CMC and Supply Chain, **Union Therapeutics**
- **Jasmina Jankicevic,** VP Clinical Development, **RAPT Therapeutics**
- **Jennifer Banh,** Senior Manager Clinical Supply Chain, **Formerly of GBT / Pfizer**
- **Margaret Pese,** Associate Director Clinical Supply Chain, **Olema Oncology**
- **David Larwood,** CEO, **Valley Fever Solutions**
- **Ying Cai,** Director Supply Chain, **Ashvattha Therapeutics, Inc**
- **Brandon Newell,** Executive Director Quality Assurance, **Structure Therapeutics**
- **Christopher Ohms,** Executive Director Supply Chain**, Rigel Pharmaceuticals**
- **John McGinley,** Senior Director Quality Assurance, **Pfizer**
- **Kevin Liao,** Associate Director Supply Chain, **Caribou Biosciences**
- **Brittney Elko,** Director Technical Operations & Supply Chain, **Aligos Therapeutics**
- **Anu Arora,** Senior Manager Clinical Supply Chain, **Agios Pharmaceuticals**
- **Bonnie Bain,** Global Head of Pharma and Executive VP of Healthcare Operations and Strategy, **GlobalData**
- **Isaac Blum,** Senior Clinical Supply Manager**, ALX Oncology**
- **Marc Trombella,** Associate Director Clinical Supply Chain Planning, **BioMarin Pharmaceuticals**
- **Thomas Tredennick,** Associate Director Supply Chain, **ArsenalBio**
- **Ronald Schaefer,** Consulting Head of Certification Programs (CEIV Pharma), **IATA**
- **Chidi Umeh,** Director of Quality, **Telios Pharma**
- **Prasun Mishra,** CEO, **Agility Pharma**
- **Jenifer Shahan McIntosh,** Attorney, **Ferguson Braswell Fraser Kubasta PC**

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#CTSWestCoast | @ArenaIntPharma

- **Paul Wartenberg,** Vice President/vCIO, **Meriplex**
- **Chris Driver,** Director IT Architecture, **IQVIA**
- **Edo Madussi,** Managing Director, **EuromedPharma**
- **Tom Gottschalk,** Vice President Business Development, **TrialCard**
- **Melanie Manrique**, Associate Director, Quality Management, **Endpoint Clinical**
- **Jennifer Fenwick**, Senior Manager Personalized Supply Chain, **World Courier**
- **Tracy Robinson,** RTSM Solution Specialist, **Medidata**

DAY ONE – TUESDAY, 9TH MAY 2023

07:45	**Registration and refreshments**
08:25	**Chair's opening remarks** **David Larwood,** CEO, **Valley Fever Solutions**
08:30	**FDA's role in maintaining a secure and resilient supply chain** • Supply chain resiliency • Lessons learned • Government to Government interactions • FDA inspections and pre-arrival data • Role of CBP, FDA, and PGAs • 21 CCF • ACE 2.0 • Communication with import divisions • Resources **Dan Solis,** Assistant Commissioner for Import Operations, **U.S. Food and Drug Administration**

09:00	**Clinical trial logistics: Evolving supply models and new therapies highlight emerging trends**
	
	• Decentralized trial logistics
	  ○ The role of DTP in maximizing benefits of DCT
	  ○ Overcoming DTP complexities
	• Emergence of Cell and Gene Therapies
	  ○ Unique logistics considerations for CGTs
	  ○ Ensuring quality through technology solutions
	
	Jennifer Fenwick, Senior Manager Personalized Supply Chain, **World Courier**

09:30	**Tackling global trade compliance in clinical supply chain to meet regulations and avoid unnecessary delays** • Valuation of clinical items moving through borders • HTS codes for blinded clinical shipments versus clinical supplies moving to distribution sites • Overall best practices to approach your clinical studies from a customs perspective • VAT expenses: how they apply, when and how they can be recovered • Sanctions and exemptions in the pharmaceutical industry **Matt Burns,** Director Global Trade Compliance, **Gilead Sciences Inc**

10:00	**Innovative processes to better address today's trial dynamics**
	• Supply chain efficiency
	  ○ Why do extra work and spend more money than necessary?
	• Payment process efficiency
	  ○ Leverage an existing workflow process that sites use everyday
	• Understanding the total value a vendor can provide

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	○ Select a vendor that can demonstrate its total value (and make you look good in the eyes of your company) **Tom Gottschalk,** Vice President Business Development, **TrialCard**	
10:30	**Morning refreshments and networking**	
	Clinical Trial Supply Operations **Chair: David Larwood,** CEO, **Valley Fever Solutions**	**Clinical Trial Supply Innovation & Technology** **Chair: Bonnie Bain,** Global Head of Pharma and Executive VP of Healthcare Operations and Strategy**, GlobalData**
11:15	**Fireside Chat: Forecasting effectively for clinical trials to save time and pre-plan efficiently for a small or start-up company** • Creating a strategy for small and start-up companies to effectively forecast • Highlighting affordable forecasting alternatives for small companies to reduce time spent on manual processes • Considering pros and cons of using of IRT within small companies **Moderator: David Larwood,** CEO, **Valley Fever Solutions** **Margaret Pese,** Associate Director Clinical Supply Chain, **Olema Oncology**	**What can we do to take advantage of high prevalence of disease in populous countries where systems are either rudimentary or non-existent?** • Key drivers for trial enrolment and in time completion • Population and high prevalence of disease in developing countries • Barriers and hurdles to access vast pool of patients • Strategies and solutions to penetrate through barriers and pass hurdles **Umar Hayat,** VP, CMC and Supply Chain, **Union Therapeutics**
11:45	**Negentropy in clinical trial supplies "systems"** • Entropy cases - what's not getting better • Negentropy cases - when we allow new objects in a closed system see what happens • Enough with physics - what about biochemistry and biology? The latest trends in comparator sourcing **Edo Madussi,** Managing Director, **EuromedPharma**	**Reducing the impact of emerging macroeconomic pressure on trial supply** • Clinical trial supply management in IRT – the past, present and future ○ Why optimizing your trial supply is more critical than ever • Automating the optimization of clinical trial supply ○ How sponsors are saving every day, with no additional effort • Reducing the risk in clinical supply chain ○ How to achieve even more automation and savings **Chris Driver,** Director IT Architecture, **IQVIA**
12:15	**Contractual obligations for privacy in clinical trials: three pillars to understanding new privacy requirements** • What is a DPA or the SCCs? • Standard requirements found in DPAs or SCCs ○ SCC based security measures and how to get there ○ GDPR based operational practices and how to get there	**Utilizing IRT and understanding its essential role in decentralized clinical trials to simplify supply planning and management** • Identifying key characteristics of IRT required for DCT or hybrid trials • Handling dispensing protocols, calculating dosage, predicting demand and inventory management • Strategies to planning for various doses, formulations, and titrating doses

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	• Why privacy laws matter beyond participant data **Jenifer Shahan McIntosh,** Attorney, **Ferguson Braswell Fraser Kubasta PC** **Paul Wartenberg,** Vice President/vCIO, **Meriplex**	• Controlling dispensing logistics to track transit and monitor temperatures • Managing documentation including returns, reconciliation and accountability for drug • Strategies for direct-to-patients shipment **Jennifer Banh,** Senior Manager Clinical Supply Chain, **Formerly of GBT / Pfizer**
12:45	**Lunch and networking**	
14:00	**Modifying standard supply chain requirements and processes to incorporate cell and gene therapy clinical trials** • Transferring clinical supply chain from traditional pharma to cell therapy pharma • Understanding the requirements and importance of chain of identity and chain of custody within cell and gene therapy trials • Challenges and considerations for cell therapy cold chain logistics • Identifying technology and tracking systems to assist with cell and gene therapy supply chain tracking and monitoring **Kevin Liao,** Associate Director Supply Chain, **Caribou Biosciences**	**Leveraging RPA (Robotic Process Automation) to automate clinical supply activities** • RPA overview • Case study: proactively monitoring low site inventory using RPA - Problem Statement - How to leverage RPA tools to address issue - Reviewing a solution • Exploring other use cases • Lessons Learned **Anwar Mahmood,** Director Clinical Technology Solutions, **EXELIXIS** **Aviral Srivastava,** Senior Director, Digital Transformation, **EXELIXIS**
14:30	**DTP, DFP Considerations for Successful Execution of Decentralized Trials** A speaker from Yourway will be sharing case study insights into clinical trial and supply chain logistics to help your trial run smoothly **Senior Representative, Yourway**	**Optimize your trial execution with the strategic use of an experienced IRT/RTSM technology solutions team** • study design recommendations • blinding concerns • mid-study changes • supply management **Tracy Robinson,** RTSM Solution Specialist, **Medidata**
15:00	**Panel Discussion: Highlighting how clinical supplies and quality assurance teams can collaborate to ensure trials are compliant, reducing timely and costly delays** • Aligning early phase vs late phase quality assurance considerations with supply chain protocols to minimize disruptions and backlogs in supply chain • Understanding importance of role and responsibility of a Qualified Person and timelines required for QP release • Establishing challenges and differences between UK and EU site perspectives since changes to Brexit regulations	**Panel Discussion: Overcoming recent challenges, uncovering latest trends and driving innovation in clinical trials** • Future supply chain considerations since the impact of challenges provoked by regulatory changes, Covid-19, Brexit and the Russia-Ukraine conflict • Current opportunities to enhance supply chain and processes through data driven technologies • New and emerging technologies and concepts for future development **Moderator: Bonnie Bain,** Global Head of Pharma and Executive VP of Healthcare Operations and Strategy, **GlobalData**

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	• Uncovering common QA compliance oversights and how to avoid them • Improving communication channels between clinical supplies and QA teams **Moderator: David Larwood,** CEO, **Valley Fever Solutions** **Panelists:** **Brittney Elko,** Director Technical Operations & Supply Chain, **Aligos Therapeutics** **Isaac Blum,** Senior Clinical Supply Manager**, ALX Oncology** **Chidi Umeh,** Director of Quality, **Telios Pharma**	**Panelists:** **Christopher Ohms,** Executive Director Supply Chain**, Rigel Pharmaceuticals** **Jennifer Fenwick**, Senior Manager Personalized Supply Chain, **World Courier** **Prasun Mishra,** CEO, **Agility Pharma**
15:45	**Afternoon refreshments and networking**	
16:15	**Evaluating and increasing use of decentralized and hybrid trials, reviewing the impact on supply chain whilst meeting patient centric demand** • Implementing an effective DCT strategy defining which aspects can be carried out remotely and evaluating the best patient centric approach • Determining factors to outsource or run trials independently, assessing technology and tools to select appropriate vendors • Adapting trials to include more shipments, tracking multiple site delivery to overcome delays and wastage • Considering legal and regulatory challenges of decentralized trials to ensure safe, compliant, and successful trials • Analyzing the pros and cons of DCTs, lessons learned and if this remains the way forward post pandemic **David Larwood,** CEO, **Valley Fever Solutions**	**CMO governance to support clinical supply for a virtual company** • Regulations impacting a virtual company • Quality agreements • Vendor management • Change control • Deviations • Audits **John McGinley,** Senior Director Quality Assurance, **Pfizer**
16:45	**Panel Discussion: Disaster and disruption planning to prepare clinical trial industry for the unexpected and ensure contingency plans are in place** • Discussing contingency planning to factor into your early-stage trial planning to consider any form of unforeseen future disruption, learning from Brexit, Covid-19 and Russia-Ukraine conflict • Creating communication plans to enable a fast response to disruption • How to talk to clinical teams to prepare shipments and have more visibility on shipment strategies and options in face of disruption • Ensuring minimum impact to patients during disruption to support the ongoing clinical trial and supply **Moderator:** Bonnie Bain, Global Head of Pharma and Executive VP of Healthcare Operations and Strategy, **GlobalData**	

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Burlingame, CA, USA 9th-10th May 2023

	Panelists: **Yuyi Shen,** VP Technical Operations, **Abcuro** **Brandon Newell,** Executive Director Quality Assurance, **Structure Therapeutics**
17:15	**Chair's summary and close of day 1**
17:30	**Drinks reception**

DAY TWO – WEDNESDAY 10TH MAY 2023

08:15	**Registration and refreshments**
08:50	**Chair's opening remarks** **Bonnie Bain,** Global Head of Pharma and Executive VP of Healthcare Operations and Strategy**, GlobalData**
09:00	**The state of the biopharmaceutical industry 2023** • Benchmark the impact of major themes on the biopharmaceutical industry in 2023, including: - Emerging technologies - Regulatory trends - Macroeconomic trends - Industry trends • Identify themes that will have the greatest positive or negative impact • Explore how inflation will affect the pharmaceutical industry **Bonnie Bain,** Global Head of Pharma and Executive VP of Healthcare Operations and Strategy, **GlobalData**
09:30	**Industry secrets to enhance clinical trial supply chain management** • Discover why technology is critical in achieving and maintaining visibility and traceability of the clinical trial supply chain • Learn how oversight and control, through technology, improve the patient and site experience • Tips on what to look for in a clinical trial supply chain management technology vendor/partner o What questions to ask? o What roadblocks to acknowledge and plan for **Melanie Manrique**, Associate Director, Quality Management, **Endpoint Clinical**
10.00	**Effective clinical distribution & label/pack vendor selection and management: creating agile relationships to ensure aligned goals and successful partnerships** • Navigating the vendor market/how to assess vendors to find the best vendor(s) for your supply chain network needs • Maintaining real time conversations with vendors to monitor disruption and delays, contingency planning together through open discussions • Important capabilities to consider when completing your assessments • Overcoming challenges when working with multiple vendors to ensure aligned goals **Brittney Elko,** Director Technical Operations & Supply Chain, **Aligos Therapeutics**

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10:30	**Morning refreshments and networking**
11.00	**Fireside Chat: Ascertaining the advantages and challenges of packaging and labeling strategies to enhance supply chain flexibility** • Decreasing large batch labeling to improve efficiency and reduce wastage • Enabling differing label requests for new countries, sites or patients within trials • Maximizing use of drug product with short expiration dates • Reviewing the impact of just in time labelling on cost, forecasting and supply chain management in intensified timeframes Moderator: **Prasun Mishra,** CEO, **Agility Pharma** **Marc Trombella,** Associate Director Clinical Supply Chain Planning, **BioMarin Pharmaceuticals**
11:30	**Fireside Chat & Audience Q&A: Discussing autologous cell therapy supply chain challenges for start-ups** • Resource considerations to solve the immediate need while considering future growth - Single product to multi-product - Demand growth - Clinical site expansion - Gameplan for rapid expansion • Navigating clinical launch including onboarding and managing of clinical sites • Planning and scheduling considerations • Vetting critical partners Moderator: **Prasun Mishra,** CEO, **Agility Pharma** **Thomas Tredennick,** Associate Director Supply Chain, **ArsenalBio**
12.00	**Clinical supply chain responsibilities for study close out, end of trial and returns** • Clinical Trial Master File and Data Base Lock • IRT compliance – expected reports, accountability logs, what auditors are looking for • Requirements for temperature documentation and compliance • How to prepare for closeout at study design to ensure reporting is maintained throughout • Pre-planning for supply destroys and returns to ensure compliance destroying onsite or nearby to minimize transport and customs requirements **Anu Arora,** Senior Manager Clinical Supply Chain, **Agios Pharmaceuticals**
12.30	**CEIV Pharma: Raising the standard of pharmaceutical logistics** • Learn about risks and potential gaps in cold chain when transporting temperature-sensitive pharmaceutical products by air • Discover how IATA's standards and certification can improve handling of pharmaceutical cargo, ensuring compliance with regulations • Understand benefits of participating in IATA's CEIV Pharma program and how it can help organizations establish a complete cold chain logistical process to maintain shipment integrity • Engage in the process of a simplified audit solution against clear standard criteria developed by the industry and provide constructive feedback on IATA's proposed solution **Ronald Schaefer,** Consulting Head of Certification Programs (CEIV Pharma), **IATA**
13:00	**Lunch, networking and prize draw**
14.30	**Evolving use of AI and Big Data in clinical trial supply chain to reduce costs and streamline processes**

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	• Identifying where and how data-driven technologies can be incorporated to streamline processes within clinical supply chains and decentralized trials • Reviewing cost savings through use of AI and big data • Evaluating benefits of using blockchain technologies to enhance conduction and management of trials • Highlighting successes of implementing AI and machine learning tools through case study examples **Prasun Mishra,** CEO, **Agility Pharma**
15.00	**U.S. Customs & Border Control: Hear from the Pharmaceuticals, Health & Chemicals Center** • Overview of U.S. Customs and Border Protection's Centers for Excellence and Expertise (CEE) • Focus on the Pharmaceuticals, Health, and Chemicals CEE and its role in the importation process • How industry partnerships are mutually beneficial • Biologic import requirements **Brandy Porter**, Assistant Center Director, Enforcement Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise, **U.S. Customs & Border Protection** **Gina Reneau**, Biological Threat Exclusion Coordinator, **U.S. Customs & Border Protection**
15:30	**Speaker Hosted Round Tables** 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 lasts for 30minutes, delegates can select up to 2 roundtables.
RT 1	**Roundtable: Study protocols and clinical development plans to recognize and overcome feasibility issues: best practices and common mistakes to avoid** **Jasmina Jankicevic,** VP Clinical Development, **RAPT Therapeutics**
RT 2	**Roundtable: U.S. Customs & Border Control: ask the experts** **Brandy Porter**, Assistant Center Director, Enforcement Pharmaceuticals, Health, and Chemicals Center of Excellence and Expertise, **U.S. Customs & Border Protection** **Gina Reneau**, Biological Threat Exclusion Coordinator, **U.S. Customs & Border Protection**
RT 3	**Roundtable: Current challenges and issues in supply chain** **Ying Cai,** Director Supply Chain, **Ashvattha Therapeutics, Inc**
RT 4	**Roundtable: Managing expiry dates to comply with regulation and avoid wastage** **Margaret Pese,** Associate Director Clinical Supply Chain, **Olema Oncology**
16:30	**Chair's summary and close of conference**

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