INNOVATION X CHANGE
BY ARENSIA

PRESENTED BY ARENSIA



TATIANA EIDUS
Head of US Operations



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

OUR PANELISTS



DR. GIOVANNI ABBADESSA, MD, PHD



MARY WEST
Vice President, Clinical Operations
Tectonic Therapeutic



JENNIFER BURG
Senior Vice President of Clinical Development Operations
Axonis Therapeutics



DR. LUKE GELINAS, PHD
Senior Advisor, Chairperson
Advarra IRB

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

24 SEP 2024
BOSTON
THE RITZ-CARLTON

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.

ARENSIA
EXPLORATORY MEDICINE

AGENDA
AT-A-GLANCE

INNOVATION X CHANGE
BY ARENSIA

08:30 REGISTRATION
09:15 BREAKFAST

09:15 WELCOME
09:30 INTRODUCTION

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

OPTIMIZING OPERATIONAL EFFICIENCY
LEVERAGING REGIONAL BENEFITS FOR STREAMLINED REGULATORY APPROACHES
CASE STUDIES: PATIENT RECRUITMENT, TIMELINES, BUDGETS

10:30 FROM WHITE BOARD TO DATABASE LOCK:
11:30 THE RIGHT PLANNING SAVES YEARS AND MILLIONS

THE RIGHT TEAM; THE RIGHT GEOGRAPHY;
THE RIGHT STUDY DESIGN; THE RIGHT VENDOR

11:30
12:00

12:00 FOCUS ON PATIENTS & DIVERSITY: WORDS VS. ACTIONS
13:00

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

13:00
14:00

14:00 INVESTING IN CLINICAL RESEARCH:
15:00

TOP THERAPEUTIC AREAS AND DRUG CLASSES DRAWING INVESTOR INTEREST
VARIATIONS IN INVESTMENT STRATEGIES BY INVESTOR TYPE
INFLUENCE OF POLITICAL AND ECONOMIC UNCERTAINTIES ON INVESTMENT DECISIONS

15:00
15:30

15:30 THE FUTURE NOW: PANEL DISCUSSION
16:15

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

16:15 GENERAL Q&A
16:30 REVIEW OF THE DAY

16:30
18:00

SPEAKERS & PANELISTS

09:30
10:30



TATIANA EIDUS, HEAD OF US OPERATIONS | ARENSIA EXPLORATORY MEDICINE

Tatiana Eidus received her Master's Degree in Biophysics from Moscow State University. Entering the industry a decade ago, Tatiana has accumulated wide expertise in all the operational aspects of initiating and managing Phase I-III trials across Europe and US. Prior to joining ARENSIA Exploratory Medicine, Tatiana worked for GSK and Merck. Primarily focused on early-stage exploratory programs, she conducted trials in various disease areas. In her current role as Head of Operations, Tatiana supports ARENSIA's partners in the US, supervising cross-functional coordination throughout study planning, start-up and execution.



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.

10:30
11:30



MARY WEST, VICE PRESIDENT, CLINICAL OPERATIONS | TECTONIC THERAPEUTIC

Ms. West, Vice President, Clinical Operations, brings an extensive 30-year background in complex clinical trial execution and team leadership. Most notably, she led all clinical operations at Boston-based Alnylam Pharmaceuticals for their lead product, Onpattro®, in a successful registration trial and led to the historic approval of the fist siRNA therapy in late 2018. Ms. West has previously served in clinical operations leadership roles at Talaris, BlueRock, Skyhawk, Paratek, Momenta, Acambis, Millennium and Pfizer. Ms. West received her M.S. in project management from Boston University and her B.S. in dietetics from Michigan State University.



JENNIFER BURG, SENIOR VICE PRESIDENT OF CLINICAL DEVELOPMENT OPERATIONS | AXONIS THERAPEUTICS

Jennifer currently holds the position of Senior Vice President of Clinical Development Operations at Axonis Therapeutics, leveraging over 25 years of experience in the biotech industry. As a seasoned leader, she has consistently demonstrated her expertise in managing clinical development operations teams, particularly within emerging and early-stage biotechnology companies. Jennifer's extensive background and hands-on experience uniquely position her to excel in optimizing global clinical trials and driving the acceleration of drug development.

SPEAKERS & PANELISTS

15:30
16:15



DR. MURRAY ABRAMSON, MD, MPH, SENIOR VICE PRESIDENT AND HEAD OF CLINICAL DEVELOPMENT | PRECISION BIOSCIENCES

Murray A. Abramson, MD, MPH is an accomplished physician and healthcare executive with over 25 years of experience in clinical research and drug development. He earned his BS in Chemistry and MD from Duke University and holds a Master of Public Health in Epidemiology from the University of North Carolina. After serving on Duke's faculty as Director of the Infectious Diseases Research Consortium, he transitioned to the pharmaceutical industry, spending 13 years at Merck and later leading global clinical operations at Biogen. Currently, Dr. Abramson is Senior Vice President and Head of Clinical Development at Precision BioSciences, overseeing key clinical programs. He has authored publications in top medical journals like The Lancet and The New England Journal of Medicine. With over 25 years of experience in clinical research and drug development, Dr. Abramson brings valuable expertise in infectious diseases, clinical operations, and strategic leadership to his roles in the biopharmaceutical industry.



MANNY LAZARO, SENIOR VICE PRESIDENT, CLINICAL DEVELOPMENT OPERATIONS | HERCULES NEWCO

Manny holds a position as Senior Vice President, Clinical Development Operations at Hercules NewCo for the last 4 weeks where he is responsible for clinical strategy, planning and execution. Manny started his industrial career 32+ years ago with positions of increasing responsibility beginning at Genetics Institute, Anika Therapeutics, Cubist Pharmaceuticals, Johnson and Johnson, Vertex Pharmaceuticals and Forum Pharmaceuticals, Jounce Therapeutics and Cerevel Therapeutics. Manny holds a Master's of Science in Drug Regulatory Affairs and Health Policy from the Massachusetts College of Pharmacy and a Bachelor's of Science in Biology from the University of Massachusetts at Boston. Before working in the device and biopharmaceutical industry, Manny served in the United States Air Force for 6 years as a Staff Sergeant.



DR. LUKE GELINAS, PHD, SENIOR ADVISOR, CHAIRPERSON | ADVARRA IRB

Dr. Gelinas is a Chairperson at Advarra IRB where he provides analysis and guidance on complex ethical issues arising in the course of clinical research study design and human participant protection. He holds a Ph.D. in Philosophy with a concentration in Ethics from the University of Toronto and an M.A. in Religion, summa cum laude, from Yale Divinity School. From 2015-2018, Dr. Gelinas was Senior Researcher at Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. There he led collaborative and multi-stakeholder projects addressing foundational and practical issues in research ethics, including projects on the ethical issues implicated in the use of social media for research recruitment, clinical trial priority-setting, and the ethical and regulatory parameters of paying research participants.

SPEAKERS & PANELISTS

12:00
13:00



DR. ILEANA STOICESCU, MD, HEAD OF ONCOLOGY RESEARCH CLINICS, ROMANIA | ARENSIA EXPLORATORY MEDICINE

Ileana Stoicescu, MD, is a senior pulmonologist with more than 20 years of hospital clinic experience in the largest pulmonology institute in Romania with a special interest in lung cancer development and parallel 15 years in early clinical research together with ARENSIA. She has experience with operational aspects of early-stage exploratory clinical trials in different therapeutic and indication areas, also managing medical and operational ARENSIA sites in Romania. She decided to put together her medical and clinical research expertise and experience focusing on oncology research, her current role being the Head of Oncology ARENSIA Research Clinic located in the Institute of Oncology.

14:00
15:00



DR. GIOVANNI ABBADESSA, MD, PHD

Giovanni Abbadessa is an MD, PhD, who specialized in Oncology in Italy, and in Genetical Oncology between the US and Italy. Giovanni is a Scientific Board Member for Biond Biologics and HiFiBio and consults for various biotech companies on clinical and preclinical strategy and prioritization. As Vice President, Head of Oncology Early Development at Sanofi, he built a team which worked on 16 clinical experimental drugs and as many preclinical ones. Prior to joining Sanofi in 2017, he has worked in small (15-110 employees) Boston biotechs since 2007, leading preclinical and clinical research teams, working on Ph1-3 clinical trials, medical affairs, strategy, business development, investor relations, board, and partnership management. In his spare time, Giovanni works with two Boston-based nonprofit organizations he founded in 2009 and 2014, respectively: Professionisti Italiani a Boston, an Italian networking and cultural organization with over 1400 members (www.PIBoston.org); and the Scuola Piccoli Italiani di Boston, the largest full-immersion Italian Saturday school for children in North America (www.ScuolaPIB.org). He loves sailing, racing cars and motorbikes, traveling, and networking.