Copenhagen, Denmark | 7th-8th June 2017

Confirmed Speakers 2017

Dan Markusson, Chief Operating Officer**, Peptonic Medical AB**
Annette Bested Toft, Director Clinical Trial Supply Management**, Ascendis Pharma**
Jonas Fransson, Director**, Swedish Orphan Biovitrum AB**
Birgitte Vestbjerg, Director Clinical Operations**, MC2 Therapeutics**
Britta Smedegaard Andersen, Project Director**, NEXT Partnership**
Carsten Jensen, Supplies Planner, Regulatory Expert, Trial Manager**, Novo Nordisk**
Tania Snioch, Director Healthcare**, GS1 Global Office**
Ronnie Nybom Kristensen, L & G Coordinator**, Novo Nordisk**
Marie Thyrgaard Jensen, Legal Advisor, **Clinical Trial Office Denmark**
Lone Margrethe Igel, Distribution Coordinator**, H.Lundbeck A/S**
Allan Rygaard Jensen, Project Coordinator**, Ascendis Pharma**
Nicolas Omdahl, Team Leader in Clinical Supplies Trial Set-up**, Novo Nordisk**
Francisco Rizzuto, Cargo Specialist, Manager for Europe**, IATA**

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	CTS Nordics | Copenhagen, Denmark **Day 1 | 7th June**
08:15	*Registration and refreshments*
08:50	*Chair's opening remarks*
	Clinical Supply Distribution Strategies
09.00	**Exploring strategies for simplifying labels to reduce cost and trial product waste in full regulatory compliance** • Identifying the label text required according to regulations and directives and avoid none-require text • Investigating how regulatory know-how can help reduce waste and cost in regards to trial supplies • How to ensure directions for use are provided in full compliance with annex 13 • Addressing the challenge of multiple languages required on labels **Annette Bested Toft**, Director Clinical Trial Supply Management, **Ascendis Pharma**
09:30	**Biologics Supply Chain: Balancing Trial requirements and supply costs** Global Trials involving biologics present some specific and considerable challenges. Using real life examples we will explore strategies that will help build a clinical supply chain that delivers optimum results in the areas of quality, time, cost, availability of and wastage of drug. Key areas include: • Early engagement of stakeholders • Kit design • Demand forecasting • Manufacturing/procurement planning • IRT • Label text • Distribution planning **Mervyn Preston**, Project Group Manager, **Almac Group**
10:00	*Morning refreshments and networking*
10:40	**Exploring the costs involved around Transportation and Logistics to understand 'Critical Control Points' and minimize risk** • Assessing your International Transportation partners to identify if they have "Risk Assessments" performed • Discussing their main "Critical Control Points" and the Risks associated with them • Exploring how your global transport provider can help you in performing your lane

	qualification • Identifying if they are performing Temperature Monitoring through the full door to door transport • Exploring the idea of a contingency plan in case of time or temperature abuse **Francisco Rizzuto,** Cargo Specialist, Manager for Europe, **IATA**
11:10	**Panel Discussion: Discussing the logistical side of Clinical Trial Supply to improve transportation processes and cost effectiveness** • Addressing the logistical challenges when faced with strict regulations on moving drugs internationally in order to improve our import/export processes • Discussing the security challenges within the clinical supply chain to minimize risk during transportation of IMP • Debating the underlying issues associated with distribution and storage of IMP to reduce cost and increase efficiencies **Francisco Rizzuto**, Cargo Specialist, Manager for Europe, **IATA**
11:40	**Industry Survey Results: Assessing the Current and Future State of Clinical Trial Supplies** **Carina Tillo**, Sales Manager, **Berlinger**
12:00	*Lunch and networking*
13:30	**CASE STUDY: Developing a placebo for a sterile comparator suspension** • Selecting the right comparator for your trial • Evaluating blinding options for sterile comparators • Developing a specification for a comparator placebo, with no information on comparator particulars • Developing and manufacturing the comparator placebo, lessons learned **Jonas Fransson**, Director of Drug Product Development, **Swedish Orphan Biovitrum**
14:00	*Presentation reserved*
14:30	Afternoon refreshments and networking
15:00	**Speaker Hosted Roundtables** 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 session lasts for 45 minutes, and delegates may attend up to 2 roundtables
RT1	Discussing how the 'last mile' can make or break your clinical study and patients- including how track temperature monitoring **Birgitte Vestbjerg**, Director Clinical Operations, **MC2 Therapeutics**
RT2	Debating the impact Brexit may have on clinical trial supply and its effect on future trial documentation for long-term preparation **Lone Margrethe Igel**, Clinical Supply Distribution Coordinator, **H.Lundbeck A/S**
RT3	Discussing temperature maintenance challenges throughout the whole clinical supply chain **Francisco Rizzuto,** Cargo Specialist, Manager for Europe, **IATA**
16:30	*Chair's Closing Remarks*
16:40	*Close of Day One*

	CTS Nordics | Copenhagen, Denmark **Day 2 | 8th June**
08:15	*Registration and refreshments*
08:50	*Chair's opening remarks*
09.00	**Exploring EU and non-EU labelling regulations to ensure your supply chain is compliant in all geographies** • Identifying the changes Annex 13 will bring to decide on new labelling strategies • Addressing the challenge of having expiry dates on all products particularly when new data emerges from trials to reduce wasted product • Outlining the benefit of exploring both regional and national regulations when working with new markets to ensure all label requirements are met

	• Establishing an in-house group of experts to interpret labelling requirements of non-EU countries whose written regulations are unclear **Carsten Vendelbo Jensen**, Trial Supplies Planner, Regulatory Expert & Trial Manager, **Novo & Nordisk & Nicolas Omdahl,** Team Leader in Clinical Supplies Trial Set-up, **Novo Nordisk**
09:30	**GS1 standards in the clinical supply chain to enable true visibility across your clinical supply processes** • Exploring GS1 standards for identification to uniquely distinguish all products and units from manufacturer to site • Implementing GS1 standards for capturing information, such as batch/ lot information, serial numbers and expiry dates to maximise traceability and safety • GS1 standards for data exchange to ensure traceability across the clinical supply chain **Tania Snioch,** Director Healthcare**, GS1 Global Office**
10:00	*Morning Refreshments and Networking*
10:30	CASE STUDY **Discussing the challenges and benefits of being a virtual company to ensure IMPs are produced and delivered to the clinical study in a timely fashion** • Outlining the benefits and opportunities of being a virtual company to understand their strengths and further utilise their resources • Addressing the challenges associated with virtual companies and how to implement strategies to improve a timely distribution of IMP • Using real life examples to demonstrate how virtual companies can successfully produce and distribute products • Looking into the future to improve on clinical trial supply logistics and plan for success • Planning go from phase II studies to two big phase III studies **Dan Markusson**, Chief Operating Officer, **Peptonic Medical AB**
11:00	PANEL DISCUSSION: Split into 2 parts **Exploring methods for clinical supply vendor selection and management to make the most of your resources and improve your outsourcing model** • Identifying a successful selection process by liaising with multiple vendors initially to decide which methodology is most suitable and feasible for your clinical trial • Discussing the best vendor management strategies to determine which is most efficient for your company **The case for use of global standards as a factor in vendor relationships**

	• Exploring the possibilities for use of global standards in collaboration between vendors and manufacturers • How to use this collaborative and common baseline to drive the clinical supply chain to be more time and cost efficient **Nicolas Omdahl,** Team Leader in Clinical Supplies Trial Set-up, **Novo Nordisk & Tania Snioch,** Director Healthcare, **GS1 Global Office**
12:00	*Lunch and Networking*
13:00	**NEXT the Public-Private Partnership making Denmark a Preferred Country for Clinical Trials & Clinical Trial Supply** • Exploring how the NEXT partnership works • Identifying why NEXT is so successful • Exploring the future with clinical trials and clinical trial supply in Denmark **Britta Smedegaard Andersen**, Project Director, **NEXT Partnership**
13:30	**Obtaining a comprehensive overview of legal and administrative aspects regarding clinical trial supply and medical device testing in Denmark** • When politics, industry and academia creates a common focus on increasing the number of clinical studies in Denmark • Exploring legal aspects of clinical trials • Discussing negotiations and national templates **Marie Thyrgaard Jensen**, Legal Advisor, **Clinical Trial Office Denmark**
14:00	*Afternoon Refreshments and Networking*
14:30	**Speaker Hosted Roundtables** 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 session lasts for 45 minutes, and delegates may attend up to 2 roundtables
RT1	Debating methods to simplify the labelling process to reduce cost and trial product waste **Ronnie Nybom Kristensen**, L & G Coordinator, **Novo Nordisk**

RT2	Discussing the latest technologies available for real time monitoring to avoid temperature deviations **Annette Bested Toft,** Director Clinical Trial Supply Management**, Ascendis Pharma/ Allan Rygaard Jensen,** Project Coordinator**, Ascendis Pharma**
RT3	Discussing the challenges of clinical trial supply from a smaller companies perspective **Nikolous Rottolpotes**, Head of Quality Operations, **Valneva Sweden AB**
RT4	Evaluating the challenges associated with ambient shipping and considering new technologies to avoid temperatures going beyond 25^{o}C *Roundtable reserved for event sponsor*
16:00	Chair's summation and close of conference