Clinical Trial Supply Europe

6th – 7th March 2024 I Barcelona
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'Achieving true supply chain agility in response to increasingly complex trial demands'

2024 edition of the Clinical Trial Supply Europe conference will be hosted in Barcelona, where large, medium and small pharma and biotechs will have the opportunity to discuss, debate and consider new technologies and processes to streamline supply chain operations.

Speakers

- **Niklas Mattson,** Director Comparator Management, **MSD**
- **Giuseppe Coppola,** Head of Global Clinical Supply Operations, **Novartis**
- **Arnaud Dourlens,** Global Head of Clinical Supply Chain Operations, **Sanofi**
- **Kamal Amin,** Head of Clinical Supplies Management, **Galderma**
- **Brendan Krause,** Head of International, **Uber Health**
- **Luiz Barberini,** Head of External Manufacturing, Latin America, **Bayer**
- **Thomas Thoma,** Head Managed Access Programs CTS, GHT, SR, **Teva Pharmaceuticals**
- **Mattia Scarafoni,** Senior Manager Global Clinical Supply Chain, **Incyte**
- **Jürgen Wieland,** Development Environmental Sustainability Lead, **Novartis**
- **Landry Giardina,** Global Head of Clinical Supply Chain Operations, Innovation & Technology, **Sanofi**
- **Claudio Semeraro,** Associate Director, Cell and Gene Therapy Lead, **UCB**
- **Pierre-Gaultier Delheid,** Head of Clinical Vendor Management and Clinical Supply, **UCB**
- **Ingrid Lux,** Head of Quality Disposition, Director, Oncology and External Supply Small Molecule EU, **Takeda**
- **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**
- **Adam Pitt,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**
- **George Amerson,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**
- **Révérien Uwacu,** Clinical Trial Supply Management, **UCB**
- **Marcus Wajngarten,** Senior Director Home Supply, **AstraZeneca**

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Clinical Trial Supply Europe

Barcelona 6th-7th March 2024

DAY ONE – WEDNESDAY 6TH MARCH 2024

7:30	**Registration and refreshments**	
8:15	**Chairperson's opening remarks** **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**	
8:30	**Keynote: Focusing on sustainability in supply chain to improve ESG responsibilities and comply with upcoming regulations** • Preparing for EU Corporate Sustainability Reporting Directive (CSRD) • Understanding how to measure carbon footprint • Considering quick wins to do now and focuses for future **Jürgen Wieland,** Development Environmental Sustainability Lead, **Novartis**	
9:00	**Reserved for Medidata**	
9:30	**Securing your global supply chain through designing an agile and resilient end to end supply chain that maximises adaptability** • Designing an adaptable supply chain to remain agile in the face of disruptions • Improving quality processes to shorten supply chain lead times and drive agility • Leveraging technologies to improve your visibility and end to end supply chain **Arnaud Dourlens,** Global Head of Clinical Supply Chain Operations, **Sanofi**	
10:00	**Reserved for N-Side**	
10:30	**Morning refreshments and networking**	
	STREAM A: Clinical Supply Logistics and Operations	**STREAM B: Clinical Supply Technology and Innovation**
	Chair: **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**	*Chair:*
11:00	**Fireside Chat: Effectively forecasting and organising pool supply to reduce wastage and increase sustainability** • Working together to harness benefits and overcome challenges of pool supply • Using just in time labelling to increase flexibility of drug use • Reducing waste and improving sustainability **Mattia Scarafoni,** Senior Manager Global Clinical Supply Chain, **Incyte**	**Increasing diversity: supply chain considerations for clinical trials in Africa** • Navigating benefits and challenges: a deep dive into the diverse landscapes of African clinical trials, highlighting the unique opportunities and overcoming prevalent obstacles • Optimizing supply logistics: strategies for efficient and compliant shipment of trial supplies from Europe into Africa, with a focus on navigating the entry requirements and logistics networks • Regulatory navigation and compliance: an exploration of the regulatory environment

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Sales Enquiry
Jarvinder Sidhu
Senior sponsorship Manager
T: +44 (0)207 9472755
E: jazsidhu@arena-international.com

Speaker Enquiry
Ruth Atterbury
CTS Portfolio Manager
E:ruth.atterbury@arena-international.com

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

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		• across Africa's varied jurisdictions, ensuring trial supply compliance with local and international standards • Cultural competence in trial supply management: addressing the need for sensitive and appropriate packaging and labeling, including translations and adaptations, for clinical trials across different African cultures and languages **Révérien Uwacu,** Clinical Trial Supply Management, **UCB**
11:30	**Reserved for Berlinger**	**Reserved for Suvoda**
12:00	**Global shortages on a rise - urgent actions for sustainable CTS procurement needed** • Highlighting challenges and impacts of global supply shortages • Realising urgent need to increase sustainability and life cycle of drug products to avoid limiting innovation due to shortages • Overcoming shortages to keep your trial on track **Thomas Thoma,** Head Managed Access Programs CTS, GHT, SR, **Teva Pharmaceuticals**	**Clinical supply chain performance ecosystem synergies** • Tools • E2E supply • R&D goals **Landry Giardina,** Global Head of Clinical Supply Chain Operations, Innovation & Technology, **Sanofi**
12:30	**Reserved for TecEx Medical**	**Reserved for 4G Clinical**
13:00	**Lunch and networking**	
14:00	**Transforming comparator sourcing models to improve supply optimization** • Sharing contacts within clinical trial sales and comparator sourcing widely to enable easy access and direct negotiations • Outlining advantages for sponsors, manufacturers and wholesale suppliers • Uncovering case study examples and successes of new sourcing model **Niklas Mattson,** Director Comparator Management, **MSD**	**Case Study: Seizing the benefits of e-labelling in conjunction with user apps** • Scanning barcodes or QR codes on e-labelling: benefits and challenges • Tracking patient data and GDPR considerations • Implementing and using e-labelling with patient apps
14:30	**Reserved for Abacus Medicine**	**Reserved for IQVIA**

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15:00	**Working hand in hand with quality team to ensure compliance and reduce 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 • Uncovering common QA compliance oversights and how to avoid them	**Understanding how a strategic partnership is essential to adapt to Gene Therapy paradigm shift of the entire supply chain** • Reviewing strategic partnering model for gene therapy • Considering supply chain requirements specific to cell and gene therapy • Analysing how the partnership was key for successful implementation **Claudio Semeraro, Associate Director,** Cell and Gene Therapy Lead, **UCB** **Pierre-Gaultier Delheid,** Head of Clinical Vendor Management and Clinical Supply, **UCB**
15:30	**Afternoon refreshments, networking and prize draw**	
16:00	**State of the biopharma industry: the outlook for drugs, trials, and manufacturing** • What's coming in the pharma pipeline? • Drug manufacturing for clinical trials • Emerging trends: gene therapy, mRNA, and AI • Opportunities for contract development and manufacturing organisations (CDMOs) **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**	**Evolving use of automation, AI and machine learning in clinical trial supply chain to reduce costs and streamline processes** • Identifying where and how data-driven technologies can be incorporated to streamline processes within clinical supply chains • 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
16:30	**Reserved for Almac**	**Reserved for TSS**
17:00	**Panel Discussion: Selecting clinical trial supply vendors wisely and maintaining oversight to keep your trial on track** • Vetting supply vendors, considering size and scale to ensure best fit • Considering how to maintain oversight of multiple vendors within one clinical trial study • Deciding how much oversight is right for each different vendor • Setting clear objectives and communicating effectively between sponsor and vendors to ensure the most efficient collaboration **Panellists:** **Giuseppe Coppola,** Head of Global Clinical Supply Operations, **Novartis**	**Panel Discussion: Leveraging technology to assist with increasingly complex supply chains** • Simplifying processes via use of technology to reduce complexity challenges • Reviewing available technology and processes to assist with monitoring supply chain • Driving end to end supply chain digitalisation to improve visibility and data exchange • Leveraging digitalization in conjunction with quality requirements for complex supply chains – what we can learn from commercial supply **Panellists:** **Ingrid Lux,** Head of Quality Disposition, Director, in Oncology and External Supply Small Molecule EU, **Takeda**

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17:30	**Chairperson's closing remarks**

NETWORKING DRINKS

DAY TWO – THURSDAY 7TH MARCH 2024

8:00	**Registration and refreshments**	
	STREAM A: Clinical Supply Logistics and Operations	**STREAM B: Clinical Supply Technology and Innovation**
08:55	*Chair:* **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**	*Chair:*
9:00	**Panel discussion: Preparing for and mitigating against risk in clinical supply chain to avoid delays** • Creating a risk management plan for clinical supply chain • Considerations for security risk management • Preparing for unexpected and natural disasters • Monitoring temperature control risk management **Panellists:** **Kamal Amin,** Head of Clinical Supplies Management, **Galderma** **Luiz Barberini,** Head of External Manufacturing, Latin America, **Bayer**	**Creating a successful direct to patient supply distribution strategy** • Creating and implementing suitable strategies per study • Complying with regulatory frameworks • Optimising supply chain flexibility within direct to patient trials • Overcoming common challenges and pitfalls in direct to patient supply **Marcus Wajngarten,** Senior Director Home Supply, **AstraZeneca**
9:30	**Reserved for Biocair**	**Reserved for event sponsor**
10:00	**Working closely with clinical departments to reduce supply impacts further down the line** • Communicating early regarding patient recruitment; sites and countries for supply team logistics • Considering the size of the trial; amount of supply required to forecast and distribute • Understanding import, packaging and labelling regulations for multiple countries	**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 • 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

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10:30	**Reserved for event sponsor**	**Reserved for event sponsor**
11:00	**Morning refreshments and networking**	
11:30	**Navigating multiple regulatory agencies to help expedite supply chain times** • Understanding the requirement and options for declaring biological materials to U.S. Customs and Border Protection (CBP) • Review of key U.S. regulatory agency authorities, such as CDC, FDA, USDA, and CBP • Discovering the latest non-compliant shipment issues for biological materials and pharma products and tips to avoid them • Learning about valuable resources and contacts for assistance **Adam Pitt,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection** **George Amerson,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**	
12:00	**Reserved for event sponsor**	
12:30	**Fireside Chat: Working with Uber Health transportation in clinical trials to improve equity and increase participant retention** • Increasing socio demographic diversity in clinical trials by supplying to patients who can't attend sites without assistance • Improving adherence to clinical trial participation by providing transportation for repeat appointments • Sharing case study examples and results **Brendan Krause,** Head of International, **Uber Health**	
13:00	**Lunch, networking and prize draw**	
14:00	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into two '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 trial supply. After 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*	
	ROUNDTABLE 1: **Importing and exporting biological materials to or from the U.S** **Adam Pitt,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection** **George Amerson,** Biological Threat Exclusion Coordinator, **U.S. Customs and Border Protection**	
	ROUNDTABLE 2: **Discussing impacts of CTIS on clinical supply teams**	

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	ROUNDTABLE 3: **Overcoming Import of record challenges in clinical supplies**
15:30	**Chairperson's closing remarks** **Fiona Barry,** Editor in Chief Associate Director Pharmsource, **GlobalData**
END OF CONFERENCE	

OTHER AVAILABLE TOPICS

Adapting to impacts of CTIS on clinical supplies to avoid supply disruptions and wastage

- Reviewing affects and challenges from CTIS on supply teams
- Changing mindset and timelines to fit CTIS lead times and feedback
- Preparing and manufacturing IMP at optimal time to avoid reducing shelf life
- Adapting workloads with multi country trials approved simultaneously

Managing returns and destruction of supplies: can we reduce carbon footprint without higher costs?

- Implications of local destruction vs returns to depot
- Assessing methods to reduce carbon footprint
- Considering impacts on budget and lead times at sites

Integrating and using Enterprise Resource Planning (ERP) Systems in supply chain

- Understanding how to implement an ERP system
- Considering effects on IRT and how the two can be integrated
- Reviewing benefits and challenges of using ERP systems in supply chain

Uncovering regulatory challenges for data safety sheets to remain compliant and avoid shipping delays

- Reconsidering importance of material data sheets to avoid shipping hold up
- Reviewing latest requirements to ensure compliance with GMP and trade compliance
- Finding vendors and solutions to help categorise dangerous goods when API has no data safety sheet

Considering technology options to assist with supply distribution of direct to patient trials

- Reviewing technology options and suitability e.g IRT, eCOA, RTSM solutions
- Selecting technology providers for your decentralized trial

Tracking and serialisation: how systems can benefit your clinical supply chain

- Comparing serialisation and tracking systems in Europe and beyond
- Integrating multiple systems to ensure real-time tracking of drug shipments
- Understanding the regulatory environment surrounding tracking and serialisation

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