ARENA
INTERNATIONAL EVENTS GROUP

CLINICAL OPERATIONS IN ONCOLOGY TRIALS EUROPE 2023

Munich, Germany

28th – 29th November 2023

Key Speakers:

Michael Forstner, Global Head of Clinical Safety and Pharmacovigilance, BBU, Biogen International GmbH
Sumeet Ambarkhane, Chief Medical Officer, Alligator Bioscience AB
Robert Dobosz, Director Clinical Trials Solutions, Ryvu Therapeutics
Sonnika Lamont, Analyst, GlobalData
Nicolas Schneider, Director, Clinical Operations and Alliance Management, ITM Isotope Technologies Munich SE
Monika Kouba, Vice President Head Clinical Operations, T-Knife Therapeutics
Stefanie Schier-Mumzhiu, Director Global Program Operational Head, MorphoSys
Andriy Krendyukov, VP Medical Affairs and Clinical Development /PhD fellow at Mannheim University (Innovation and Management)
Malte Oppermann, Senior Director Clinical Operations, Medigene
Pauline Frank, Patient Engagement and Insights Director, Oncology Worldwide Medical Affairs, Novartis
Cesare Spadoni, Founder and COO, Oncoheroes Biosciences
Stefano Ferrara, Director of Clinical Science, BeiGene
Daniela Duffett, Senior Solutions Consultant, Suvoda
Claudia Hesselmann, PhD, Founder & CEO, ARENSIA
Praveen Huber, Director, Head of Alliance and Project Management, Leukocare
Jessica Cordes, Clinical Operations Expert
Rachel Horovitz, VP, Medidata AI Strategy
Achilleas Zaras, Senior Manager, Solution Consulting, eClinical Solutions
Brian Deighan, Program Director, Teckro
Jane Bentley, VP Oncology Therapeutic Strategy and Innovation, Syneos Health

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Clinical Operations in Oncology Trials Europe

Munich, Germany 28th - 29th November 2023

	Clinical Operations in Oncology, Munich **Day One | 28th November 2023**
8:15	Registration and Refreshments
8:50	Chair's Opening Remarks **Sonnika Lamont**, Analyst, **GlobalData**
9:00	**New technologies, old problems** • Examining the fundamental shifts that have emerged in recent years in the realm of oncology clinical studies • Highlighting the key areas impacted in trial design and what the current major challenges are facing the industry • Recognizing the importance of prioritizing patients' needs, experiences, and perspectives in clinical trials • Lessons learned in the past few years and how we as an industry can adapt and improve **Stefano Ferrara,** Director of Clinical Science, **BeiGene**
9:30	**Precision technologies for precision trials: streamlining patients', sites' and sponsors' trial experience** • Specific clinical trial operations challenges created by the uncertainties inherent in oncology trials • How eConsent, IRT and eCOA can be set up to maximize sponsors' operational efficiency and minimize stress on clinical teams • Oncology case studies from Suvoda's portfolio to demonstrate how flexible IRT functionalities can help novel trial designs in oncology trials run more smoothly and streamline bringing medications to market • The implications of future innovations in cancer treatment and how that may impact oncology trials and the technology designed to support them **Daniela Duffett,** Senior Solutions Consultant, **Suvoda**
10.00	**Innovative Approaches for Patient Recruitment in Oncology Trials** • Strategies for improving patient awareness and engagement in oncology trials through effective communication and outreach campaigns • Leveraging social media, patient registries, and community networks for targeted patient recruitment • Role of patient advocacy groups and patient-centric trial design in enhancing recruitment rates • Addressing barriers and challenges in recruiting diverse patient populations for oncology trials **Stefanie Schier-Mumzhiu,** Director & Global Program Operational Head, **MorphoSys**

10:30	*Morning Refreshments and Networking*
11:00	**Advances in Real-World Data and Evidence (RWD/RWE) integration in oncology trials** • Discussing the pros and cons of using RWD/RWE in all stages of a clinical trial • Methods for capturing, analyzing, and integrating RWD/RWE in oncology trial design and decision-making • Regulatory guidelines and considerations for utilizing RWD in oncology trials • Examples of integration of RWE to support oncology trials **Michael Forstner,** Global Head of Clinical Safety and Pharmacovigilance, BBU, **Biogen International GmbH**
11:30	**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 **Claudia Hesselmann**, PhD, Founder & CEO**, ARENSIA**
12:00	**Investigating the patient perspective for better patient experience and recruitment in Oncology Trials** • Key challenges and barriers for patient participation in clinical trials – including patient & HCP awareness and engagement, and approaches to more inclusive clinical trial design/conduct • Solutions proposed by patients based on actual trial experience • In-person vs digital patient preferences • Role and expectations of patient organizations in patient-centric oncology trials **Pauline Frank**, Patient Engagement and Insights Director, Oncology Worldwide Medical Affairs, **Novartis**
12:30	*Lunch and Networking*
13:30 	**Workshop : What small and mid-size Pharma/Biotechs could do to help foster patient collaboration in Oncology Trials** • Working in group format to share ideas and needs from a smaller company perspective on what you require from patients • What you need to do internally and externally to foster patient collaboration – identify the gaps, challenges, resources, services and skills required

	• How can stakeholders in clinical research and development (Pharma/Biotech, CRO, investigators, healthcare providers, etc) have an influential part to play in the overall patient experience **Pauline Frank**, Patient Engagement and Insights Director, Oncology Worldwide Medical Affairs, **Novartis**
14:15	**Running up that hill: accelerate cycle times & reach patients faster with elluminate** • Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety • Improved study oversight with a holistic view of risk across all data sources • 50 out-of-the-box visualizations to support supports cross-study analysis for deeper insights with self-service access to clinical and operational analytics • Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles **Achilleas Zaras**, Senior Manager, Solution Consulting, **eClinical Solutions**
14:30 	**Panel: Analysing key functions to reduce study start-up time and bring your drug to market quicker** • Preparing for possible hurdles which can often slow down trials and in turn, result in increased costs • Identifying innovative technologies that can assist in the swift startup of a clinical trial • Sharing experiences in trial design, the do's and don'ts of early-stage trials **Chair: Sumeet Ambarkhane,** Chief Medical Officer, **Alligator Bioscience AB** **Andriy Krendyukov,** VP Medical Affairs and Clinical Development /PhD fellow at Mannheim University (Innovation and Management) **Stefano Ferrara,** Director of Clinical Science, **BeiGene** **Jessica Cordes,** Clinical Operations Expert **Daniela Duffett,** Senior Solutions Consultant**, Suvoda**
15:00	15 Minute Tech Spotlight
15:15	*Afternoon Refreshments and Networking*

15:45	**Paediatric Oncology Clinical Development: Operational challenges and opportunities** • When To Approach Regulators: Importance Of Early Interaction With Regulators • Understanding The Role Of International Networks: Where Do We Find Investigators? • Unveiling The Differences: First In Human vs. First In Child • Uncovering Ways To Plan A Study In A Heterogeneous Population • Formulation Issues: How Do We Tackle It? • Assessing Potential Rewards For Paediatric Regulatory Approval **Cesare Spadoni,** Founder and COO, **Oncoheroes Biosciences**
16:15	Session Reserved for Precision for Medicine
16:45	**Case Study: A modern T-Cell Therapy study and how to plan from preclinical and beyond** • Highlighting the key differences when creating a novel trial in this indication • What steps to avoid when creating your study protocol • Finding a partner for your T-Cell study • Inevitable changes in study design and how best to adapt at the worst times **Monika Kouba,** Vice President Head Clinical Operations**, T-Knife Therapeutics**
17:15	Chairman's Summation and Drinks Reception

	Clinical Operations in Oncology, Munich **Day Two | 29th November 2023**
8:30	Registration and Refreshments
8:50	Chair's Opening Remarks
9:00	**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. 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**.**
Roundtable 1	Navigating trial budgets in times of uncertainty, strategies for effective management **Jessica Cordes,** Clinical Operations Expert
Roundtable 2	Improving patient enrolment in new trials, enhancing your trial uptake **Sumeet Ambarkhane**, Chief Medical Officer, **Alligator Bioscience AB**
Roundtable 3	Selecting the ideal CRO for your study: ways to create an effective partnership **Praveen Huber**, Director, Head of Alliance and Project Management, **Leukocare**
Roundtable 4	Addressing patient diversity in oncology trials **Jane Bentley, VP Oncology Therapeutic Strategy and Innovation, Syneos Health**
10:00	*Morning Refreshments and Networking*
10:30	**Identifying CROs / Vendors as a small biotech, how to ensure you pick the right vendor** • Finding the right solution for your companies needs • Ensuring your partner is interested in working with a smaller biotech • Working alongside both smaller and larger vendors for overall success • Managing your partners after a deal, how to ensure a mutually beneficial relationship **Nicolas Schneider,** Director, Clinical Operations and Alliance Management, **ITM Isotope Technologies Munich**
11:00	**Demystifying Site Engagement: Best Practice Communication and Enhanced Oversight** • Recognize the barriers: Increasingly complex protocols, a lack of answers, frustrating portals… are just a few of the known site challenges. • Shift your focus: Sponsors and study teams know that PIs and site staff are overwhelmed. Are you ready to think differently about site engagement? • Prioritize authenticity: Hear how authentic, enduring site relationships are a game-changer for complex oncology trials • Transform your approach: Learn how sponsor study teams are embracing communication best practices and pursuing a higher standard of study oversight **Brian Deighan**, Program Director, **Teckro**
11:30	**Negotiating with CROs as a small biotech; ensuring how to get the most value out of your contracts** • Collaborating with your partner to achieve mutual benefits

	• How to qualify your vendors as a small company • How to safely proceed with contracts as a small company • Ensuring that your CRO is taking accountability **Robert Dobosz,** Director Clinical Trials Solutions, **Ryvu Therapeutics**
12:15	**Optimising Study Planning to Drive More Efficient and Diverse Oncology Trials** • Overview of complexities in the oncology clinical trial landscape today, current industry trends, and data that can be leveraged to address challenges • Methods to meet regulatory requirements around diversity while taking into account operational needs • Tools pharmaceutical companies and CROs can utilize to leverage operational and clinical data along with patient insights and achieve clinical trial and diversity goals **Rachel Horovitz**, VP, **Medidata AI Strategy**
12:45	*Lunch Break & Apple Prize Draw*
14:15	**Dealing with new expectations: impact of IVD regulation changes for early stage clinical trials** • Highlighting the key challenges to be faced in clinical trials which incorporate an IVDs • Considerations Strategies for design planning when running a trial requiring the use of IVD's • Exploring the challenges faced by smaller biotechs in optimizing trial timelines and budgets with accordance to new regulations **Malte Oppermann**, Senior Director Clinical Operations, **Medigene**
14:45	Session Reserved for Event Sponsor
15:15	**The Landscape of Precision and Personalized Medicine (PM) Clinical Trials** • The competitive landscape of PM indicating the top industry sponsors, CROS, non-industry sponsors, regions and countries leading the way • The research landscape of PM included the top therapy areas, indications, drugs in PM clinical trials • Use of virtual components in PM studies

	• Leading causes of trial termination/suspension/withdrawal (Low accrual, financial, business/strategic decision) **Sonnika Lamont**, Analyst, **GlobalData**
15:45	Chairman's Summation and Close of Conference