

# INNOVATION X BY ARENSIA

## CHANGE

THE DOLDER GRAND

PRESENTED BY ARENSIA



**DR. CLAUDIA HESSELMANN, PhD**  
Founder & CEO



**DR. EVGENY LEVENKO, MD, PHD**  
Country Manager, Ukraine

### OUR PANELISTS



**FREDRIK ELG**  
Managing Director  
Pracipio Ltd



**NICOLA PITTNER**  
Director, GCO Cluster Head Emerging Markets, EMEA  
BeiGene Switzerland GmbH



**MARTA PEREZ-NOGUERA**  
Director Clinical Operations EU  
Luzsana Biotechnology Europe AG



**SEZCAN OZTURK**  
Vice President and Head of Europe  
Luzsana Biotechnology Europe AG



**DR. FRANK RICHARD, MD, MBA**  
Vice President Medical  
Heidelberg Pharma AG

### AMONG THE TOPICS

- 🏁 Strategic considerations for the efficient conduct of POC trials: case studies budget and timelines
- 🏁 Next frontiers in cell & gene therapies
- 🏁 Patient-oriented trial designs incorporating AI advancements
- 🏁 Updates on the regulatory environment in the European Union

# 12<sup>th</sup> MAY 2025 ZÜRICH

## PROOF-OF-CONCEPT: BOLD MOVES, BIG WINS AND KEY LESSONS

The world is evolving at an extraordinarily fast pace. Technological advancements are impacting humanity at an unprecedented scale. Staying competitive requires flexible, innovative thinking combined with adaptability and rapid execution of business needs.

Clinical Drug Development is facing complex challenges caused by turbulent events in politics, disruptions of supply chains, human resource shortages. The application of innovative strategies and bold planning has proven that clinical trials can maintain necessary flexibility and can be executed on time and within budget.

Following our annual tradition, ARENSIA is excited to gather highly experienced clinical research executives during a one-day face-to-face event to exchange a frank discussion of these challenges.

A highly esteemed panel of speakers with in-depth expertise in early-phase drug development has been assembled to share their experiences from recent case studies covering regulatory, operational, clinical, and patient viewpoints.



PARTICIPATION BY INVITATION ONLY  
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# AGENDA

## AT-A-GLANCE

<b>REGISTRATION BREAKFAST</b>	<b>08:30 09:15</b>	<b>12:30 13:30</b>	
<b>WELCOME INTRODUCTION</b>	<b>09:15 09:30</b>	<b>13:30 14:15</b>	<b>NEXT LEVEL OF RESEARCH COMPLEXITY: CASE STUDIES FROM ARENSIA CLINICS</b>
<b>WHY SO SLOW? INSIDER INSIGHTS FROM THE CLINIC FLOOR ON FAST-TRACKING PROOF-OF-CONCEPT TRIALS</b>  PATIENTS AS INNOVATORS: FASTER, SMARTER TRIALS REGULATORY PATHWAYS: CHALLENGES & OPPORTUNITIES THE RIGHT TEAM: POWERING SPEED & EFFICIENCY	<b>09:30 10:00</b>	<b>14:15 15:00</b>	<b>OUTSHINING COMPETITION WITH A SMART REGULATORY STRATEGY</b>  MASTERING CTIS SUBMISSIONS FOR SEAMLESS APPROVALS TURNING REGULATORY DIFFERENCES INTO ADVANTAGES VENDOR SELECTION: A CHALLENGE OR KEY TO SUCCESS?
<b>OPTIMIZING SITE SELECTION FOR CAR-T AND GENE THERAPY TRIALS</b>  ROBUST FEASIBILITY ASSESSMENTS FOR BEST SITE SELECTION ENHANCING SITE CAPACITY FOR ADVANCED THERAPIES BEST PRACTICES FOR MANAGING AES: CRS, ICANS, AND BEYOND	<b>10:00 11:00</b>	<b>15:00 15:15</b>	
	<b>11:00 11:30</b>	<b>15:15 16:00</b>	<b>INNOVATIVE STUDY DESIGN &amp; ENDPOINTS FOR POC TRIALS</b>  BALANCING INNOVATION WITH OPERATIONAL FEASIBILITY MASTERING THE SELECTION OF OPTIMAL ENDPOINTS ENSURING QUALITY IN COMPLEX STUDY DESIGNS
<b>PANEL DISCUSSION: SHAPING THE FUTURE OF CLINICAL TRIALS</b>  HARNESSING AI FOR SMARTER, MORE EFFICIENT TRIALS FINANCING INNOVATION AMID INDUSTRY UNCERTAINTY BUILDING A SUSTAINABLE PIPELINE FOR LONG-TERM SUCCESS	<b>11:30 12:30</b>	<b>16:00 16:15</b>	<b>GENERAL Q&amp;A REVIEW OF THE DAY</b>
		<b>16:15 17:30</b>	

# SPEAKERS & PANELISTS

09:30  
10:00



**DR. CLAUDIA HESSELMANN, PhD, FOUNDER & CEO | ARENSIA EXPLORATORY MEDICINE**

Claudia, a chemist by training, with a PhD in molecular biology has twenty years of expertise in the early phases of drug development. Her experience includes co-founding and holding management positions in various companies. Claudia's extensive background and social acumen, along with her first-hand knowledge of the industry, led to co-found ARENSIA Exploratory Medicine in Düsseldorf, Germany.

10:00  
11:00



**FREDRIK ELG, MANAGING DIRECTOR | PRACIPIO LTD**

Fredrik has more than two decades of experience in strategy and planning support and together with the wider team at Pracipio is recognized, among other services, as a go-to-experts for demand and capacity planning for ATMPs, including autologous cell and gene therapies, such as CAR-Ts, and other on demand manufactured advanced therapeutics such as radiopharmaceuticals.

11:30  
12:30



**NICOLA PITTNER, DIRECTOR, GCO CLUSTER HEAD EMERGING MARKETS, EMEA | BEIGENE SWITZERLAND GMBH**

Nicola is a highly dynamic clinical operations leader with over 17 years' experience leading teams across both the APAC and EMEA regions within big pharma (Roche) and over the last 5 years, at BeiGene. At BeiGene, Nicola successfully established the strategy to support region EMEA portfolio growth by critically assessing cluster capabilities, expanding to new markets and growing talent pools. Under her leadership, her team of talented individuals spread across 16 markets has been responsible for approximately 30% of the enrolment contributions to the regional portfolio of global clinical trials in EMEA during 2024, which represents a diverse number of new drugs and studies in both early and late phase. Nicola's innovative and forward-thinking approach to clinical trial delivery, along with her talent for articulating her vision to her teams, lends itself well to successful portfolio delivery in a highly diverse and complex environment.

11:30  
12:30



**MARTA PEREZ-NOGUERA, DIRECTOR CLINICAL OPERATIONS EU | LUZSANA BIOTECHNOLOGY EUROPE AG**

A results-driven Clinical Operations Director with 15+ years of experience leading global clinical trials in CROs and pharmaceutical companies. Expertise in strategic planning, vendor management, and regulatory compliance, ensuring efficient and high-quality trial execution. Skilled in feasibility, site selection, budget negotiations, and cross-functional leadership to optimize operations and accelerate study timelines. Passionate about innovation, quality assurance, and operational excellence to drive impactful clinical outcomes.

# SPEAKERS & PANELISTS

11:30  
12:30



**SEZCAN ÖZTÜRK, VICE PRESIDENT AND HEAD OF EUROPE | LUZSANA BIOTECHNOLOGY EUROPE AG**

Sezcan Öztürk is a seasoned leader with 20+ years of experience in clinical operations management, specializing in multi-country trial execution, strategic planning, and operational efficiency. As Vice President and Head of Europe at Luzsana Biotechnology Europe AG, he oversees business and clinical development across the region. He has held key leadership roles at Novo Nordisk and Hengrui Europe Therapeutics, driving trial operations excellence and organizational transformations. Sezcan holds a B.Sc. in Chemistry from Hacettepe University, Turkey. His expertise spans oncology, diabetes, hematology, cardiovascular diseases, and obesity.

13:30  
14:15



**DR. EVGENY LEVENKO, MD, PHD, COUNTRY MANAGER, UKRAINE | ARENSIA EXPLORATORY MEDICINE**

Evgeny Levenko, MD, PhD, is a cardiologist with over 25 years of clinical research experience. He has managed over 100 Phase I-III trials, showcasing his expertise in project management and execution. Before joining ARENSIA, Evgeny held key roles in international CROs, where he refined his leadership skills. As ARENSIA's Country Manager in Kyiv, he oversaw the establishment of the company's largest research clinic and has driven rapid growth in the region. Evgeny is known for his strategic vision and leadership, making him integral to ARENSIA's success in Ukraine.

14:15  
15:00



**CORNELIA BAUMGARTNER, FOUNDER, MANAGING DIRECTOR | CETACEA CLINICAL**

Cornelia Baumgartner is the founder and managing director of Cetacea Clinical GmbH, which specializes in the operational support of biotech start-ups during their first clinical trials. With over 20 years of experience in clinical operations, her focus is on efficient study planning, pragmatic implementation and the development of audit-ready quality management systems (QMS). Cetacea Clinical offers a ready-to-use, adaptable QMS - including SOPs and templates - that is specifically tailored to the needs of growing organizations. Cornelia started her career at Pfizer as a CRA and subsequently held senior positions at NBE-Therapeutics (Boehringer-Ingelheim), Aridis Pharmaceuticals, Mundipharma EDO and Light Chain Bioscience, among others.

15:15  
16:00



**DR. FRANK RICHARD, MD, MBA, VICE PRESIDENT MEDICAL | HEIDELBERG PHARMA AG**

Frank Richard is VP Medical at Heidelberg Pharma AG with over 20 years of R&D experience. He leads clinical trials for cancer treatment using ADCs and enhances dose prediction through data modeling. His expertise spans immune-oncology, respiratory and rare diseases. He holds an MD, MBA, and is a board-certified Clinical Pharmacologist. He also brings unique insights into Bayesian Statistics.

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The timeless Dolder Grand Hotel is hosting ARENSIA's InnovationXchange day in the heart of Zurich. Surrounded by the breathtaking panorama of the majestic mountains, this venue transforms into an immersive journey that echoes the footsteps of greatness and visionary figures from Albert Einstein to Winston Churchill. The event emerges as an ideal space for a lively exchange on contemporary challenges and forthcoming trends in early drug development. Enhancing the experience, participants can indulge in exceptional gastronomy and award-winning wine tasting from Eastern Europe.

The hotel is offering special accommodation rates for ARENSIA guests.

We look forward to welcoming you!

