# Outsourcing in Clinical Trials: Medical Devices Europe

## Munich, Germany

## 21st – 22nd February, 2023

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The 2023 programme will offer a fresh insight into the latest regulatory updates, global clinical trials, advanced technologies such as digital health and connected devices space, and more. With presentations and panel discussions on all the hottest industry trends and outsourcing challenges.

## 2023 Speakers

- **Karel Volenec**, CEO, **ELLA-CS**
- **Renata Čížková**, Head of Clinical Department**, ELLA-CS**
- **Laia Casas Papiol,** Clinical Project Leader, **Noucor Health**
- **Yana Arlouskaya**, Project Manager for Clinical Investigations, **Hartmann Group**
- **Manuel Opitz**, CEO, **Deepeye Medical**
- **Miron Tokarski,** CEO**, Genomtec**
- **Paulo Neves,** Vice President Clinical and Medical Affairs, **Xeltis**
- **Sandra Kohler,** Director of Clinical Ops, **Xeltis**
- **Claire Woodthorpe**, Chief Operating Officer**, Lightpoint Medical**
- **Pavel Kušnierik**, Head Of Regulatory Affairs, **Contipro**
- **Marta Carnielli,** Head of Certification, **TÜV SÜD**
- **Catherine Longworth**, Editor, Medical Device Network, **GlobalData**
- **Carlos Fuste**, Medical Director Spain / France, **Fidia Farmaceutici SpA**
- **Luana Clerico,** Clinical & Medical Affairs Director, **Polytech**
- **Olli Keränen**, CEO, **Medtentia**
- **Deborah - Ann Schuster,** Clinical Project Manager, Hospital Patient Monitoring, **Phillips**
- **Jana Meschede,** Project Manager**, ZEISS Medical**
- **Danish Mairaj,** Principal Engineer Medical Device Design**, Resyca**
- **Dr Camilla Fleetcroft, VP Clinical & Regulatory Affairs, Ex-MHRA Deputy Director Medical Devices. ECLEVAR UK**

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#MeddevicesEurope| @ArenaIntPharma

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## DAY ONE – TUESDAY 21ST FEBRUARY 2022

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|---|---|
| 8:00 | Registration & Refreshments |
| 8:55 | Chairman's Opening Remarks |
| 9:00 | **How to build a good relationship with your clinical trial site and how it can improve clinical trial performance**<br>• Highlighting the role that the clinical trial site plays and how to work with the site during the planning phase<br>• How to ensure a study will stand out at a clinical trial site<br>• Exploring some key advice on how to get the most out of your site<br>• Focus points moving forwards, how both CRO's and sponsors can work with a site to improve the quality of a trial<br><br>**Paulo Neves,** Vice President Clinical and Medical Affairs, **Xeltis** |
| 9:30 | **Preparing for Medical Device Approval: Strategies for Meeting US and European Regulatory Standards**<br>• Current advancements and projected schedules for EU MDR conformity<br>• Tactics for tackling significant obstacles encountered by the industry<br>• The digital transition imperative to competently abide by EU MDR regulations and surpass them<br><br>**Fiona Maini,** Senior Director, Global Compliance and Strategy**, Medidata** |
| 10:00 | **A New Phase In Good Clinical Practice: Are We Ready To Implement All Aspects Of ICO 2020 Requirements?**<br>• What are the shifts in the scope of requirements on clinical investigations?<br>• Working on the connection between Good Clinical Practice requirements together with other standards and MDR?<br>• Unveiling experience with dealing with ethics committees and competent authorities under new set of requirements<br><br>**Pavel Kušnierik,** Head Of Regulatory Affairs, **Contipro** |
| 10:30 | Morning Refreshments & Networking |

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| 11:00 | **Navigating operational challenges for start-ups starting their clinical journey**<br>• Exploring all the lessons learned from two digital health start ups<br>• Finding committed clinical partners for trials<br>• Designing trials for reimbursement, not (only) regulatory<br>• From retrospective to prospective trials, from structural to functional endpoints<br><br>**Manuel Opitz**, CEO, **Deepeye Medical** |
| 11:30 | **Post Market Clinical Follow-up: Dealing with the rising costs of clinical trials**<br>• Why collecting high-quality and relevant data from outside EU can be a cost-effective solution?<br>• How do Notify Bodies view data from outside the EU?<br>• How to ensure you are collecting high-quality and relevant data from sites outside EU?<br><br>**Chems Hachani,** CEO**, ECLEVAR MEDTECH** |
| 12:00 | **Effectively Using Patient Reported Outcomes (Pros) To Garner Quality Clinical Data**<br>• Patient Reported Outcomes: the new frontier of real-world evidence<br>• Planning and setting up a well-defined process to garner quality data from PROs<br>• Addressing ongoing challenges to improve the feasibility of patient reporting<br>• Case study – Data collected from patient survey<br>• How this survey helped to meet the evidence requirements and demonstrate the safety and performance of the device according to the clinical benefits<br><br>**Luana Clerico,** Clinical & Medical Affairs Director, **Polytech** |
| 12:30 | Lunch |
| 1:30 | **Is There Any Room For Innovation During The Era Of MDR? Ensuring Competitiveness And Innovation During Uncertain Regulations**<br>• Understanding the significant impact of MDR on innovation in medical device industry<br>• Is the innovation moving to the US: Uncovering the impact of MDR on the European market<br>• Assessing practical solutions in compliance with competent authorities and ethics committee<br><br>**Deborah-Ann Schuster,** Clinical Project Manager, Hospital Patient Monitoring, **Phillips** |
| 2:00 | **EU MDR: How Attractive is Europe for Innovation**<br>• What are the main regulatory challenges for new medical devices after EU MDR?<br>• How MedTech companies are reacting?<br>• Is CE-mark still "first choice" by start-ups and SMEs<br><br>**Enrico Perfler,** CEO**, 1MED SA** |

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| 2:30 | **A deep dive into PMCF, exploring a full cycle and the key points at each stage**<br>• Conception of an idea and moving it forward<br>• Seeking the right approval by notified bodies and expert panels<br>• Overcoming hurdles in implementation<br><br>**Aude Yulzari,** Clinical Affairs Manager, Precisis |
| 3:00 | Afternoon Networking & Refreshments |
| 3:30 | **Uncovering the benefits of remote monitoring in modern trials**<br>• Exploring the place that remote trials have in the modern clinical world<br>• Reviewing the positives and negative aspects of remote patient and data monitoring<br>• What are the operational challenges of reviewing data remotely compared to site visits<br>• Do we lose an element of trust when we take away the site relationship?<br><br>**Claire Woodthorpe**, Chief Operating Officer, **Lightpoint Medical** |
| 4:00 | **Advancing Digital Technologies in Daily Study Management**<br>• Regulatory requirements and increasing demand for digital technologies<br>• Commonly seen digital technologies for study integration<br>• Challenges implementing digital technologies<br>• The future of digital technologies<br><br>**Frank Keulen**, Director, Program Delivery, Medical Device and Diagnostics, **Premier Research** |
| 4:30 | **Is Innovation In Medical Devices Industry Dependent On Smaller Firms? Understanding The Impact Of MDR On The Dynamics Of Medical Industry**<br>• Does the high levels of bureaucracy prevent innovation driven by smaller firms?<br>• Unveiling the impact of liquidity issues on medical device innovation<br>• Is there a way out? Tackling the complexity of regulations for the sake of a more innovative medical device industry<br>•<br>**Karel Volonec**, CEO, **ELLA-CS**<br>**Renata Čížková,** Head of Clinical Department**, ELLA-CS** |
| 5:00 | **Case Study: How to bring your product out to the market through clinical trials.**<br>• Finding alternatives outside of the EU and US to start off a clinical cycle<br>• Working with first in human trials as a way to prove safety and efficacy<br>• The possibilities of working without a CRO at the early stages of clinical testing<br><br>**Olli Keränen,** CEO, **Medtentia** |
| | Chairman's Closing Remarks & Drinks Reception |

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| 5:30 | |

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## DAY TWO – WEDNESDAY 22ND FEBRUARY 2023

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|---|---|
| 8:30 | *Registration and Refreshments* |
| 8:50 | Chair's Opening Remarks |
| *9:00* | **Speaker Hosted Roundtables**<br>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 30 minutes, and delegates may attend up to 2 roundtables |
| *RT1* | **Discussing The Current Issues With Efficient Supply Chain Management For Clinical Trials Of Medical Devices**<br><br>**Sandra Kohler,** Director of Clinical Ops**, Xeltis** |
| *RT2* | **Addressing The Challenges With MDR: How to Plan the Clinical Investigation for a Medical Device To Generate an Appropriate Evidence Compliant with the New Regulation?**<br><br>**Yana Arlouskaya,** Project Manager for Clinical Investigations**, Paul Hartmann AG** |
| *RT3* | **Developing Effective Procedures For Study Risk Management In Your Medical Device Trial**<br><br>**Danish Mairaj,** Principal Engineer Medical Device Design**, Resyca** |
| *RT4* | **Developing Effective Vendor Management Tools to Oversee Your Clinical Investigation**<br><br>**Dr Hans-Heinrich Nickell,** Business Development Consultant**, Lumis Life Science Consulting GmbH** |
| *10:00* | *Morning Refreshments & Networking* |
| *10:30* | **Panel: CROs As Partners: How To Find Best CRO According To Your Requirements?**<br>• Understanding the benefits of long term partnership with CROs<br>• How can the CROs help medical manufacturers to expand their studies outside Europe? |

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| | • Ensuring efficient CRO selection: Are CROs up to date with new MDR regulations?<br>• Discovering different ways to engage with CROs<br>• Unveiling the changing CRO requirements for companies with different sizes<br><br>**Sandra Kohler**, Director of Clinical Ops, **Xeltis**<br>**Jana Meschede,** Project Manager**, ZEISS Medical**<br>**Autumn Lang,** Director Clinical Affairs, **VeriSkin**<br>**Moderator: Catherine Longworth,** Editor, Medical Device Network, **GlobalData** |
| *11:00* | **Finally obtained CE certification, what is needed next?**<br><br>• How to collect PMCF clinical data for your device to stay CE marked on the market.<br>• What are your options?<br><br>**Wouter Mattheussens,** Junior Clinical Project Manager, **Qserve, Quentin MD** |
| *11:30* | **Discussing the IVDR state of play with a focus on the challenges of Small/Medium Enterprises**<br>• Providing a regulatory update on the current field<br>• Sharing the current status of transition and how the industry is doing<br>• Focusing on the challenges that SMEs face in these trying times<br><br>**Marta Carnielli,** Head of Certification, **TÜV SÜD** |
| *12:00* | **Defining Sample Size for Pre- and Post-Market Clinical Activities**<br>• How to justify the sample size<br>• How to prepare for sample size calculation<br>• How clinical experience influences sample size<br><br>**Jón I. Bergsteinsson,** Founder**, SMART-TRIAL by Greenlight Guru** |
| *12:30* | *Networking Lunch* |
| *1:30* | **Case Study - How to improve the outcome of clinical performance studies of IVD products by meeting EN 62366 12015 A12020 standard**<br><br>• Discussing some of the main challenges of meeting the new standards with IVD products<br>• How to get the most out of your product and ensure that the user is able to work with the device easily<br><br>**Miron Tokarski,** CEO**, Genomtec** |
| *2:00* | **IVDR and Companion Diagnostics Challenges in Clinical Studies**<br>• Review the conformity assessment procedure for companion diagnostics<br>• Discover the when and how of clinical performance studies, including clinical evidence and submission requirements<br>• Learn sponsor responsibilities within a companion diagnostics clinical performance study<br><br>**Mariangela Sociale,** Regulatory Consultant, **IQVIA Medtech** |

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| *2:30* | **Growing Trends on the Use of RWE for Clinical Development**<br>• Understanding how the regulatory landscape is evolving, with growing acceptance of RWE by regulators around the world<br>• The increasing usage of Real World Evidence and Real World Data will be explored in a global context<br><br>**Carlos Fusté,** Medical Director Spain / France, **Fidia Farmaceutici SpA** |
| *3:00* | **Fireside Chat: Tackling The Reasons For A Much Needed Change: Benefits Of Inclusive Terminology For Patient Documentation In Med-Device Clinical Trials:**<br>• A look at current ISF patient documentation policy: Is it really inclusive?<br>• How does a gender bias affect the medical device clinical trials?<br>• Understanding the benefits of an inclusive terminology for medical devices<br><br>**Laia Casas,** Clinical Project Leader**, Noucor Health** |
| *3:30* | *Close of Conference* |

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