ARENA
INTERNATIONAL EVENTS GROUP

OUTSOURCING IN CLINICAL TRIALS DACH 2023

Movenpick Zurich Hotel Regensdorf, Switzerland

21st – 22nd November 2023

Outsourcing in Clinical in Trials DACH

Movenpick Zurich Hotel Regensdorf, Switzerland

21st November – 22nd November 2023
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'Providing a specific platform for the clinical trials community in the DACH region to develop innovative clinical operations and outsourcing strategies'

After a hugely successful 2022 conference, we are pleased to announce that the Outsourcing Clinical Trials DACH event will be returning to Zurich on 21st - 22nd November 2023. This exclusive event brings together attendees from established pharma, large and small, alongside biopharmaceutical companies and gives opportunity to dive into the operational challenges and innovations in clinical development found within the DACH region.

2023 Speakers

Giulia Rancati, Ph.D. Market Solutions Lead for R&D, Roche
Rolf Banholzer, Global Head Development Operations QA, Novartis Pharma
Sonnika Lamont, GlobalData Analyst – Trials Intelligence, GlobalData
Domenico Merante, Therapeutic Area Clinical Lead Nephrology, Rare and Orphan Diseases, CSL Vifor
Henrik Schou, Vice President, Global Head Evidence Generation, VIFOR Pharm
Cornelia Baumgartner- Diolaiuti, Clinical Operation Manager, NBE-Therapeutics
Dr. Claudia Hesselmann, Founder and CEO, ARENSIA
Dr. Frank Richard, MD, MBA, Senior Medical Director, Sotio Biotech
Benoît Marchal, Founder & CEO, PicAps (Patient in control, anonymity privacy secure)
Sol Yates, Associate Director, European Regulatory Affairs, Shionogi Europe
Leon Hooftman, Chief Medical Officer, ISA Pharmaceuticals
Dr. Nicolas Schneider, Director Clinical Operations and Alliance Management, ITM Isotopen Technologien München
Robert Corbé, Evidence Delivery Associate Director, AstraZeneca
Edward Walsh, Senior Director, Regional Clinical Trial Operations Europe, Seagen
Eric Hajjar, Associate Director, Global Medical Research Operations, Biogen
Tomasz Kowalczyk, PharmD, Regional Director, Clinical Sites Liaison Consultant, Agenus
Magdalena Gołos, PhD, Head of Clinical Study Management Team, Polpharma S.A.
Pauline Frank, Patient Engagement and Insights Director, Oncology Worldwide Medical Affairs, Novartis
Francois Curtin, CMO/Medical Director for Personalized Health Programmes, Swiss Federal Institute of Technology Zurich
Prof. Dr. Med. Andreas Trojan, Co-Founder and CMO, Mobile Health AG, Medical Oncologist and Leading Physician, Breast Center Zürichsee
Claudine Rigal, PharmD, ClinBio Vice President, Global Testing Services, Labcorp

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21ST – 22ND NOV | Movenpick Zurich Hotel Regensdorf, Switzerland

Outsourcing in Clinical Trials DACH

DAY 1 – Tuesday 21st November 2023

8:00	**Registration and refreshments**
8:40	**Chairperson's opening remarks** **Dr. Frank Richard**, MD, MBA, Senior Medical Director, **Sotio Biotech**
8:45	**KEYNOTE PRESENTATION with Q&A** **DACH REGULATIONS** **Revision of the guidelines on good clinical practice** ICH E6 (R3) guideline has been released for consultation on the 19th May 2023 - this an opportunity to review the differences between the current version and the draft guideline. **Natalia Buchneva,** Risk Management Lead, Clinical Data & Innovations, UCB and European Federation of Pharmaceutical Industries and Associations Working Team Member
9:30	**Clinical Trial Information System(CTIS) Unveiled: Helping Biotech/Pharma to Streamline Regulatory processes in EU** • Success Stories and Lessons Learned in CTIS Implementation • Real-World Insights: Case Studies that Unravel the CTIS Landscape **Diana Filipescu,** Business Development Manager, EastHORN **- A Novotech Company**
10:00	**Solving the Clinical Data Challenge** Patient centricity requires data centricity to integrate and manage a growing variety of data sources. The challenge lies in integrating and managing those sources to deliver high-quality data. How do we overcome this? • Moving from manual, reactive data review and cleaning to proactive, risk-based approaches based on integrated data • Providing clinical data management and monitoring teams with workflows and analytics that support their day-to-day functions • Leveraging technologies that incorporate AI to automate manual tasks and identify potential issues sooner **Andy Gurd,** Senior Director, Product Marketing, **Medidata**
10:30	**Morning refreshments and networking Sponsored by Aixial**

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	STREAM A: Clinical Operations	STREAM B: Innovation & Technology
	Chair: ***Dr. Frank Richard****, MD, MBA, Senior Medical Director,* ***Sotio Biotech***	*Chair:* ***Sonnika Lamont****, GlobalData Analyst – Trials Intelligence,* ***GlobalData***
11:00	**Strategies for Site Selection;** ***enhancing one's knowledgebase for the best move forward*** • Robust feasibility for clinical trials; from protocol design to site selection • Access to sites and site selection within the DACH region • Analysing whether to choose a full-service provider or a network of providers, is there any rational behind this decision making • Looking into the driving force of site selection; *finances, talent, internal resources, competing studies at sites, investigator interests* **Ulrike Grimm,** Head of Project Management, Opterion Health AG	**Presentation and Q&A** **The 2023 EMA Guidance on computerized systems and electronic data in clinical trials: A clinical trial-risk-centric review and perspective** *In this session, the new EMA guidance doc will be discussed as follows:* • Purpose and scope: Is it a technical guidance on computerized systems, tools, data, or is it more? • Principles vs requirements: How can we deal with it? • The pro's and con's from a clinical trial centric point of view: ○ How can we benefit from this guidance? ○ What are the pain-points? • Can we learn something new on Health Authority inspection readiness? ○ E.g. by applying a hierarchical approach to Clinical trial risk management and the role of technology and computerized systems? ○ Are sponsor's and CROs structured well enough to comply with the guidance? *The session will address elements of clinical trial data-flow between CROs and sponsors, data quality management and assurance and thoughts on (business) audit trail review(s)* **Rolf Banholzer,** Global Head Development Operations QA, **Novartis Pharma**
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	*Session Reserved for Event Sponsor*

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	• 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	**Update on EHDS Regulative process, consequence for clinical trial** • What is European Health Data Space? • Result of legislative process • Consequence for RWD for clinical trials • Consequence for clinical trial data sharing **Benoît Marchal**, Founder & CEO, PicAps (Patient in control, anonymity privacy secure)	**Bridging the gap from RCTs through Real World Evidence into clinical practice; exploring how to improve patient focussed disease management** • Relevance of generating Real World Evidence data in rare ad orphan kidney diseases • The urgent need to access main clinical data, including those from still unpublished clinical studies • Bridging an existing gap between randomized clinical trials results and clinical practice evidence for people affected by rare and orphan kidney diseases • Development of 'personalized' treatment algorithms to improve patient-focused outcomes in patients suffering from these diseases ***Domenico Merante**, Formerly Clinical Research Lead TA Orphan-Nephrology, CSL Vifor* ***Henrik Schou,** Formerly, Vice President, Global Head Evidence Generation, **VIFOR Pharm***
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 Trials • Case Studies **Dr. Claudia Hesselmann,** Founder and CEO, ***ARENSIA***	**15-minute Tech Spotlight** **Accessibility functionalities: Using scientific validation to maintain data integrity in clinical trials** • Share results of research based on FDA demand for greater patient accessibility to clinical trials • Review an industry-first clinical research study on the ePRO instrument equivalence across accessibility features and patient communication modality preferences • Demonstrate how to ensure data integrity can be maintained once accessibility functionalities are implemented **Valdo Arnera, M.D.,** Medical Scientific Advisor and General Manager, Geneva Office, **Clario**

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		12:45 15-minute Tech Spotlight **Re-discovering the patient journey in decentralized clinical trials** • Role of patient-centered, dynamic, and intuitive symptom tracking as well as corresponding ePROs in decentralized clinical trial settings • Medidux patient platform : Accurate, timely, and integrated data collection ○ Enrichment of data through IoT wearables & laboratory parameters • Medidux reports: Enabling efficient patient-physician collaboration ○ Ensuring ePRO reliability through patient-physician symptom review ○ Towards an Early Warning System in "patient at home" settings **Prof. Dr. Med. Andreas Trojan,** Co-Founder and CMO, Mobile Health AG, Medical Oncologist and Leading Physician, Breast Center Zürichsee
13:00	**Lunch and networking**	
14:00	**Case Study – Training and engagement of study volunteers for the study execution – key success factor** • How to find volunteers? • Appropriate training of volunteers in order to standardize administration of the product • Looking at study design – appropriate procedures • Considering experienced CRO **Magdalena Gołos, PhD,** Head of Clinical Study Management Team, **Polpharma S.A.**	**How does Regulation Help or Hinder Innovation?** • Looking into aligning regulation with innovation at the pre-conceptual stage • Discussing the regulatory environment for innovative products or services • Examining the relationship between innovation, creativity, and regulations. • Looking at what our selling points as a region are and what can be improved **Tomasz Kowalczyk,** PharmD, Regional Director, Clinical Sites Liaison Consultant, **Agenu**

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14:30	**Where Science and Operations Meet: Delivering Complex Clinical Trials** • Disruptors, the new normal and challenges ahead • Collaborating in new ways to create life-changing approaches • The intersection of science and operations: a case study **Claudine Rigal,** PharmD, ClinBio Vice President, Global Testing Services, **Labcorp**	*Session Reserved for Event Sponsor*
15:00	**INTERACTIVE SESSION** **Targeted approach in dose selection and development in oncology – clinical and regulatory aspects** • FDA Project Optimus and ESMO Guidelines • Systemic approach to increase R&D productivity • AI & Machine Learning transforming drug development in future **Dr. Frank Richard**, MD, MBA, Senior Medical Director, **Sotio Biotech**	**Fireside Chat** **Data Generation in Post Marketing setup** • Spectrum of medical research possibilities, from Independent Investigator Sponsored Research to Collaborative to fully company sponsored. • Defining areas of interest, Scientific data gap and strategies from global – regional - local • Setting up registries; opportunities and challenges when working with RWE • Tracking and reviewing Performance and outcomes **Moderator: Sonnika Lamont**, GlobalData Analyst – Trials Intelligence, **GlobalData** **Eric Hajjar**, Associate Director, Global Medical Research Operations, **Biogen**
15:30	**Afternoon refreshments and networking**	
16:00	**Managing Teams Successfully in new modern remote working environment** • How to build a hybrid team • Challenges & Successes to meet upfront ensuring productivity • Keeping team motivated and driven • Always thinking ahead but being in the moment **Edward Walsh, Senior Director, Regional Clinical Trial Operations Europe, Seagen**	**The Landscape of Precision and Personalized Medicine (PM) Clinical Trials:** *This presentation will highlight:* • 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)

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		Sonnika Lamont, GlobalData Analyst – Trials Intelligence, **GlobalData**
16:30	**Panel: Reversing the Conversation: What the clinical trial industry really wants from its service providers** *We've all had to sit through several 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: ***Dr. Frank Richard****, MD, MBA, Senior Medical Director,* ***Sotio Biotech*** Panellists: **Malgorzata Szerszeniewska,** Head of Operations Europe, **Novotech** **Natalia Buchneva,** Risk Management Lead, Clinical Data & Innovations, UCB and European Federation of Pharmaceutical Industries and Associations Working Team Member **Eric Hajjar**, Associate Director, Global Medical Research Operations, **Biogen**	
17:15	**Chairperson's closing remarks** **Dr. Frank Richard**, MD, MBA, Senior Medical Director, **Sotio Biotech**	
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Outsourcing in Clinical Trials DACH

DAY 2 – Wednesday 22nd November 2023

8:00	**Registration and refreshments**
8:50	**Chairperson's opening remarks** **Dr. Frank Richard**, MD, MBA, Senior Medical Director, **Sotio Biotech**
9:00	**PANEL** **Pinpointing how the DACH region can "lobby" to enhance our leadership role in global clinical trials** • Exploring maintenance and growth of research delivery • Unlocking costing for commercial contract research • Addressing localised site selection and accessibility • Concentrating on streamlining DACH processes of running trials with those globally **Moderator:** ***Dr. Frank Richard****, MD, MBA, Senior Medical Director,* ***Sotio Biotech*** **Panellists.** **Dr. Nicolas Schneider,** Director Clinical Operations and Alliance Management, **ITM Isotopen Technologien München** **Robert Corbé,** Evidence Delivery Associate Director, **AstraZeneca** **Francois Curtin,** CMO/Medical Director for Personalized Health Programmes, **Swiss Federal Institute of Technology Zurich**
9:45	**How a combined CTMS and eTMF will optimize the Collaboration across Clinical Study Teams!** The digitalization of clinical trials and operations has been at the forefront of pharmaceutical and med-tech modernization strategies over the last two decades. However, many companies are still struggling to digitize their clinical operations for various reasons: old habits, fear of adopting, rolling out and maintaining an electronic solution, potential delays on deadlines, or concerns about quality, data security and compliance. During this presentation Harald and Jan would like to share with you how a combined CTMS and eTMF will not only optimize the overall trial and regulatory document management across the boarders but as well optimize the collaboration with the involved site organizations. **Jan Nielsen**, Community Manager Life Sciences, BSI Life Sciences **Harald Wagner,** Director Clinical Operations, AMS Advanced Medical Services
10:15	**Experience with EU Clinical Trial Regulation – Updates from January 2023** • Submitting a study within the framework of the new regulations, what are the differences? • Understanding the updated CTR guidelines to enable sponsors to submit one application and gain approval to run a clinical trial in several European countries • Working with the CTIS portal for trial applications • Examples and common issues • Sharing experiences with various Health Authorities

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	Sol Yates, *Associate Director, European Regulatory Affairs,* ***Shionogi Europe***
10:45	*Morning refreshments and networking*
11:15	**Overview of AI applications for clinical trials, what are today's possibilities?** This presentation offers a concise exploration of current AI applications to augment and accelerate clinical trials. By highlighting tangible areas of implementations, the overview underscores the transformative potential across diverse aspects of clinical research, and how AI can increase efficiency, accuracy, and innovation within this critical domain. **Giulia Rancati, Ph.D.** Market Solutions Lead for R&D, **Roche**
11:45	**Building CRO Relationships. What are the critical factors to consider when procuring from a CRO?** • Choosing the right CRO for you – one or many? • Ensuring your CRO is fit for purpose • Establishing common ground with your CRO • Ascertaining the critical factors to think about when you collaborate with a CRO • Exploring how the concept of Co-development between Pharma & CRO is working best • Overcoming the differences between Pharma & CRO business models to work in harmony • Underlining the factors which could be limiting what choice you make? **Cornelia Baumgartner- Diolaiuti,** Clinical Operation Manager, **NBE-Therapeutics**
12:15	**Digitalization in clinical trials, a 360 view** • Presenting on how to digitalize clinical trials in e.g. endpoints, and study designs • Highlighting the possibilities that digital trials bring, whilst moving away from the common brick-and-mortar sites • Discussing the rigorous standards and scientific integrity required by regulators, whether a regular brick-and-mortar trial or a digital trial • How we tend to focus too much on technology when it's actually the processes for the patients and the sites that matter even more • Major points to consider in designing digital trials; building blocks and practical examples to best prepare you to meet the needs of regulators whilst keeping the patient and sites front of mind **Sverre Bengtsson,** Co-Founder, Viedoc

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12:45	**Lunch and networking**
13:45	**Baking patient-centricity into clinical development and trial design** • Discussing the personal experiences of the patient • Considering the patient's voice during study planning • Defining 'patient centricity' • Exploring how inclusion in trials and boosting of diversity may impact recruitment and retention • Patients' roles in the reconceptualising of hybrid trials • Gender bias in trial design and preclinical R&D and how this plays out in inclusion / exclusion criteria • What are the benefits of using multi-stakeholder approaches **Estelle Jobson,** EUPATI Fellow and **Patient Expert**
14:15	*Session Reserved for Syneos Health*
14:45	**Safety collection in non-interventional studies** • Non-interventional vs. Low-interventional studies • Primary data collection vs. Secondary use of data • Interpreting GVP • Limitations and possibilities in non-interventional study design **Robert Corbé,** Evidence Delivery Associate Director, **AstraZeneca**

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15:15	**Afternoon refreshments and networking with Prize Draw**
15:45	**PROBLEM-SOLVING ROUNDTABLE DISCUSSIONS** *During the roundtable discussion session, the conference hall will be divided into two '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 in oncology trials. After 30 minutes, delegates will have the opportunity to swap and choose a different table, and each roundtable will run twice.*
	ROUNDTABLE 1: Discussion around the consultation release of ICH E6 (R3) guideline **Natalia Buchneva,** Risk Management Lead, Clinical Data & Innovations, UCB and European Federation of Pharmaceutical Industries and Associations Working Team Member
	ROUNDTABLE 2: How can clinical trial designs accelerate oncology drug development? **Francois Curtin,** CMO/Medical Director for **Personalized Health Programmes, Swiss Federal Institute of Technology Zurich**
	ROUNDTABLE 3: What do patients want for a better clinical trial experience, and how can we address the gaps and expectations? **Pauline Frank,** Patient Engagement and Insights Director, Oncology Worldwide Medical Affairs, **Novartis**
	ROUNDTBALE 4: A discussion addressing Site Burden in Clinical Trials **Dr Nicole Woik,** Global Clinical Operations – Clinical Country & Site Lead, **Biogen**
16:45	**Chairperson's closing remarks** **Dr. Frank Richard**, MD, MBA, Senior Medical Director, **Sotio Biotech**

END OF CONFERENCE

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