Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

Day 1: 12th November 2024

08:10 – 08:40	**Registration & Morning Refreshments**
08:40	**Organiser's Welcome Address** **Alexander O'Leary** – Director – **PBC Group**
08:45	**Chair's Welcome Address**
08:50	CMO & MD Keynote Interactive Panel **Putting Patients at the Heart of Clinical Trials: Strategies for Enhancing Patient-Centricity, Diversity, and Stakeholder Collaboration** *In the rapidly evolving landscape of clinical trials, patient-centricity has emerged as a critical priority for biopharmaceutical companies. This panel brings together a group of distinguished bay-area Chief Medical Officers to discuss strategies for putting patients at the heart of clinical trial design and execution.* Through this interactive panel discussion, attendees will gain valuable insights into the evolving role of the CMO in driving patient-centricity, diversity, and stakeholder collaboration in clinical trials. The panel will discuss practical strategies and real-world examples to inspire and inform clinical development leaders as they work to bring innovative therapies to patients in need. **Rob van Maanen – CMO – Biophytis**
09:30	Keynote **RESERVED**
09:50	Keynote **Evaluating Europe, and the Netherlands, as Prime Destinations for Clinical Research** *Remaining competitive as a region in clinical research is necessary to promote investment, drive the research-driven economy, and allow access to innovative new treatments. Losing market share to the US and Asia, Europe is collaboratively working to make it the go-to destination.* In this session Bart will explore the latest strategic initiatives and unique advantages which position Europe as an attractive hub for clinical research, discussing how to make Europe more appealing for international trial sponsors. Spotlighting on the Netherlands' strength as a region for early-phase clinical research. **Bart Scheerder – Chair – Dutch Clinical Research Foundation (DCRF)**
10:20	Keynote **RESERVED**
10:50	**Coffee Break**

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

	Stream A **Clinical Outsourcing & Patient Engagement**	Stream B **Supply Vendor Management & Site Selection**
11:20	Interactive Panel **What do Biopharma Think of Suppliers?** *Outsourcing aspects of clinical trials to CROs and functional vendors has become standard practice but also introduces challenges in choosing the right vendor, oversight, and communication – to name a few.* This panel will bring together experts to demystify best practice for outsourcing. Covering vendor selection, establishing transparency, data protection, personalised service models, strategies for small biotechs, and what to avoid! **Andy Thurstan – Senior Director, Patient Services – Wave Life Sciences** **Tom Lazenby – CEO & Founder - Mayet**	Interactive Panel **Clinical Trial Supply: Strategies for Vendor Selection and Effective Oversight** *Ensuring a robust and reliable clinical trial supply chain is crucial for the success of any clinical study. Selecting the right vendors and maintaining effective oversight can make the difference between a seamless trial and one plagued by delays and quality issues.* Panellists will share real-world case studies, best practices, and lessons learned from their extensive experience in managing clinical trial supply chains. **Vanessa Dekou – Managing Director – CSI**
11:55	Insight **RESERVED**	Insight **Clinical Trial Supply Forecasting and Optimization: Challenges, Solutions, and Future Directions** *The challenges and solutions in clinical trial supply forecasting; delving into the complexities of managing unpredictable variables and high costs and examine the shift from traditional spreadsheets to advanced forecasting systems.* Cédric will share the benefits these systems bring, such as improved risk management, cost efficiency, and sustainability. Understanding how AI advancements are set to further enhance supply forecasting. This session will provide valuable insights for anyone involved in clinical supply planning and optimization. **Cédric Druck - CEO/CTO - Trialzen**
12:25	Insight **Strategies for Patient Recruitment & Retention for Early-Stage Biopharma** *It's never too early to begin patient engagement efforts. The power of the patient voice is essential to drive trial success and future regulator approval.* In this session Julie will share Pleco Therapeutics' processes for reaching patient groups and care givers	Insight **Sustainable Clinical Research: Standardised Methods for Measuring and Predicting Environmental Impact** *Empowering the scientific community to make informed, eco-conscious decisions in clinical research planning, to contribute to more sustainable practices in healthcare innovation.*

Clinical Outsourcing Group Europe
Novotel Amsterdam
12th & 13th November 2024

to help shape their clinical development strategy. Discussing advocate organisations, as well as forming patient panels.

Julie Powell – Communications Director – Pleco Therapeutics

In this session Jason will share standardized guidance document and methodology for assessing the environmental impact of clinical trials. Demonstrating a publicly available predictive modelling tool that allows researchers to estimate the environmental footprint of proposed trial designs.

Jason LaRoche – Director, Innovative Health – Janssen Pharmaceuticals

12:55 **Lunch**

	Stream A **Efficiency & Legal**	Stream B **Supply, Logistics & Packaging**
13:55	Case Study **Maximising Trial Efficiency** *Utilising data, driving diversity and streamlining processes can help create more efficient trials, and more positive regulator outcomes.* In this session, Kawita will share steps taken to make clinical trials more efficient. Based on her vast experience, she will discuss the need to utilise data as early as possible, as well as the benefits of addressing patient diversity from Phase I. **Kawita Kanhai – Clinical Evidence Expert – NLC Health Ventures**	Case Study **Building a Resilient and Agile Global Clinical Supply Chain** *When conducting multi-site, multi-country trials Biopharma organisations face the critical challenge of designing and maintaining a robust, agile, and resilient global supply chain.* In this presentation Henshaw explores innovative strategies for optimising end-to-end clinical supply chain management, focusing on maximising adaptability, and mitigating risks in the face of complex global challenges. From strategic planning and risk assessment to supplier relationship management and advanced technology adoption. **Henshaw Mandi – Head, The ENABLE Lassa Research Programme – CEPI**
14:25	Insight **Unlocking Success: Navigating Clinical Research Contracts with Sites & Vendors** *When engaging vendors & sites, successful planning and contract management can vastly improve your negotiation position and benefit your study timelines, which will drive positive management throughout the duration of clinical studies.* In this session, Myrthe will share key insights into how trial sponsors can position themselves through	Insight **RESERVED**

planning, negotiation, and contract execution to reduce costs, gain leverage, and protection against overruns.

Myrthe Trompert – CEO – Salvius Legal

14:55

Case Study

Optimising Obesity Clinical Trials: From Site Selection to Patient Reach

The Biopharma sector has seen a surge in research and investment into obesity drugs in recent years, driven by growing recognition of obesity as a serious health concern, and recent approvals of treatments.

In this session Rob will delve into the steps taken at Biophytis when selecting sites, designing the trial, and methods of feasibility assessments for their planned Obesity trial.

Rob van Maanen – CMO – Biophytis

Workshop

Navigating the Biologics Manufacturing Bottleneck: Scaling Up in a Capacity-Constrained World

When looking to manufacture biologics on a large scale for late phase clinical programmes, sponsors often need to consider external manufacturing – but how do you do this if the capacity doesn't exist?

In this session Ruud will explain the lack of capacity in the world of biologics manufacturing, delving into his experience seeking supply, and the needed funding for this. Expanding into a workshop style session to field suggestions from the audience.

Ruud Brands – President – Alloksys Life Sciences

15:25 **Coffee Break**

	Stream A **Patient Experience**	Stream B **Supply, Logistics & Packaging**
15:55	Case Study **Improving Patient's Exposure to Healthcare** *Patients are often over or under treated due to poor diagnosis, and lack of sufficient resources and treatments in a healthcare setting.* In this presentation Karine aims to provide a comprehensive overview of the challenges faced when diagnosing and treating breast cancer. Sharing patient stories from diagnosis to treatment, and what can be done as an industry to improve survival rates. **Karine Clauwaert – CEO – ABSCINT**	Case Study **Utilising Clinical Packaging to Drive Trial Adherence** *Innovative clinical packaging solutions have the potential to significantly improve trial adherence, ultimately leading to more successful outcomes.* In this presentation XXX explore cutting-edge strategies and technologies in clinical packaging that aim to streamline the patient experience, promote engagement, and drive adherence. Spotlighting smart packaging concepts, and integrated remote technology.
16:30	Insight	Insight

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

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		Plenary **Investment: Bench to Clinic**
17:00	CEO Keynote Interactive Panel **Fuelling the Future: CEO Perspectives on Funding Clinical-Stage Biopharma** *Securing sufficient investment remains challenging for biotech companies, whether they are seeking to enter clinical trials, or seeking investment to move to later stages. Clear communication of drug/device candidate potential, as well as possible creative funding/ equity models.* This CEO panel will bring together leaders of biopharma to discuss strategies for financing clinical pipelines. Topics will include international trends in venture capital, public markets, licensing deals, local government funding, and cross-border partnerships. **Ivo Timmermans – CEO – Pleco Therapeutics** **Ruud Brands – President – Alloksys Life Sciences** **Sanj Singh – CEO – Temple Therapeutics** **Cedric Bogaert – CEO – myNEO Therapeutics** Chair: **Sam Vakili – AI & Go-To-Market Strategist – Invest.In.Tek**	
17:50	**Chair's Day 1 Summary**	
17:55		**Networking Drinks & Canapés Reception** ***(complementary admission to all conference participants)***

Day 2: 13th November 2024

08:15 – 08:55	**Registration & Morning Refreshments**
08:55	**Chair's Day 2 Welcome Address**
09:00	Keynote **Revolutionizing Clinical Trials: Innovations in Trial Design for Faster, Smarter, and More Efficient Drug Development** *The landscape of clinical trials is evolving rapidly, driven by the need for faster, more efficient, and patient-centric drug development. This panel discussion will explore the latest innovations in clinical trial design, focusing on strategies that can accelerate timelines, improve data quality, and enhance patient engagement.* Exploring adaptive trial designs, the integration of advanced technologies such as AI and machine learning, and the growing trend of decentralized trials. Sharing insights on the application of real-world evidence, innovative statistical approaches, and patient-reported outcomes to complement traditional randomized controlled trials.

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

09:30 Keynote

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10:00 Panel Discussion

Positioning the Benelux Region as a Leader in Clinical Research

The global landscape for clinical trials is constantly evolving, presenting both challenges and opportunities for biopharmaceutical companies.

This panel will explore the opportunities to conduct clinical research in the Benelux region. Spotlighting initiatives from Belgium, the Netherlands, and Luxembourg to attract trial sponsors. Focusing on opportunities in site/patient engagement.

Manon Gantenbein – Head of Clinical & Epidemiological Investigation Center – Luxembourg Institute of Health

10:40 Insight

Building the Dream Team: Site Selection and Engagement in Phase I Clinical Trials

For emerging biopharma companies, running their first clinical trial is a critical milestone that sets the foundation for future success. Central to this endeavour is the selection and engagement of the right clinical trial sites and the assembly of a high-performing study team.

In this presentation Jens details the key considerations and practices for identifying, evaluating, and partnering with the optimal sites while building a cohesive and experienced team to ensure the smooth execution of a Phase I trial.

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Jens Wuerthner – CMO – Scenic Biotech

11:10 **Coffee Break**

11:40 Insight

Preparing for Successful Phase I Trials

With the cost of phase I clinical trials reported at around $4m, it is essential for trial sponsors to plan and prepare for their Phase I trials accurately, engaging regulators, ethics committees, and working with the right vendors.

In this presentation Mike aims to provide a comprehensive guide to the steps needed to conduct successful Phase 1 trials. Sharing knowledge based on engaging regulators and ethics committees across his career.

Mike de Leeuw – CEO – Oncolize

12:10 Insight

Navigating the Grand Dutchy: Conducting Clinical Research in Luxembourg

Clinical Outsourcing Group Europe
Novotel Amsterdam
12th & 13th November 2024

With a population of under 700,000 (2022), Luxembourg may not be your first port of call for conducting clinical research. However, following the execution of a 10-year plan, Luxembourg has positioned itself with a unique offering for trial sponsors.

In this on-stage interview, Manon will explore how innovative programmes have allowed Luxembourg to position itself as a beacon of clinical research in Europe. Discussing the population's response to participate in research, programmes run by the Institute of Health to aid participation, and drive patient engagement.

Manon Gantenbein – Head of Clinical & Epidemiological Investigation Center – Luxembourg Institute of Health

12:40 Workshop

Unleashing the Power of AI in Clinical Operations

Artificial Intelligence is revolutionising the clinical development landscape, offering opportunities to optimise trial design, streamline operations, and accelerate the delivery of life-saving therapies to patients.

This interactive workshop aims to bring together the audience of clinical research professionals, data scientists, and AI experts to explore the transformative potential of AI in clinical trials and brainstorm current and future applications.

Sam Vakili – AI & Go-To-Market Strategist – Invest.In.Tek

13:10 **Lunch**

14:10 Keynote

Evolving Frameworks: Cross-Border Clinical Studies & Patient Engagement in Research

The landscape of clinical research in Europe is undergoing significant transformation, driven by EU initiatives to promote cross-border collaboration and enhance patient involvement. Presenting both challenges and opportunities for researchers, reshaping how clinical trials are conducted and how patient perspectives are integrated into the research process.

In this session Joséphine shares two critical developments in European clinical research. First, examining the EU's initative to facilitate cross-border clinical trials to promote collaboration and efficiency across member states. Secondly, discussing the EU mandate to increase patient involvement in the research process.

Joséphine Mosset-Keane – Policy Officer – Cancer Patients Europe

14:40 Keynote

Preparing for Phase III: Excellence in Trial Design & Execution

When planning for Phase III trials it is essential to ensure you have the right proof-of-concept data to gain regulator approval. Data collected from earlier phases will help shape trial design, and aid execution for a much larger phase III programme.

In this presentation Erik shares the recent start-up and execution of ANeuroTech's ANT-01 programme, detailing the steps taken to promote regulator approval, and how the study's design was influenced by data collected in previous studies. Executed in partnership with IQVIA Biotech.

Erik Buntinx – Founder & CEO – ANeuroTech

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

15:10	Closing Keynote **RESERVED**
15:40	**Chair's Day 2 Summary & Closing Remarks**

End of Conference

SPARE SESSIONS

Building the Dream Team: Site Selection and Engagement in Phase I Clinical Trials

For emerging biopharma companies, running their first clinical trial is a critical milestone that sets the foundation for future success. Central to this endeavour is the selection and engagement of the right clinical trial sites and the assembly of a high-performing study team.

In this presentation XXX details the key considerations and practices for identifying, evaluating, and partnering with the optimal sites while building a cohesive and experienced team to ensure the smooth execution of a Phase I trial.

Strategies for Attracting Funding in the Current Biopharma Landscape

Following the series of Biopharma presentations, in this panel session a group of seasoned investors will offer their expertise and insights to help emerging biopharma companies refine their investment propositions.

The investor panel will provide constructive feedback and practical advice on how to effectively position each company's unique value proposition to maximize their chances of securing funding.

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

Investment Strategies for Emerging Biopharma

Do you represent an emerging biopharma looking to connect with investors and discuss future investment strategies? Join this interactive workshop where you'll have the opportunity to engage in open discussions and gain valuable insights from experienced investors.

This drop-in session is designed to provide a platform for emerging biopharma to explore various investment options, discuss funding challenges, and learn about the latest trends in the industry. You'll have the chance to share your experiences and receive guidance on navigating the complex landscape of biopharma investments.

Mastering Oversight and Vendor Monitoring in Clinical Studies

Effective oversight and monitoring of CROs and FSPs are critical components of successful clinical study management. As sponsors increasingly rely on outsourcing to conduct clinical trials, it is essential to establish robust oversight.

In this session XXX will provide attendees with a comprehensive understanding of the best practices and tools for overseeing and monitoring CROs and vendors in clinical studies.

Building Effective Partnerships Between Trial Sponsors and Investigators

Strong partnerships between trial sponsors and investigators are crucial to facilitating efficient, high-quality clinical research. Aligning priorities and effective collaboration enables successful trial execution, recruitment, and data collection.

In this presentation XXX will examine best practices for building robust partnerships between clinical trial sponsors and investigator sites. It will outline strategies to align priorities, incentives, and expectations to conduct high quality, efficient trials.

Harnessing Digital Health Technologies to Transform Clinical Trials

As the Biopharma sector continues to embrace digital transformation, the integration of digital health technologies into clinical trials has become a game-changer. Trial sponsors are realising the benefits of technology to drive efficiencies throughout clinical development.

In this presentation XXX explores how innovative digital tools and platforms are reshaping the clinical trial landscape, offering opportunities to enhance efficiency, data quality, and patient centricity. From remote monitoring and telemedicine to wearable devices and artificial intelligence, delving into the latest advancements in digital health technologies and their practical applications in clinical research.

Embedding Quality by Design: Safety and Excellence in Trial Design

Quality by Design (QbD) has emerged as a crucial approach to ensuring the highest standards of safety, reliability, and data integrity in clinical trials. Effective use of quality methodology means that sponsors and researchers can mitigate risks, optimise trial processes, to deliver safer, more effective therapies to patients.

In this presentation XXX examines the fundamental principles of QbD and its application in the design and execution of clinical trials. Sharing practical examples of how to integrate quality considerations throughout the entire clinical trial lifecycle.

Clinical Outsourcing Group Europe

Novotel Amsterdam

12th & 13th November 2024

Strategic Financial Planning & Analysis for Trial Oversight

Properly structured financial plans and insightful analysis are crucial for ensuring your trial costs are accounted for.

In this session, XXX will share tips and tricks for achieving trial dominance through effective financial planning and analysis. The session will cover key priorities in financial planning, compliance considerations, and essential components of a trial's financial plan and analysis framework.

Enhancing Clinical Trial Engagement Through Technology Adoption

Technology has emerged as a powerful enabler for improving patient engagement, optimising trial operations, and accelerating the development. Technology is increasingly being used to engage patients to reduce trial drop-out rates.

In this session XXX will explore the latest trends, best practices, and success stories in technology adoption for clinical trial engagement, providing attendees with practical insights and actionable strategies to harness the power of digital innovation in their studies.