

**THE NEW NORMAL IN EXPLORATORY
CLINICAL TRIALS: CHALLENGES
AND FUTURE TRENDS**

📅 Tuesday, 1ST November 2022
📍 Argonaut Hotel San Francisco



COVER

AGENDA-AT-A-GLANCE

KEY OPINION LEADERS

HOTEL & TRAVEL

OUR UNIQUE MEETING FORMAT

In today's fast-changing world, staying competitive requires innovative thinking and adaptability. With the rise of novel technologies, keeping the pulse on developments has become more critical than ever before. The Clinical Development industry is facing competition with unprecedented challenges caused by disruptive events. Application of innovative strategies has proven that early phase clinical trials can maintain necessary flexibility and can be executed on time and within budget.

After two years of virtual meetings, we are excited to launch our face-to-face spotlight to facilitate the frank discussion of these challenges. A specialist panel of early phase industry professionals has been assembled to share their experiences from actual case studies, from a range of different perspectives. These include medical, regulatory, clinical, sponsor, and patient viewpoints. Including feedback from the full gamut of stakeholders and participants will be critical in progressing from Early Phase strategies to Proofs-of-Concept. The focus will be on practical aspects of the new normal in planning and execution of early phase clinical trials with real-life case studies.

Among other exciting topics, we will discuss:

- Understanding that Early Phase Trials are not small scale Phase III trials
- Enhancing Cohort Management through reducing the number of sites
- Strategies for flexibility and resilience embedded into study designs
- Future Concepts for Early Phase Clinical Trials

KEY OPINION LEADERS



Claudia Hesselmann

Chief Executive Officer
ARENZIA Exploratory Medicine GmbH,
Düsseldorf, Germany



Heather Paden

VP, Clinical Operations
PureTech Health, Boston, USA



Cara Pilowa

Senior Director, Clinical Operations
VirBio Inc., San Francisco, USA



Dr. Alina Jucov

Medical Director
ARENZIA Research Clinic, Chisinau. Moldova



Julia Ford

Associate Director, Clinical Operations
Gossamer Bio, San Diego, USA



Evgeny Levenko

Country Manager
ARENZIA Research Clinic, Kyiv, Ukraine

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08:30-09:15 REGISTRATION & BREAKFAST

09:15-09:30 WELCOME & INTRODUCTION

 **Claudia Hesselmann, CEO, ARENSIA Exploratory Medicine GmbH, Düsseldorf, Germany**

09:30-10:30 PLANNING AND EXECUTION OF INCREASINGLY COMPLEX PHASE I/II PATIENT TRIALS WITH ADAPTIVE DESIGNS

- Strategies for country and site selection for trials with adaptive multi-cohort designs
- Efficient infrastructure for study execution: vendor selection & cross-functional coordination
- Challenges in balancing flexibility and predictability: number of sites, budget, IMP planning, study systems, etc.
- Approaches for cohort management: 'real-time' data collection, cleaning, and review etc.

 **Cara Pilowa, Senior Director, Clinical Operations, VirBio Inc., San Francisco, USA**

10:30-11:00 MORNING REFRESHMENTS

11:00-12:00 PERFORMANCE OF COMPLEX EXPLORATORY TRIALS UNDER UNPRECEDENTED GLOBAL CHALLENGES: INSIGHTS FROM ARENSIA RESEARCH CLINICS


- Unique model of dedicated research clinics
- Strategies for patient enrollment and retention
- Take away from pandemic experience
- Keeping operations open during war in Ukraine

 **Claudia Hesselmann, CEO, ARENSIA Exploratory Medicine GmbH, Düsseldorf, Germany**

 **Evgeny Levenko, Country Manager, ARENSIA Research Clinic, Kyiv, Ukraine**

12:00-13:00 ASSURING STUDY QUALITY IN DISRUPTIVE TIMES


- Unyielding rules vs practical feasibility under state of emergence
- Collaboration with Regulatory Authorities to adapt to new challenges
- How to make the processes more flexible to be able to adapt to new realities faster while assuring quality and integrity


 **Heather Paden, VP, Clinical Operations, PureTech Health, Boston, USA**

13:00-14:00 LUNCH

14:00-15:30 CLINICAL TRIAL THAT PUT PATIENTS FIRST: BALANCING RESEARCH OBJECTIVES AND PATIENTS' NEEDS

- Developing patient-friendly study design
- Bringing the study to the patient: off-site study visits and their limits
- Use of digital platforms and social media for better patient engage

 **Pharmaceutical company representative: Julia Ford, Associate Director, Clinical Operations, Gossamer Bio, San Diego, USA**

 **Site side: Dr. Alina Jucov, Medical Director, ARENSIA Research Clinic, Chisinau, Moldova**

*Reserved for representative from biopharmaceutical company' as a panelist
Reserved for IRB representative*

15:30-16:00 AFTERNOON BREAK

16:00-17:00 PHASE I/II CLINICAL TRIAL OF THE FUTURE

- Developing patient-friendly study design
- Bringing the study to the patient: off-site study visits and their limits
- Use of digital platforms and social media for better patient engage

17:00-17:30 GENERAL Q&A, REVIEW OF THE DAY

17:30-18:00 DRINKS RECEPTION & CANAPE

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Country Manager
ARENZIA Research Clinic, Kyiv, Ukraine

Claudia Hesselmann, a chemist by training, with a PhD in molecular biology. Claudia has twenty years of expertise in the early phases of drug development. Her experience includes co-founding and holding management positions in various CROs. Her extensive background and social acumen, along with her first-hand knowledge of the industry, led Claudia to co-found ARENSIA Exploratory Medicine in Düsseldorf, Germany. Her primary aim is the contribution of innovative approaches to bring about substantial acceleration to the drug development process and enable more agile patient access to novel therapeutics.

Heather Paden, Vice President and Head of Clinical Operations and Data Management, has more than 20 years of diverse experience in clinical research operations management, clinical science, trial management and monitoring, respiratory therapy, and education. Ms. Paden has extensive experience in cross-disciplinary management of large and small trials and has provided substantial contributions to the writing of protocols, clinical study reports, abstracts, and manuscripts. Her work has covered the therapeutic areas of rare disease, oncology, cardiovascular disease, CNS and respiratory disease. Early in her career, Ms. Paden practiced and taught in the field of respiratory therapy. She has authored several journal articles and has been recognized with corporate research rewards for her work in cardiovascular health.

Cara Pilowa is a skilled Clinical Operations professional with 14 years of experience. Cara has led Ph1-3 global clinical trials across an array of therapeutic areas such as oncology, infectious disease and inflammatory diseases. Cara is currently leading Clinical Operations- Chronic Disease at Vir Biotechnology. In addition to overseeing clinical programs, she has an interest in strategic planning and process development to launch dynamic programs while supporting organizational growth.

Alina Jucov, MD, PhD is an Assistant Professor at the Department of Gastroenterology, State University of Medicine and Pharmacy, Chisinau, Republic of Moldova. Dr. Jucov is board certified internist and gastroenterologist. Currently, she is also Medical Director for ARENSIA Moldova Exploratory Medicine. Dr. Jucov has been the Principal Investigator for clinical trials related to viral hepatitis, including novel agents. She also is the co-investigator for numerous clinical trials in ulcerative colitis. Dr. Jucov is the author and co-author of national and international abstracts and publications in the field of viral hepatitis, NASH, and IBD. She is also a regular member of several international organizations such as EASL, UEG, ECCO, EPC, and national gastroenterological and hepatological organizations from Moldova and Romania.

Bio Here

Evgeny Levenko, MD, PhD, specialist in cardiology is the Country Manager, Ukraine. Evgeny leads ARENSIA activities in Ukraine, which primarily take place in the two ARENSIA Research Clinics located in Kyiv, Ukraine. With over 20 years of experience in Clinical Research, Evgeny has extensive experience in leading, planning (project management), conducting, as well as supervising in more than 80 studies of phases I – III of all degrees of complexity and size. Prior to joining ARENSIA, Dr. Levenko worked in the Ukrainian branches of several international CRO's.

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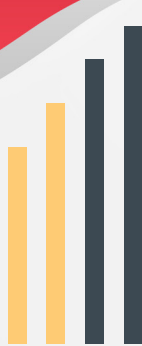
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VENUE

ARGONAUT™
A NOBLE HOUSE HOTEL



We will have the following COVID measures in place for your reassurance:

- Rapid test station will be open at the registration desk
- Health status and temperature check will be done at the registration desk
- Face masks are optional; the venue will have permanent fresh-air flow. Mask requirements will be adjusted depending on recommendations at the time of the event.

ARGONAUT HOTEL

495 Jefferson Street
San Francisco, CA, 94109

MAP & DIRECTIONS 

Housed within Fisherman's Wharf historic Haslett Warehouse building, the Argonaut Hotel merits a term like iconic both for its past and its present. A recipient of the AAA Four Diamond Award for 18 consecutive years, the Argonaut boasts a location just as noteworthy. Guests wake to views of the San Francisco Bay, Alcatraz, and the Golden Gate Bridge before venturing mere steps to next door Ghirardelli Square & Hyde Street Pier.



Uncover legendary history & remarkable views at our award-winning boutique hotel.

