

# Agenda

## ***ARISE III: THE MIDDLE MENINGEAL ARTERY (MMA): A PATHWAY TO INNOVATIVE TREATMENTS***

***New Perspectives on***

***Migraine Management, Transarterial, Transvenous Csdh Removal, New Generation of Liquid Embolics and Requirements***

***AI, Robotics (Remote vs in Hospital), Pros and Cons, Adaptation Into Clinical World***

***Preclinical Data (Simulation vs Biological Systems)***

ARISE starts with a one full day meeting focusing on cutting-edge clinical and research study designs, analytic methods, novel drugs/devices, biomarkers, and outcomes. The specific sessions included in the program are:

- **SESSION 1: Intracerebral hemorrhage (ICH) – NEW DATA, NEW LANDSCAPE, NEW APPROACHES**
- **SESSION 2: Cerebral Venous Diseases: NEW DATA, NEW LANDSCAPE, NEW APPROACHES**
- **SESSION 3: Intracranial Atheroocclusive Disease (ICAD): NEW DATA, NEW LANDSCAPE, NEW APPROACHES**
- **SESSION 4: REGULATORY PERSPECTIVE ON KEY CLINICAL TRIAL ISSUES**

The second day of the ARISE is focused on the consensus process to develop recommendations. Participating experts from academia, industry and regulatory institutions are divided into 3 groups for preparation of the consensus recommendations. They are provided equal opportunity to contribute to a facilitated discussion process, during which recommendations developed by leading academic thought leaders in ICH, ICAD, and CVD are presented, openly discussed, and may

be amended, expanded, replaced, and refined by the group. Each of the 3 content groups then present their recommendations to the entire assembly. Writing committees draft the manuscripts for review of the group and the resulting articles are then published.\*The program is preliminary and could be subject to changes

**7:00 – 8:00 amMORNING NETWORKING**

**Location: Metropolitan Galleries 4-6 Foyer 8:00 – 8:15**

**amACADEMIA/INDUSTRY/FDA/NIH ROUNDTABLE ON MIDDLE MENINGEAL ARTERY(MMA): A PATHWAY TO INNOVATIVE TREATMENTS, NEURO-AI/ROBOTICS/AUTOMATION AND NON-CLINICAL REQUIREMENTS IN NEURO-IR**

**Location: Metropolitan Galleries 1-3**

**Chairs: Ajay Wakhloo, TUFTS University School of Medicine, USA  
Adam Arthur, University of Tennessee, USA**

**Introduction: Marc Fisher, Beth Israel Deaconess, Harvard Medical School, Boston, MA 8:15 – 11:00 amSESSION 1: MIDDLE MENINGEAL ARTERY (MMA): A PATHWAY TO INNOVATIVE TREATMENTS**  
**Location: Metropolitan Galleries 1-3**

**Chairs: Arthur Adam, University of Tennessee, TN  
Fawaz Al-Mufti, New York Medical College, NY**

**8:15 – 8:35**

**REFRACTORY MIGRAINE**

**08:15 – 08:25 Presentation by Adnan Qureshi, University of Missouri, School of Medicine, Columbia, MO**

**08:25 – 08:35 Comments by Italo Linfante, Miami Cardiac and Vascular Institute and Baptist Neuroscience Institute, Miami, FL**

**8:35 – 9:00**

**ENDOVASCULAR ACCESS TO SUBDURAL SPACE AND BRAIN SURFACE**

**08:35 – 08:45 Presentation by Luis Savastano, University of California, San Francisco, CA**

08:45 – 08:55 Presentation by **Jose Morales**, Pacific Neuroscience Institute, CA

08:55 – 09:00 Comments by **Pedro Lylyk**, University of Buenos Aires, Argentina

**9:00 – 9:30**

**MMA INFUSIONS/EMBOLIZATION FOR HA**

09:00 – 09:20 Presentation by **Peter Kan**, UTMB, Galveston, TX

09:20 – 09:30 Comments by **Akash Patel**, Baylor University, Houston, TX

**9:30 – 9:50**

**REQUIREMENTS FOR A NOVEL LIQUID EMBOLIC AGENT**

09:30 – 09:40 Presentation by **Upma Sharma**, Arsenal, Boston, MA

09:40 – 09:50 Comments by **David Altschul**, Montefiore Medical Center, NY

**09:50 – 11:00 ROUNDTABLE PANEL DISCUSSION**

**Chris Kellner**, Mt Sinai, NYC, NY;

**Mark Bain**, Cleveland Clinic, Cleveland, OH;

**David Fiorella**, Stonybrook University School of Medicine, Stonybrook, NY

**Violiza Inoa**, Semmes Murphey Clinic, TN

**Raul Nogueira**, UPMC Stroke Institute, PA

**Nagesh Uppuluri**, Terumo Neuro, USA

**Sudha Iyer**, Medtronic, USA

**Scott Janis**, NIH, USA **11:00 – 11:15 am** BREAK

**Location: Metropolitan Galleries 4-6 Foyer** **11:15 am– 1:30 pm**

**SESSION 2: NON-CLINICAL REQUIREMENTS IN NEURO-IR**

**Location: Metropolitan Galleries 1-3**

**Chairs: Matthew Gounis**, UMASS Chan School of Medicine, Worcester, MA

**Ajay Wakhloo**, TUFTS University School of Medicine, Boston, MA

**11:15 – 11:45**

## **VALUE OF BIOLOGICAL SYSTEMS**

11:15 – 11:30 Presentation by **Ram Kadirvel**, Mayo Clinic, Rochester, MN

11:30 – 11:45 Comments by **Juhana Frosen**, Tampere University and University Hospital Tampere, Finland

**11:45 – 12:30**

## **VALUE OF SIMULATED USE EXPERIMENTATION**

11:45 – 12:00 Presentation by **Steven Kreuzer**, University of Texas at Austin

12:00 – 12:15 Comments by **Demetrius Lopes**, Advocate Health, Chicago, IL

12:15 – 12:30 Comments by **Ramesh Grandhi**, University of Utah, Salt Lake City, UT

**12:30 – 1:30**

## **ROUNDTABLE PANEL DISCUSSION**

**Vania Anagnostakou**, UMASS Chan School of Medicine, Worcester, MA;

**Carlos Pena**, University of Buffalo, NY;

**Patrick Brouwer**, JNJ, USA

**Angelo Delgado**, Stryker, USA

**Giovanni Ughi**, Spryte Medical, USA

**Francesca Bosetti**, NIH, USA **1:30 – 2:30 pmBREAK**

**Location: Metropolitan Galleries 4-6 Foyer 2:30 – 5:00**

**pmSESSION 3: AI & ROBOTICS****Location: Metropolitan Galleries 1-3**

**Chairs: Vitor Pereira**, University of Toronto and St. Michael's Hospital, Canada

**Ferdinand Hui**, Queen's University Medical Group, Honolulu, HI

**David Liebeskind**, University of California, Los Angeles, CA

## **2:30 – 3:15 THE EU AI ACT 2024: IMPLICATIONS FOR U.S. HEALTH CARE**

2:30 – 2:45 Introduction to AI by **Andrew Menard**, Johns Hopkins, MA

2:45 – 3:00 Presentation by **Mathias Unberath**, Johns Hopkins, MA

3:00 – 3:15 Comments by **Joshua Hirsch**, MGB, Harvard Medical School, Boston, MA

### **3:15 – 3:50 ROBOTICS**

3:15 – 3:30 Presentation by **Omar Choudhri**, University of Penn, PA

3:30 – 3:50 Presentation by **Max van Apeldoorn**, Philips, Boston, MA

### **3:50 – 4:50**

#### **ROUNDTABLE PANEL DISCUSSION**

**Yasmin N Aziz**, University of Cincinnati College of Medicine, OH;

**Ameer Hassan**, University of Texas, Austin, TX;

**Aquill Turk**, University of South Carolina-Greenville, SC;

**Michael Froehler**, Vanderbilt University Medical Center

**J Mocco**, Mt. Sinai, New York, NY

**Mathias Unberath**, Johns Hopkins, MA

**Sean Kyne**, Philips, USA

**Andre Cesarski**, ViZ AI, USA

**Mark Ashby**, Medtronic, USA

**Kerstin Mueller**, Siemens, USA

**Clinton Wright**, NIH, USA **5:15 – 6:15 pm****SESSION 4: REGULATORY PERSPECTIVE ON KEY CLINICAL TRIAL ISSUES** Location: Metropolitan Galleries 1-3

**Chairs: Adnan Siddiqui**, State University of New York, USA;

**Ricardo Hanel**, Baptist Health, USA;

**Xiaolin (Lin) Zheng**, FDA, USA

### **5:15–5:35 FROM BENCH TO FIRST-IN-HUMAN: WHAT IS NEEDED FOR AN EARLY FEASIBILITY STUDY IDE?**

**Xiaolin (Lin) Zheng**, FDA, USA

- Understanding the transition from bench research to the

initial stages of human trials.

- Identifying the critical elements required to initiate Early Feasibility Study IDEs in the U.S.
- FDA Panel (CDER & CDRH) Answers to Stroke Community Questions

**5:35 – 6:15**

## **ROUNDTABLE PANEL DISCUSSION**

### **Panelists:**

**Adnan Siddiqui**, State University of New York, USA; **Philipp Taussky**, BIDMC/Harvard Medical School, USA; **Ricardo Hanel**, Baptist Health, USA; **Guilherme Dabus**, Miami Cardiac and Vascular Institute and Baptist Neuroscience Institute, USA; **David Altschul**, Montefiore Medical Center, USA; **Adel Malek**, Tufts Medical Center, USA; **Xiaolin (Lin) Zheng**, FDA, USA; **Gabriela Suarez-Mier**, FDA, USA; **Amy Smith**, MicroVention, USA

**6:30 – 9:30 pm** **EVENING OF NETWORKING: BUILDING CONNECTIONS AND OPPORTUNITIES FOLLOWED BY SPECIAL PRESENTATION**

**Location: Metropolitan Galleries 4-6 Foyer**

**Introduction:** Adam Arthur, University of Tennessee, TN

## **BRAIN COMPUTER INTERFACE**

**Thomas Oxley**, CEO Synchron, New York, NY **7:00 – 8:00**

**am** **MORNING NETWORKING**

**Location: Metropolitan Galleries 4-6 Foyer** **8:00 – 10:45**

**am** **WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS**

Participants are divided into three groups – each to develop recommendations for planned publication in a major scientific journal.

**Location: Metropolitan Galleries 1-3**

### **Workshop #1**

**MIDDLE MENINGEAL ARTERY (MMA): A PATHWAY TO INNOVATIVE TREATMENTS**

**Moderators: Peter Kan, UTMB, Galveston, TX**  
**Edgar Samaniego, University of Iowa, Iowa City, IA**  
**Matthew Amans, UCSF, CA**

**Location: Dupont**

**Workshop #2**

**NON-CLINICAL REQUIREMENTS IN NEURO-IR**

**Moderators: Ricardo Hanel, Baptist Health, Jacksonville, FL**  
**Matthew Gounis, University of Massachusetts Chan School of Medicine, Worcester, MA**  
**Dorothea Altschul, St. Joseph's Health, New Jersey, NJ**

**Location: Dupont**

**Workshop #3**

**AI & ROBOTICS**

**Moderators: Vitor Pereira, University of Toronto and St. Michael's Hospital, Canada**  
**Brian Hoh, University of Florida, Gainesville, FL**  
**Andrew Menard, John Hopkins**

**10:45 – 11:00 am**BREAK

**Location: Metropolitan Galleries 4-6 Foyer** **11:00 am – 12:00 pm**  
**WORKSHOP CHAIRS PRESENT RECOMMENDATIONS TO FULL ASSEMBLY**

**Location: Metropolitan Galleries 1-3****DRAFTING OF CONSENSUS STATEMENT IS INITIATED**

**Chaired by Adam Arthur, University of Tennessee, USA**  
**Ajay K Wakhloo, TUFTS University School of Medicine, USA**  
**12:00 – 12:15 pm**CLOSING COMMENTS AND ADJOURNMENT