Outsourcing in Clinical Trials: Medical Devices Europe

Munich, Germany

30th-31st January 2024

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'Bringing intellectual minds and key innovators under one roof to examine the latest cutting-edge advancements in artificial intelligence across the pharmaceutical industry.'

We are excited to welcome you back to the 12th annual Outsourcing in Clinical Trials conference for Medical Devices. This year's programme offers a fresh insight into the latest regulatory updates, techniques of running trials for a small company, the latest innovations and many more topics. The 2-day event promises to provide the European medical device and diagnostics community with an unmissable opportunity to learn and network to help them succeed in a challenging industry.

2024 Speakers

John Shillingford, Director, Clinical Research, **Afon Technology**
Pavel Kušnierik, Head of Regulatory Affairs, **Contipro**
Heinrich Martens, Vice President Regulatory Affairs, BU INS, **Fresenius Kabi MedTech**
Jie Jia, Medical Director, BU INS, **Fresenius Kabi MedTech**
Balint Feher, Project and Senior Clinical Research Manager, eClinical Lead, **Geistlich Pharma**
Sonnika Lamont, Analyst, Clinical Trials Intelligence, **GlobalData Plc**
Stefan Meyer, Chief Technology Officer, **Implandata Ophthalmic Products**
Carine Cochereau, Vice President, Regulatory International (OUS)**, Integra LifeSciences**
Shauna Coen, Regulatory Affairs Manager, **iThera Medical GmbH**
Heike Schon, Managing Director, **Lumis International**
Deborah-Ann Schuster, Clinical Project Manager, Hospital Patient Monitoring, **Philips**
Aude Yulzari, Senior Clinical Affairs Manager, **Precisis**
Danish Mairaj, Principal Engineer Medical Device Design, **Resyca**
Harald Schnidar, Chief Executive Officer, **Scarletred**
Ya-Hsuan Lin, R&D Project Manager, **SciVision Biotech**
Abdessamad Belhamdi, Director, Quality and Regulatory Affairs, **SPARTHA Medical HQ**
Anna Mayer, Lead Auditor, Non Active Medical Devices, **TÜV SÜD**
Marta Carnielli, Head of Certification, **TÜV SÜD**
Yvonne Hoogeveen, Director, Clinical Affairs, **Wellinq**
Sandra Koehler, Director, Clinical Operations, **Xeltis**

Join our new OCT community on LinkedIn
#OCTMedDevice #MedDevicesEurope #ClinicalTrials | @ArenaIntPharma

DAY ONE – TUESDAY 30TH JANUARY 2024

DAY ONE	
8:15	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **John Shillingford,** Director, Clinical Research, **Afon Technology**
9:00	**The AI revolution in medical devices trials: accelerating data analysis in clinical trials** • Understanding the need for AI and software incorporation to handle paperwork efficiently • Exploring the potential for AI to make processes more efficient and improve patient outcomes • Exploring the use of AI in accelerating data analysis during clinical trials • Discussing how AI-powered data analysis can speed up clinical trial timelines • Identifying opportunities for optimising trial efficiency through AI • Discussing the benefits of AI in streamlining regulatory compliance **Danish Mairaj,** Principal Engineer Medical Device Design, **Resyca**
9:30	**Session reserved for Medidata**
10:00	**Optimising trial endpoints and endpoint selection in medical device trials** • Understanding the significance of selecting appropriate trial endpoints for study success • Addressing challenges faced by midsize and small companies in conducting large-scale trials • Highlighting the need to consider alternative endpoints for trials with limited resources • Identifying essential information needed to demonstrate device safety and performance • Discussing the interplay between regulatory requirements, safety considerations, and product development goals **Jie Jia,** Medical Director, BU INS, **Fresenius Kabi MedTech**
10:30	**Session reserved for featured sponsor**
11:00	**Morning refreshments and networking break**

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11:30	**Expanding horizons, exploring the opportunities and challenges of moving trials abroad** • Comparing advantages and challenges of running trials in smaller countries vs established trial hubs. • Analysing the significance of a comprehensive global strategy for clinical trials • Addressing the rationale behind prioritising MDR compliance over US market entry • Top tips and tricks for successful international expansion • Evaluating the feasibility of running trials in multiple regions simultaneously **Carine Cochereau**, Vice President, Regulatory International (OUS), **Integra LifeSciences**
12:00	**Session reserved for 1MED**
12:30	***Topic TBC*** **Balint Feher,** Project and Senior Clinical Research Manager, eClinical Lead, **Geistlich Pharma**
13:00	**Lunch and networking**
14:00	**Navigating the challenges of post-market clinical follow-up studies for drug-device combination products** • Understanding the concept of PMCF studies mandated by EU MDR • Working closely with notified bodies to comply with guidelines and regulations • Use cases and best practice for medical device and drug-device combination products **Heinrich Martens,** Vice President Regulatory Affairs, BU INS, **Fresenius Kabi MedTech**
14:30	**Session reserved for SMART-TRIAL by Greenlight Guru**
15:00	**PANEL DISCUSSION: Effective collaboration for maximising synergy while working alongside CROs in medical device development** • Understanding the benefits of working with CROs in medical device development • Identifying common challenges faced while working with CROs • Promoting open communication channels for effective problem-solving • Defining clear roles and responsibilities to avoid overlap and confusion • Identifying potential risks associated with collaboration and outsourcing • Strategies for building long-term partnerships with CROs **MODERATOR:** **Sonnika Lamont,** Analyst, Clinical Trials Intelligence, **GlobalData Plc** **PANELLISTS:** **Sandra Koehler,** Director, Clinical Operations, **Xeltis** **Abdessamad Belhamdi,** Director, Quality and Regulatory Affairs, **SPARTHA Medical HQ** **Stefan Meyer,** Chief Technology Officer, **Implandata Ophthalmic Products**

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	Senior representative, Medidata
15:30	**Afternoon refreshments and networking**
16:00	**Optimising outsourcing strategies: balancing in-house capabilities, CRO selection, and the role of people in successful partnerships** • Addressing the critical decision of whether to completely outsource or retain some aspects in-house • Understanding the advantages and challenges of each approach • Discussing strategies for efficiently managing multiple CRO partnerships • Identifying ways to find a balance between cost and quality in outsourcing • Exploring the range of services and expertise offered by different CROs • Strategies for effective contract negotiations with CROs • Understanding the value of building strong, long-term partnerships with CROs **Stefan Meyer,** Chief Technology Officer, **Implandata Ophthalmic Products**
16:30	**Session reserved for GCP-Service International**
17:00	**CASE STUDY: Software as a medical device: opportunities, challenges and lessons learned** • An overview of Scarletred's software as a medical device technology • Opportunities created by AI and data driven technology: how can this revolutionise the MedTech industry? • Developing and testing software as a medical device through clinical trials: overcoming challenges and ensuring success **Harald Schnidar,** Chief Executive Officer, **Scarletred**
17:30	**Chairperson's closing remarks** **John Shillingford,** Director, Clinical Research, **Afon Technology**
NETWORKING DRINKS RECEPTION AND END OF DAY 1	

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DAY TWO – 31st JANUARY 2024

DAY TWO	
8:15	**Registration and refreshments**
8:45	**Chairperson's opening remarks** **John Shillingford,** Director, Clinical Research, **Afon Technology**
09:00	**Best practices, utilising a pragmatic approach to CRF development** • Emphasising the importance of pragmatic CRF development to meet MDR requirements • Recognising the challenges posed by complex CRFs with multiple effective endpoints • Sharing real-life experiences and challenges encountered during endpoint selection • Strategies for simplifying CRFs to improve data collection and trial management **Ya-Hsuan Lin,** R&D Project Manager, **SciVision Biotech**
9:30	**Session reserved for Premier Research**
10:00	**Navigating reimbursement challenges in clinical trials: insights on contract negotiations and site compensation** • Understanding the reimbursement structure and its importance in clinical trials • Variances in reimbursement across sites and countries, case studies highlighting the differences in reimbursement models • Streamlining contract negotiations, mitigating delays and potential roadblocks • Identifying common challenges faced during the negotiation phase • Exploring potential developments and innovations in reimbursement strategies **Deborah-Ann Schuster,** Clinical Project Manager, Hospital Patient Monitoring, **Philips**
10:30	**Session reserved for Q Serve**
11.00	**Morning refreshments and networking**

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11:30	**Data lifecycle in clinical investigation: manufacturer's perspective** • Is it possible to have efficient data collection from investigators and sites? • Statistics fascinating transforming of collected data or boring evil necessity? • Possibilities to assess reliability of collected and processed data • Understanding statistical reports and issues with results interpretation • EU MDR requirements on data in clinical investigations **Pavel Kušnierik,** Head of Regulatory Affairs, **Contipro**
12:00	**Notified Body´s perspective on clinical data generation within the medical device life cycle** • Presenting updates on regulatory trends and changes in clinical investigations for medical devices • Identifying gaps in outsourcing: safeguarding expertise for outsourcing and robustness of outsourced activities • Harmonization in quality assurance of clinical data **Anna Mayer,** Clinical Auditor, **TÜV SÜD**
12:30	**Real-world data collection: making the most of what's already available** • Understanding the importance of collecting real-world data for medical devices • Sharing best practices and case studies on leveraging real-world data for device improvement • Laying out a plan in early stages of what you can do post-market **Aude Yulzari,** Senior Clinical Affairs Manager, **Precisis**
13:00	**Lunch and networking**
14:00	**Lessons learned: performance evaluation requirements according to IVDR** **Marta Carnielli,** Head of Certification, **TÜV SÜD**
14:30	**Diving into market entry for the global market compared to an EU focused approach** • Highlighting the benefits of gaining a comprehensive understanding of global market dynamics • Discussing strategies for registering products in various global markets • Examining trial design strategies based on target markets and regulatory requirements **Shauna Coen,** Regulatory Affairs Manager, **iThera Medical GmbH**
15:00	**Trends and themes in medical device clinical trials: how to stay ahead of the curve** • Medical device clinical trials in Europe: an overview of the landscape • Innovation and technology: what's new, and what's upcoming? • Changes in technology, strategy and regulatory affairs for the European medical device industry **Sonnika Lamont,** Analyst, Clinical Trials Intelligence, **GlobalData Plc**
15:30	**Afternoon refreshments and networking**
15:55	**EXHIBITION APPLE PRIZE DRAW** *Visit our exhibitors' booths throughout the day and collect stamps in order to enter our Prize Draw and be in for a chance of winning Apple devices or Amazon vouchers. The Prize Draw will take place in the Exhibition Hall, make sure you don't miss out!*

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16:00	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into four '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 clinical operations.*
	ROUNDTABLE 1: MDR certification for drug-device combination products **Yvonne Hoogeveen,** Director, Clinical Affairs, **Wellinq**
	ROUNDTABLE 2: Reserved for Lumis International **Heike Schon,** Managing Director, **Lumis International**
	ROUNDTABLE 3: Key challenges in post-market clinical studies **Aude Yulzari,** Senior Clinical Affairs Manager, **Precisis**
	ROUNDTABLE 4: Navigating CRO and vendor relationships **John Shillingford,** Director, Clinical Research, **Afon Technology**
17:00	**End of conference**

END OF CONFERENCE – SEE YOU NEXT YEAR!

Additional topic suggestions:

Clinical utility benefit-risk analysis, unravelling insights through case studies and real-world experiences

- Understanding the significance of clinical utility benefit-risk analysis in medical decision-making.
- Identifying strategies to strike a balance between benefits and potential risks for early stage trials
- Presenting examples of actual benefit-risk assessments in clinical settings
- Addressing common challenges encountered during benefit-risk analysis
- Demonstrating how benefit-risk analysis contributes to improved patient safety and treatment effectiveness

Unleashing the potential of software and AI as medical devices, key learnings, innovations, and overcoming obstacles

- Exploring the growing interest in using software and AI in medical applications
- Discussing the challenges and considerations in testing and regulating AI-powered devices
- Understanding the potential impact on medical imaging and other healthcare fields
- Identifying unique challenges and opportunities in this evolving field
- Discussing the impact of AI on treatment planning and decision-making

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- Addressing common obstacles faced during software and AI implementation and approval
- Understanding the regulatory landscape for AI-driven medical devices
- Anticipating upcoming innovations and trends in the AI space

Exploring the future of medical device and drug combination products: insights from EMA and key considerations for MR and MDR compliance

- Understanding the increasing trend of combining medical devices and drugs
- Gaining insights from the European Medicines Agency (EMA) on the future of medical device and drug combinations
- Explaining the distinction between Medical Devices Regulation (MDR) and Medical Devices Directive (MR) for combination products
- Identifying compliance requirements and implications based on the device's primary mode of action
- Presenting various regulatory pathways available for combination products
- Understanding how partnerships can drive innovation and development in this domain

Exploring ways to leverage CRO expertise and innovation in medical device development

Adapting clinical trials post-covid: lessons learned, decentralised trials, and preparing for the future

- Understanding the importance of adapting trial systems for future preparedness
- Understanding the impact of technology in enabling remote and decentralised trial operations
- Discussing how DCT can improve trial efficiency and patient participation
- Discussing potential advancements in decentralised and remote trial approaches

Advancing pre-clinical talks, exploring design development, risk management, and usability in medical device development

- Discussing how certain aspects contribute to the success of medical device development
- Highlighting the importance of incorporating risk management strategies in device development
- Emphasising the value of usability considerations to enhance product performance and user experience
- Presenting case studies showcasing successful product journeys and development processes.
- Identifying when and what changes may require conducting new trials

Navigating notified bodies: looking at best practices, soft skills, and understanding the NB perspective in medical device registration

- Exploring strategies to foster productive collaborations and maximise efficiency
- Strategies for effective communication with regulatory authorities
- Exploring diverse aspects beyond clinical affairs in understanding MDR compliance

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- Highlighting successful examples of company-NB collaborations in the registration process

WORKSHOP: Soft skills, leadership strategies and project management excellence

- Optimising processes, communication, and sponsor-CRO relationships in medical device development
- Exploring the diverse skills and techniques required to manage multiple projects
- Highlighting the significance of proactive project management in MDR implementation
- Encouraging the improvement of communication practices in medical device development
- Exploring methods to enhance collaboration, information sharing, and decision-making
- Implementing strategies to optimise processes and achieve better project outcomes

Unravelling regulatory loopholes in clinical trials: understanding CE-based trials, purpose-based trials, and early feasibility studies

- Defining regulatory loopholes and their significance in clinical trial operations
- Navigating regulatory pathways for trials requiring CE compliance
- Examining trials exempt from CE requirements and the associated implications
- Exploring the intersection of academic funding and adherence to regulations
- Highlighting regulatory provisions that can be advantageous for trial sponsors

Streamlining CRO selection, effective strategies and criteria for making informed choices

- Exploring the impact of CRO selection on trial success and overall project outcomes
- Identifying essential criteria for evaluating and comparing different CROs
- Emphasising the importance of effective communication and collaboration with CRO partners
- Utilising industry insights and feedback to validate CRO performance
- Developing strategies to mitigate potential risks associated with CRO selection

Fostering positive CRO relationships: tips and best practice

- Understanding the sponsor's role in driving successful collaborations with CROs
- Identifying practices that foster productive and cooperative sponsor-CRO relationships
- Mitigating sponsor-CRO Challenges
- Addressing common challenges that sponsors pose to CROs during clinical trials
- Strategies to balance expectations and optimise sponsor-CRO interaction