Clinical Trial Supply Nordics

Clarion Hotel Copenhagen Airport, Denmark

24th-25th October 2023

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'Enabling local knowledge-sharing, benchmarking and network-building between Nordic biopharma and device industry peers'

This is the unmissable event for the pharmaceutical, biotechnology, and medical device communities to come together to discuss and share best practices, strategies and novel technologies to meet the demands of a complex clinical trial supply chain. Co-located with our OCT Nordics event, this is the perfect platform for professionals from across a range of clinical trial functions to meet, network, and hear about latest developments.

2023 Speakers

- **Sonia Ben Hamida**, Head of Special Cargo, **IATA**
- **Pierre-Gaultier Delheid,** Head of Clinical Vendor Management, **UCB Pharma**
- **Pernille Hemmingsen,** Chief Technology Officer, **Adcendo**
- **Jasmin Hellwig,** Associate Director Vendor Relationship Management, **MSD**
- **Tanja Villumsen,** Clinical Supply Specialist, **Novo Nordisk**
- **Stephen Lutsch,** Senior Director Clinical Trial Digital Innovation, **Genmab**
- **Alexandru Popa,** Associate Director, Blockchain for Digital Supply Chain, **MSD**
- **Linda Collstedt,** Senior Clinical Supply Program Lead, **AstraZeneca**
- **Anna Arnsvik,** ESG Sustainability Lead and Nordic Head Neuroscience, **Novartis**
- **Alastair Clewlow,** Senior Director Data Management Statistical Programming and Digital Solutions, **Lundbeck**
- **Andrew Thompson,** Director of Therapy Research & Analysis, Medical Devices, **GlobalData**
- **John Zibert,** Chief Medical Officer, **Coegin Pharma**
- **Morten Lind Jensen,** VP Medical Science, **UNION Therapeutics**
- **Viktorija Terebaite,** Head of Digital Health Technologies**, Lundbeck**
- **Christoffer Johansen,** Head, CASTLE - Cancer Late Effect Research, **Center for Surgery and Cancer, Rigshospitalet**
- **Susan Suchdev,** Chief Operating Officer, **Annexin Pharmaceuticals**
- **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**
- **Juan Munoz-Pujol,** VP of RTSM, **CALYX**

Join our new OCT community on LinkedIn

#OCTNordics #CTSNordics #OCTCTSNordics | @ArenaIntPharma

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DAY ONE – TUESDAY 24TH OCTOBER 2023

CLINICAL TRIAL SUPPLY	
7:30	**Registration and refreshments**
8:15	**Chairperson's opening remarks** **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**
8:30	**Choosing the right CMO and making it your partner to manufacture your product** • Importance of a network design to act strategically and not tactically • Considerations when selecting your CMO, what can jeopardize the relationship and to be considered at selection • Defining clear expectations to maximise and harmonise relationships between sponsor and CMO: how to turn business relation into partnership **Pierre-Gaultier Delheid,** Head of Clinical Vendor Management, **UCB Pharma**
9:00	**Reserved for Featured Sponsor**
9:30	**Sharing updates to IATA Temperature Control Regulations and best practice for temperature-controlled airfreight global logistics for clinical trials** • Providing an update on latest changes to IATA Temperature Control Regulations • Discussing Time and Temperature Sensitive labelling and packaging • Reviewing the acceptance checklist for time sensitive shipments • Highlighting best practice and lessons learned for the sponsor perspective **Sonia Ben Hamida**, Head of Special Cargo, **IATA**
10:00	**Reserved for Featured Sponsor**
10:30	**Morning refreshments and networking**
11:00	**Patient centricity: a supply chain perspective** • Looking at patient centricity from an internal and external label and packaging perspective • Considerations for supply chain and patient centricity • Handling challenges and highlighting success factors **Jasmin Hellwig,** Associate Director Vendor Relationship Management, **MSD**

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11:30	**Modern technology solving age old problems and what it means for sponsors, sites and vendors**
	The integration of AI into Interactive Response Technology (IRT) has become more than a trend; it's a transformational shift that's reshaping patient randomization and trial supply management.
	• **Crawl - Introduction to AI in IRT**:
	  ○ **ChatGPT in Action**: Explore the initial steps of AI integration, using ChatGPT to aid in writing specifications and supply predictions
	  ○ **Demystifying LLMs**: An introductory overview of Large Language Models and their potential in IRT
	• **Walk - Advanced Techniques with ChatGPT Plus**:
	  ○ **Templates and Automation**: Learn how to utilize templates in ChatGPT, streamline repetitive tasks and enhance efficiency
	• **Run - Next-Level AI Integration**:
	  ○ **Advanced Applications**: Delve into more complex use cases, exploring how advanced AI models can further optimize IRT processes
	  ○ **Security, Data Strategy, and UX**: Address essential technical considerations for success
	• **Fly - Enterprise Adoption of LLMs**:
	  ○ **Preparing Your Organization**: Strategies to equip your organization for the full-scale adoption of LLMs in the context of IRT/RTSM
	  ○ **Future Roadmaps**: Explore potential and strategic roadmaps for LLMs within the industry
	
	Endpoint Clinical

12:00	**Panel Discussion: Overcoming recent challenges, uncovering latest trends and driving innovation in clinical trial supply** • Future supply chain considerations since the impact of challenges provoked by regulatory changes, Covid-19, Brexit and the Russia-Ukraine conflict • Improving supply chain sourcing and waste reduction • Opportunities to enhance supply chain and processes through data driven technologies **Panellists** **Pernille Hemmingsen,** Chief Technology Officer, **Adcendo**
12:30	**Reserved for CALYX** **Juan Munoz-Pujol,** VP of RTSM, **CALYX**
13:00	**Lunch and networking**
14:00	**Considerations for setting up trial supplies for stem cell based advanced therapy medicinal products** • Differences between ATIMPS and conventional trial supplies • Complying with labelling regulations • Services and equipment considerations for ultra cold supply chain **Tanja Villumsen,** Clinical Supply Specialist, **Novo Nordisk** **Sofie Dalsgaard Seiersen,** Clinical Supply Coordinator Cell Therapy, **Novo Nordisk**
14:30	**Reserved for 4G Clinical**

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15:00	**Considering disruption and uncertainty when forecasting in supply chain to pre-plan effectively** • Creating your forecasting and demand planning strategy with uncertainty in mind • Ensuring budget flexibility to overcome unexpected disruptions • Communicating with your clinical operations team for demand planning regarding uncertainty of patient enrolment • Considering technology to assist with forecasting and demand planning **Linda Collstedt,** Senior Clinical Supply Program Lead, **AstraZeneca**
15:30	**Afternoon refreshments and networking**
16:00	**Panel Discussion: Enhancing supply chain relationships with internal teams and external vendors to improve supply chain efficiency** • Considerations between clinical operations and clinical supply to ensure study success • Uncovering common QA compliance oversights and how to avoid them • Aligning early phase vs late phase quality assurance considerations with supply chain protocols to minimise disruptions and supply chain backlogs • Collaborating effectively with vendors to improve communications and oversight **Panellists** **Jasmin Hellwig,** Associate Director Vendor Relationship Management, **MSD** **Linda Collstedt,** Senior Clinical Supply Program Lead, **AstraZeneca**
16:30	**Reserved for Session Sponsor**
17:00	**Planning and executing clinical trial supply lifecycle from a small biopharma perspective** • Efficient use of available IMP considering study design, shipment, labelling, stability • Updates during study for stability, impact on labelling, shipment etc. • QP release, shipment to sites, including differences between US and EU • Preparation and administration considering regulations and available in-use study data **Susan Suchdev,** Chief Operating Officer, **Annexin Pharmaceuticals**
17:30	**Chairperson's closing remarks** **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**

END OF DAY 1 AND NETWORKING DRINKS

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DAY TWO – 25TH OCTOBER 2023

CLINICAL TRIALS TECHNOLOGY & INNOVATION	
8:15	**Registration and refreshments**
8:45	**Chairperson's opening remarks** **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**
09:00	**Evolving use of AI and Big Data clinical trials to streamline processes and reduce costs** • Identifying risks and rewards • Reviewing cost savings through use of AI and big data • Evaluating benefits of using automation and ML technologies to enhance conduction and management of trials • Highlighting successes of implementing AI and machine learning tools through case study examples **Stephen Lutsch,** Senior Director Clinical Trial Digital Innovation, **Genmab**
9:30	**Reserved for Viedoc**
10:00	**Implementing digital health technologies into clinical trials** • What is Digital Health? • How can Digital Health Technologies be used in Clinical Development? • Challenges and opportunities • Process for selection and implementation **Viktorija Terebaite,** Head of Digital Health Technologies**, Lundbeck**
10.30	**Morning refreshments and networking**
11:00	**Utilising blockchain technology to improve digital supply chain** • Highlighting benefits of blockchain technology to increase visibility and efficiency in supply chain • Considering risks and challenges of blockchain • Sharing successes and lessons learnt **Alexandru Popa,** Associate Director, Blockchain for Digital Supply Chain, **MSD**
11:30	**Reserved for session sponsor**

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12.00	**Exploring data management tools and technologies that can assist throughout end-to-end clinical trials** • Discussing technologies and tools available for each stage of the clinical trial • Outlining the risks and rewards of data management tools and technologies • Providing case study examples of successes and lessons learnt **Alastair Clewlow,** Senior Director Data Management Statistical Programming and Digital Solutions, **Lundbeck**
12:30	**Lunch and networking**
13:30	**Fireside Chat: Innovation in clinical trials – a sanity check** Participants who have completed the ATRIUM CPH course "Driving Decentralised Clinical Trials" will discuss their thoughts on decentralising and using digital health technologies in clinical development. Which direction are they setting for their organisations, and how will they work with investigators, regulators and vendors moving forward. **John Zibert,** Chief Medical Officer, **Coegin Pharma AB** **Morten Lind Jensen,** VP Medical Science, **UNION Therapeutics** **Christian Born Djurhuus, MD PhD**
14:00	**Virtual clinical trials and medical devices** • What are they • Advantages • Recent Trends • Likely future trends **Andrew Thompson,** Director of Therapy Research & Analysis, Medical Devices, **GlobalData**
14:30	**Afternoon refreshments and networking**
15:00	**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 45 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	Roundtable 1 **Overcoming challenges in clinical supply resourcing** **Pernille Hemmingsen,** Chief Technology Officer, **Adcend**
	Roundtable 2 **Discussing the role and inclusion of patient relatives in trial reporting and data** **Christoffer Johansen,** Head, CASTLE - Cancer Late Effect Research, **Center for Surgery and Cancer, Rigshospitalet**
	Roundtable 3 **Considering how to make your clinical trials more environmental and social sustainable** **Anna Arnsvik,** ESG Sustainability Lead and Nordic Head Neuroscience, **Novartis**

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	Roundtable 4 **Reserved for event sponsor**
16:30	**Chairperson's closing remarks** **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**

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