Outsourcing In Clinical Trials Nordics

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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 11th annual unmissable event that the pharmaceutical, biotechnology, and medical device communities need to come together and discuss strategies for operational success in clinical trials. Co-located with our CTS 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

- **Svend Ladefoged Nielsen,** Clinical Trial Assessor, **Danish Medicines Agency**
- **Ditte Zerlang Andersen,** EU Project Lead, Special Adviser, **Danish Medicines Agency**
- **Caroline Sandstroem,** Head of Global Clinical Quality, **Ferring Pharmaceuticals**
- **Alastair Clewlow,** Senior Director Data Management Statistical Programming and Digital Solutions, **Lundbeck**
- **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA**
- **Andrew Thompson,** Director of Therapy Research & Analysis, Medical Devices, **GlobalData**
- **John Zibert,** Chief Medical Officer, **Coegin Pharma**
- **Christoffer Johansen**, Head CASTLE – Cancer Late Effect Research, **Center for Surgery and Cancer, Rigshospitalet**
- **Viktorija Terebaite,** Head of Digital Health Technologies**, Lundbeck**
- **Morten Lind Jensen,** VP Medical Science, **UNION Therapeutics**
- **Rikke Winther,** Outsourcing Specialist, **Camurus AB**
- **Niels Hoejsgaard Joergensen,** Senior Director, Head of Global Site Management, **Leo Pharma**
- **Stephen Lutsch,** Senior Director Clinical Trial Digital Innovation, **Genmab**
- **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**
- **Ivanna Rosendal,** Senior Director, IT Business Partner, **Ascendis Pharma**
- **Matilda Hugerth,** Director Clinical and Regulatory Affairs, **Amniotics AB**
- **Pernille Hemmingsen,** Chief Technology Officer, **Adcendo**
- **Roel van der Heijde,** Facilitator & Trainer, **Patient Experience Association**
- **Morten Bang Norgaard,** Director Outsourcing, **Alligator Bioscience**
- **Ann Christine Korsgaard,** VP Regulatory Affairs, **AFYX Therapeutics**
- **Ane Jensen,** Principal Data Manager, **Zealand Pharma**
- **Andreas Cederholm,** Senior Corporate Counsel, **LEO Pharma**
- **Alexandru Popa,** Associate Director, Blockchain for Digital Supply Chain, **MSD**
- **Lisa Hellstrom,** Clinical Program Director, **Camurus AB**
- **Anna Arnsvik,** ESG Sustainability Lead and Nordic Head Neuroscience, **Novartis**
- **Dr. Claudia Hesselmann,** Founder and CEO, **ARENSIA**

Join our new OCT community on LinkedIn

#OCTNordics #CTSNordics #OCTCTSNordics | @ArenaIntPharma

- **Matt Cooper,** Executive Director, Therapeutic Strategy Lead, Oncology, **Worldwide Clinical Trials**
- **Nina Holst,** Executive Director Strategic Alliance Management, **ICON**
- **Sebastian Turek,** Executive Director Internal Medicine & Neuroscience, **TFS HealthScience**

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DAY ONE – TUESDAY 24TH OCTOBER 2023

7:30	**Registration and refreshments**
8:15	**Chairperson's opening remarks** **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA**
8:30	**Clinical Trial Regulation (CTR) and Clinical Trial Information System (CTIS): where are we now and what have we learnt?** • Sharing updates within CTR and CTIS and where we are at now since its launch • Focusing on lessons learnt and best practice from submissions so far • Highlighting challenges and benefits from user experiences and questions from sponsor perspective **Svend Ladefoged Nielsen,** Clinical Trial Assessor, **Danish Medicines Agency**
9:00	**Reserved for Novotech**
9:30	**A sponsor perspective on regulatory life with CTIS** • Highlighting the challenges seen so far • Suggesting ways to work around these challenges • Proposing thoughts on ways of working with clinical CROs in the future **Ann Christine Korsgaard,** VP Regulatory Affairs, **AFYX Therapeutics** **Ivana Glatzova,** Regulatory Affairs Manager, **AFYX Therapeutics**
10:00	**Reserved for Medidata**
10:30	**Morning refreshments and networking**

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11:00	**Navigating through the jungle of regulatory requirements for combination trials** • Reviewing key regulatory factors within CTR, MDR and IVD to ensure compliance • Best practice for ensuring all requirements are considered in parallel for submissions **Ditte Zerlang Andersen,** EU Project Lead, Special Adviser, **Danish Medicines Agency**
11:30	**Delivering oncology studies - challenges and considerations** This session will highlight the trends we have seen over the last 6 months in oncology and describe some of the new developments and issues we have seen and the ways Worldwide are addressing them. The main themes will be based around: • Project Optimus (FDA requirements for taking 2 doses into phase II) • Design trends (more push into BOIN) • Cohort management considerations (especially in CGT studies) • Treatment modalities (immune-oncology, bi-specific antibodies – biomarkers) **Matt Cooper,** Executive Director, Therapeutic Strategy Lead, Oncology, **Worldwide Clinical Trials**
12:00	**Exploring outsourcing models to assess and determine a successful outsourcing strategy** • Reviewing outsourcing models from full outsourcing to functional outsourcing to hybrid outsourcing • Determining the best outsourcing model: pros and cons and assessment tips to consider • Operating model: Finding the best service provider fit to address the needs of your company **Morten Bang Norgaard,** Director Outsourcing, **Alligator Bioscience**
12:30	**Accelerated performance of complex exploratory patient studies: Practical insights from investigational site** • Global Challenges & Industry Trends • Research Clinics dedicated to early patient trials • Key elements to consider when planning a phase IB/IIA Patient Trial • Case Studies **Dr. Claudia Hesselmann,** Founder and CEO, **ARENSIA**
13:00	**Lunch and networking**
14:00	**Maintaining financial oversight of clinical studies and development to optimise cost savings** • Creating a cost optimized study set-up to work more financially effectively • Reviewing selection processes and negotiations • Contracting best practice • Management and closure of study budget **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA**
14:30	**Reserved for TFS HealthScience** **Sebastian Turek,** Executive Director Internal Medicine & Neuroscience, **TFS HealthScience**

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15:00	**Building a flexible and efficient clinical operation organization through a strategic partnership** • Operational challenges running trials globally in medium sized pharma • Why invest in a strategic partnership between sponsor and CRO? • Experiences and learnings from from both sponsor and CRO • Site impact and initial reactions • When honeymoon is over, and the devil is in the details **Niels Hoejsgaard Joergensen,** Senior Director, Head of Global Site Management, **Leo Pharma** **Nina Holst,** Executive Director Strategic Alliance Management, **ICON**
15:30	**Afternoon refreshments and networking**
16:00	**Sourcing the right vendor and agreeing clear terms that suit both parties to ensure a successful partnership** • Considerations and best practice for assessing and selecting vendors • Understanding the budget and scope before signing a contract • Planning techniques to limit changes once contracts are in place **Rikke Winther,** Outsourcing Specialist, **Camurus AB**
16:30	**Reserved for Flex Databases**
17:00	**Panel Discussion: Reversing the conversation - what the clinical trial industry really wants from its service providers** We've all heard pitches from vendor companies telling us what they can do for us, but now it's time to reverse the conversation! Hear from the trial industry as they discuss the services they would like to see from their solution providers, including: • What they like to see in an outsourced partner organization • What they would like a partner to know about them / how they work • What things do they need a partner to do and what they don't need! • What things can be best done in house? **Moderator:** **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA** **Panellists:** **Lisa Hellstrom,** Clinical Program Director, **Camurus** **Ane Jensen,** Principal Data Manager, **Zealand Pharma** **Andreas Cederholm,** Senior Corporate Counsel, **LEO Pharma**
17:30	**Chairperson's closing remarks** **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA**

END OF DAY 1 AND NETWORKING DRINKS

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DAY TWO – 25TH OCTOBER 2023

8:15	**Registration and refreshments**	
	OUTSOURCING IN CLINICAL TRIALS & CLINICAL OPERATIONS	**CLINICAL TRIALS TECHNOLOGY & INNOVATION**
8:45	**Chairperson's opening remarks** **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA**	**Chairperson's opening remarks** **Catherine Longworth,** Editor, Medical Device Network, **GlobalData**
09:00	**Considering the future of DCTs vs hybrid trials, sharing new learnings and pitfalls to avoid** • Considerations for planning and deciding if to run a DCT • Reviewing the advantages of DCTs from taking the trial to boosting patient recruitment • Analysing the benefits and constraints of DCTs based on practical experiences • Sharing learnings from an inspection of an interventional DCT • Predicting if the future is hybrid trials as they are more realistic and practical compared to full DCTs **John Zibert,** Chief Medical Officer, **Coegin Pharma AB**	**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	**The importance of scientific validation and data integrity when using accessibility features** • Background on FDA recommendation for accessible features and designs to help increase clinical trial inclusivity such as frequently requested zoom in/zoom out functionality • Importance for patients who may have visual impairments, hearing, motor & dexterity, or cognitive difficulties that may impact inclusivity of these patients into clinical trials • Significance of deploying these functionalities where the drug under study may cause visual impairment such as certain oncology treatments or population under study, eg older adults, may have one or more impairments. • Results of an industry-first clinical study on the ePRO instrument equivalence across	**Reserved for Viedoc**

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	accessibility features and patient communication modality preferences. **Bryan McDowell**, Vice President eCOA Science and Consulting, **Clario**	
10:00	**Integrating diversity in clinical trials to increase drug safety and health equity** This interactive session will cover diversity and inequalities in clinical trials; why we have underrepresentation and why it's vital we improve this now. Roel will give a short overview on the challenges and will then open the discussion to the audience: • How can we improve engagement by paying more of a focus on race and socioeconomic disparities? • Highlighting the impact on your trial if all groups aren't adequately represented – ask ourselves why not • Brainstorming solutions: What actions can we take now to get groups interested in participating in trials? • Advice on how best to reach out to patients to understand their needs • Informing patients efficiently and translating the trial into a language they understand **Roel van der Heijde,** Facilitator & Trainer, **Patient Experience Association**	**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	**Incorporating social listening in clinical trials to increase patient centricity and recruitment** • Why social listening matters and how it can benefit clinical trials • Considering social listening tools, applications and remote measuring options • How to incorporate social listening into clinical trial design and patient recruitment **Ivanna Rosendal,** Senior Director, IT Business Partner, **Ascendis Pharma**	**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**

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11:30	**Reserved for session sponsor**	**Reserved for session sponsor**
12:00	**Panel discussion: Recognising and further integrating patient centricity and patient perspectives into clinical trials** • Omitting exclusion: improving engagement through focus on diversity and inclusion • Actively involving patients in ICF and protocol writing • Listening to the patient's voice. Reflecting on what is good for the patient and the right level of choice for the patient • Highlighting societal changes, the everyday clinic and how these two aspects feed into the trial situation **Moderator:** **Helen Johansen Blanco,** Vice President of Operations, **Cytovation ASA** **Panellists:** **Christoffer Johansen,** Head, CASTLE - Cancer Late Effect Research, **Center for Surgery and Cancer, Rigshospitalet** **Ivanna Rosendal,** Senior Director, IT Business Partner, **Ascendis Pharma** **Roel van der Heijde,** Facilitator & Trainer, **Patient Experience Association**	**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	**Clinical trial outsourcing and oversight activities – impact analysis of upcoming changes to ICH GCP** • Reviewing relevant sections of draft guideline • Discussing impact for sponsor organisations **Matilda Hugerth,** Former Director Clinical and Regulatory Affairs	**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**

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<table>
<tr><td>14:00</td><td>Assessing vendor categories to improve governance and accountabilities across clinical trial activities
Realising the need for diverse internal governance models for different types of vendors based on risk assessment
Ascertaining the right governance level, expectations and accountability for each type of supplier
Assessing and identifying ‘grey zone’ vendors in scope for GCP compliance
Caroline Sandstroem, Head of Global Clinical Quality, Ferring Pharmaceuticals</td><td>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</td></tr>
<tr><td>14:30</td><td colspan="2">Afternoon refreshments and networking</td></tr>
<tr><td>15:00</td><td colspan="2">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.</td></tr>
<tr><td rowspan="4"></td><td colspan="2">Roundtable 1
Overcoming challenges in clinical supply resourcing

Pernille Hemmingsen, Chief Technology Officer, Adcendo</td></tr>
<tr><td colspan="2">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</td></tr>
<tr><td colspan="2">Roundtable 3
Considering how to make your clinical trials more environmental and social sustainable

Anna Arnsvik, ESG Sustainability Lead and Nordic Head Neuroscience, Novartis</td></tr>
<tr><td colspan="2">Roundtable 4
Reserved for event sponsor</td></tr>
<tr><td>16:30</td><td colspan="2">Chairperson’s closing remarks
Helen Johansen Blanco, Vice President of Operations, Cytovation ASA</td></tr>
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