INNOVATION X CHANGE

BY ARENSIA

THE DOLDER GRAND



DR. CLAUDIA HESSELMANN, PhD
Founder & CEO
ARENSIA Exploratory Medicine



DR. ALINA JUCOV, MD, PhD
Medical Director
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DR. ULF GRAWUNDER, PHD
Co-Founder & CEO
T-CURX



INGEBORG HEIRMAN
Senior Director Clinical Trial Operations
Regeneron



LAURA LASSOUW
Chief Operating Officer
Sairopa



NICK CLARK
Independent Regulatory Professional

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

16th APRIL 2024 ZÜRICH

PARTICIPATION BY INVITATION ONLY

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RACE FOR PROOF-OF-CONCEPT IN TIMES OF EXPONENTIAL TRANSFORMATION: SURVIVAL OF THE BOLDEST!

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.

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AGENDA
AT-A-GLANCE

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08:30 REGISTRATION
09:15 BREAKFAST

09:15 WELCOME
09:30 INTRODUCTION

09:30 ON THE FAST TRACK:
10:00 ATTAINING PROOF-OF-CONCEPT IN 9-12 MONTHS

GLOBAL CHALLENGES AND INDUSTRY TRENDS
EFFICIENT CLINIC SET-UP
CASE STUDIES: PATIENT RECRUITMENT, TIMELINES, BUDGETS

10:00 FROM WHITE BOARD TO DATABASE LOCK:
11:00 THE RIGHT PLANNING SAVES YEARS AND MILLIONS

THE RIGHT TEAM | THE RIGHT GEOGRAPHY
THE RIGHT STUDY DESIGN | THE RIGHT VENDORS

11:00 
11:30

11:30 FOCUS ON PATIENTS & DIVERSITY: WORDS VS. ACTIONS
12:30

INTERVIEW WITH A PATIENT
CLINICAL TRIALS AS AN ALTERNATIVE TREATMENT OPTION
RAISING AWARENESS WITH PATIENTS, FAMILY, COMMUNITY
DEVELOPING PATIENT FRIENDLY STUDY DESIGN

12:30 
13:30

13:30 THE FUTURE NOW: PANEL DISCUSSION
14:30

NEXT FRONTIERS IN CELL & GENE THERAPIES
USE OF AI & MACHINE LEARNING IN CLINICAL TRIALS
WILL VIRTUAL PATIENT BECOME REALITY?

14:30 
15:00

15:00 THE NEW REGULATORY ENVIRONMENT IN THE
16:00 EUROPEAN UNION: NOT AT ALL COMPLICATED!

SUBMISSION IN THE EU THROUGH THE CTIS PORTAL

16:00 GENERAL Q&A
16:30 REVIEW OF THE DAY

16:30 
18:00

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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



INGEBORG HEIRMAN, SENIOR DIRECTOR CLINICAL TRIAL OPERATIONS | REGENERON

Ingeborg Heirman, holding a Master's degree in Biomedical Sciences and a PhD in Biotechnology, boasts almost two decades of experience in the pharmaceutical industry. She began her career at MSD Europe, where she excelled in clinical project management and spearheaded Phase 1 patient trials in Eastern Europe. Subsequently, as Chief of Staff to the Head of Translational Medicine, she transitioned to Regeneron in 2018, where she managed COVID-19 program operations. Currently serving as the Senior Director of Clinical Operations at Regeneron, Ingeborg is dedicated to advancing late-phase programs and rare disease indications.

11:30
12:30



DR. ALINA JUCOV, MD, PhD, MEDICAL DIRECTOR | ARENSIA EXPLORATORY MEDICINE

Alina is an Assistant Professor at the Department of Gastroenterology, State University of Medicine & Pharmacy, Chisinau, Moldova. She is board certified internist & gastroenterologist, acting as Medical Director and Principal Investigator for Phase I/II trials in hepatitis & GI at ARENSIA Moldova. Alina is author/co-author of national and international abstracts and publications in viral hepatitis, NASH, and IBD.



INGE DE CLERCQ, CLINICAL OPERATIONS DEVELOPMENT LEAD | ARGENX

Inge De Clercq is an experienced clinical research professional with a passion for early-phase clinical development. After 15 years of working in different roles at a Phase 1 unit, she got acquainted with the management of later phase trials at Tibotec and Amgen. Returning to her preferred environment, she led a team of phase 1 study managers at Galapagos and recently also at Argenx.



LAURA LASSOUW, CHIEF OPERATING OFFICER | SAIROPA

Laura Lassouw-Polman is a clinical professional with more than 18 years' experience in both early and late stage drug development. Currently she is the COO at Sairopa B.V. Leveraging her skills and expertise working at various international CROs and pharmaceutical companies Laura has extensive experience with strategic development and successful execution of global clinical trials.

SPEAKERS & PANELISTS

13:30
14:30



DR. ULF GRAWUNDER, PHD, CO-FOUNDER & CEO | T-CURX

Ulf Grawunder is a Biotech entrepreneur, who since 2004 has founded three Biotech companies, of which two have been successfully sold to other companies. Currently, Ulf is co-founder and CEO of T-CURX GmbH, a start-up company from the University Clinics Würzburg, Germany, focused on developed next-generation CAR-T cell therapies. A biochemist by training, Ulf did his PhD at the Basel Institute for Immunology and conducted post-doctoral research at Washington University School of Medicine, St. Louis, and at the University of Southern California, Los Angeles. Ulf also plays advisory and teaching roles across multiple Biotech organizations, contributing significantly to the industry's advancement.



DR. RICARDO GAMINHA PACHECO, MD, MBA - BUSINESS DEVELOPMENT & PARTNERING CONSULTANT

Ricardo Gaminha Pacheco, MD | MBA is a dynamic Physician Executive with extensive experience in biomedical innovation, specializing in Innovative Medicines Development & Pharmaceutical Medicine. With a background in both NHS and private practice, Ricardo transitioned to the Pharma & Biotech Industry, holding leadership roles at UCB, Takeda Pharmaceuticals, Novartis, AstraZeneca, and Roche. He has contributed to the development and launch of life-changing medicines targeting various diseases. Armed with an Executive MBA and entrepreneurship certificate from MIT Sloan School of Management, Ricardo is now focused on accelerating European biotech creation and growth, shaping strategic planning, and advancing healthcare through innovative life sciences.

15:00
16:00



NICK CLARK, INDEPENDENT REGULATORY PROFESSIONAL

Nick has over 25 years' experience working within Regulatory Affairs. During this time he has worked in various therapy areas including metabolic disease, cardiovascular diseases, HIV, oncology, and since 2016, Inflammation. Nick has contributed to 6 successful marketing applications across these therapy areas and was the European Regulatory Lead for 3 of these applications. Nick has experience as a Global Strategy Regulatory Head, leading a team of 14 regulatory professionals in both the US and the UK, with regulatory affairs portfolio oversight for inflammatory therapy area product development. Nick was the subject matter expert for clinical trials in Gilead and led the team that prepared the company for the introduction of the clinical trial regulation. Nick holds Bachelor's degree in Physiology and Biochemistry from the University of Reading, and a Ph.D in Drug Metabolism from the University of Newcastle, U.K.

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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!





