	Conference Name: 5th Annual Outsourcing in Clinical Trials Nordics **Conference location: Crowne Plaza Copenhagen Towers, Copenhagen, Denmark** **Conference Programme Day One: 10th October**
08:15	Registration and refreshments
08:50	Chairman's opening remarks
Boosting clinical trial activity in the Nordics	
09:00	**Keynote: The role of NEXT - a public-private partnership – to make Denmark an attractive country for clinical trials** • Creating clinical network to increase feasibility response rates • A national approach to increase performance in clinical trials • Building public and private sector alliances – how is the NEXT Partnership working • What is needed to be an attractive partner in clinical trials • Balancing competency, needs and incentives for maximum stimulation **Britta Smedegaard Andersen,** Project Director, **NEXT Partnership**
09:30	**Session reserved for Worldwide Clinical Trials**
10:00	**Big debate: Boosting clinical trial activity in the Nordics through collaboration and positioning** • Assessing the Nordic regulatory landscape and preparedness initiatives • What and where are the trial sponsor requirements and which regional assets to prioritise • Evaluating the regional CRO capabilities and positioning for clinical trials • How to harness local clinical sites, expertise and patient populations for maximum impact • Addressing the inherent concerns of this approach to deliver on the objectives **Britta Smedegaard Andersen,** Project Director, **NEXT Partnership** **Lene Grejs Petersen,** Senior Advisor, **Danish Medicines Agency**
10:30	Morning refreshments and networking
Clinical trial innovation and technology	
11.00	**Unravelling an effective strategy to prepare for the transition to clinical** • Deciphering between private and public funding enabling an informed decision • Creating an effective strategy for safety studies • Investigating the effectiveness of working with consulting companies • Identifying an effective strategy for sending out requests **William Dalby-Brown,** COO, **CaDo Biotechnology**
11:30	**Exploring best practices for SDV and quantitative experience in Risk Based Monitoring** • Learning about SDV's proper role in RBM trials • Identifying best practice considerations for targeted SDV • Outlining examples of SDV levels set on production trials thus far • Exploring key drivers for adjusting SDV levels mid-trial **Rich Davies,** Executive Director of Business Solutions, **OmniComm Systems, Inc**
12:00	**Big debate: Advancing data management in Nordic clinical trials without compromising quality and risk** • Discussing the current boundaries of eClinical solutions and what's next. • Leveraging common languages on the data plane and wider integration • Assessing the road to big data and how we can adopt it in trials • Balancing data privacy and ensuring appropriate risk management and compliance • Developing new value streams and the necessary set-up to benefit from them

12:30	Lunch and networking
13:30	**Case study: Implementing corrective and preventive action (CAPA) at a small orphan drug company with multiple partners** • Deteriming what to audit, how often to audit and how to track findings until closure • Agreeing mutually beneficial CAPAs and designing a fit for purpose escalation process • Carrying out effective tracking and documentation of the CAPA throughout the process • Ensuring necessary oversigh across multiple CAPAs and multiple stakeholders **Annu Suchdev**, Head of Quality R&D and HCC, **Sobi AB**
14:00	**Big debate: Moving clinical trial technology beyond the hype and into reality in the Nordics** • Outlining the current roadblocks in clinical study innovation and technology adoption • How are the sites evolving and where are we seeing clinical innovation thriving? • Delivering on the patient recruitment and retention goals through patient centric innovation • What is the quickest route to realise breakthroughs in clinical trial innovation and adoption? • Discussing the regulatory requirements and maximising the opportunity **Anette Østergaard,** VP Clinical Development**, MC2 Biotek**
Patient centricity and engagement	
14:30	**Understanding Patient Reported Outcomes in Multi-lingual Clinical Trials** • Reflecting from a linguistic perspective on whether "Quality of Life" is translatable • Outlining how standards evolved for multi-cultural Clinical Outcome Assessments in clinical trials • Explaining linguistic validation and cognitive debriefing as methodologies for instrument validation • Outlining the challenges of adapting PROs across cultures in global clinical trials • Assessing whether electronic capture alters the linguistic validity of an instrument **Speaker: Pia Søegaard Andersen,** Director, Product Strategy, Life Sciences**, Lionbridge**
15:00	Afternoon refreshments and networking
15:30	**Case study: Implementing new approaches in patient engagement, recruitment and retention** • Looking at education in medical research and development from a patient perspective • Exploring patient involvement in protocol development • Interrogating SOP development for patient involvement in medical product development • Developing a tool-box for patient education in product development and regulatory affairs • Detailing a real-life case: Bringing the European Patient Academy Tool-box to work **Ninette, Neel Florboe**, Anthropologist, **EUPATi**
16:00	**Big debate: How to capitalise on the patient centricity opportunity across the Nordics** • Discussing the lessons from orphan diseases and special patient groups • How do you define and qualify a holistic approach to patient engagement? • Evaluating where the most impact is - pre, during or post study • Re-examining driving patient recruitment and retention through incentives • Assessing the limitations of patient centricity in order to maximise the opportunity **Lasse Funch Jacobsen,** Associate Network Director – Patients Relations, **Novo Nordisk** **Amy Martinsen,** Research Coordinator, **Oslo University Hospital** **Lotte Seiding Larsen,** Principal Scientific Advisor, **Leo Pharma**
16:30	Chairman's summation and close of conference

	Conference Name: 5th Annual Outsourcing in Clinical Trials Nordics **Conference location: Crowne Plaza Copenhagen Towers, Copenhagen, Denmark** **Conference Programme Day Two: 11th October**	
08:15	Registration and refreshments	
	Pharma & Biotech Stream	**Med Devices Stream**
08:50	Chairman's opening remarks	Chairman's opening remarks
	Outsourcing and operations	**Regulatory outlook**
09.00	**Case study: Arymo – Highlights of regulatory approval of first tablet manufactured by injection molding** • Outlining the injection molding technology • Unraveling the path to FDA approval using the Guardian Technology • Outlining the 505b2 FDA submission process • Revealing the design and data of Human Abuse Potential Studies • Discovering future perspectives of injection molding for oral peptide drug delivery **Karsten Lindhardt, SVP R&D, DK Site Manager, Egalet**	**Case study: Learning to operate in a highly regulated market with a medical device start up** • Cortrium's journey from concept to CE marked active medical device • Identifying and meeting requirements on a startup budget • Building a quality management culture from scratch • Discovering lessons learnt and key takeaways **Erik Poulsen,** CEO, **Cortrium**
09:30	**Case study: Outsourcing models for small and start-up pharma and biotech companies** • Transactional outsourcing model vs a full out sourcing model • Assessing CRO fit for a virtual biotech company • Maintaining the personal effect to avoid losing site relationships • Leveraging insourcing and consultants to cover the skill gaps	**Case study: Developing a fit for purpose med device compliance and oversight strategy** • Understanding the roles of the notified bodies and the national competent authorities • Integrating risk based methodologies and transparent audit and reporting protocols • Resource allocation and budgeting for increased compliance and regulatory requirements • Aligning clinical trial outcomes and strategy within the regulatory frameworks
10:00	**Panel discussion: Effective communication and relationship management in extended teams** • Clearly defining deliverables and expectations from the outset • Importance of soft skills in outsourcing management • Evaluating strengths and weaknesses to maximise priorities • Creating a team and problem solving atmosphere **Eva Steiness,** CEO**, Serodus Pharmaceuticals**	**Panel discussion: The pros and cons of standardisation of medical device and In vitro diagnostic (IVD) device regulations** • How will standardisation affect the agility of med device & IVD device trials • What are the concerns around more stringent documentation requirements • How to implement the unique device identification requirement • What are the collaboration and guidance requirements from notified bodies **Jorunn Tverland**, Clinical Trial Manager, **Agilent Technologies** **Erik Poulsen,** CEO, **Cortrium** **Erik Rishøj Jensen,** Consults, **Region Sealand, at Operation,**

		Research og Innovation
10.30	Morning refreshments and networking	
	Regulatory outlook	**Compliance and oversight**
11:00	**Case study: Adapting clinical trial quality management for ICH GCP EC6 R2** • Outlining the effects on clinical trial auditing and reporting • Executing a risk based approach in auditing • Addressing the change management concerns of risk based auditing • Executing a fit for purpose gap analysis, action plan and project plan **Lone Hansen,** CQA Study Area Lead, Clinical Quality Assurance, **Lundbeck**	**Case study: Clinical trial outsourcing lessons from the small MedTech company behind the first FDA cleared scalp cooling system** • Reflecting on the strategies for outsourcing clinical trials at a small med tech company • Building strong relationships with CROs and investigation teams to deliver quality • Understanding the regulatory requirements to stay compliant in overseas markets • Outlining considerations when selecting a CRO and oversight of a US multicentre study **Erika Bågeman**, Clinical Affairs Director, **Dignitana**
11:30	**Danish Medicines Agency Update: Regulatory compliance in clinical trial electronic data systems** • EU GCP Inspectors Working Group Q&A issued on contracts with vendors of electronic systems, • The appropriate level of MAH/sponsor validation when purchasing an electronic system • Assessing shared activities and potential issues during ePRO inspections **Ib Alstrup**, *Medicines Inspector - IT*, **Danish Medicines Agency** **Lisbeth Bregnhøj**, Medicines Inspector, **Danish Medicines Agency**	**Case study: Implementing a robust post market clinical follow-up study strategy (PMCF)** • Updating your strategy in line with new MDR requirements for clinical data • Best practice in keeping an updated clinical evaluation report • Understanding the limitations of pre –market clinical data • Implementing finding into a competitive assessment of your medical device **Dorota Johansson,** Clinical and Research Director, **Bactiguard**
12:00	**Panel discussion: Readiness for 536/2014/CE and ICH GCP EC6 R2** • Leveraging data, predictive analytics and new tools in quality management • Understanding the depth of oversight for sponsors, suppliers and subcontractors • Preparing for regulatory inspections and audit requirements • Safety reporting and transparency requirements in 536/2014 **Lisbeth Bregnhøj**, Medicines Inspector, ***Danish Medicines Agency*** **Gunilla Andrew-Nielsen,** Head of Department of Clinical Trials and Special Permissions**, Swedish Medical Product Agency**	**Panel discussion: A holistic approach to compliance and oversight in med device trials** • Creating a feedback loop between post market feedback and product development • Preparing for the increase in transparency and vigilance reporting requirements • Working with the notified bodies and adopting a communication based approach • Planning and allocating the necessary compliance resources required **Thuy Maria Duong**, Medical Affairs Specialist, **Agilent Technologies**
12:30	Lunch and networking	

13:30	**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
Roundtable 1	**Risk based management, quality assurance and oversight in out sourcing agreements** **Nicolas Le Bec,** GCP QA Manager, EMEA Region, **Santen Pharmaceuticals**
Roundtable 2	**Exploring patient centricity, engagement and personalisation in clinical trials** **Lotte Klim,** Chair, **EUPATI Denmark**
Roundtable 3	**CRO selection strategies for clinical trials in orphan diseases and rare patient groups**
Roundtable 4	**Med devices regulatory roundtable: Preparing for the changes and sharing best practise** **Erik Rishøj Jensen,** Consults, **Region Sealand, at Operation, Research og Innovation**
15:00	Chairman's summation and close of conference