

Roundtable Discussion with Industry and Stroke Experts

05/29-30 2025

**WASHINGTON DC, USA** 











Endovascular Management of Migraine, Transarterial and Transvenous Access to Subdural Space and Brain Surface, Requirements for New Liquid Embolics.



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

## NON-CLINICAL REQUIREMENTS IN NEUROINTERVENTION

Preclinical Data (Simulation, Biological Systems, Imaging)





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

#### **MISSION:**

Over 50 independent clinical experts representing several professional societies, academic research organizations, the US Food and Drug Administration (FDA), and industry representatives. Discuss the scope of focused updates on new emerging technologies in the Neurovascular and non-vascular fields and review and revise specific clinical endpoints. A writing committee of independent experts will chair workshops. The multidisciplinary process will result in important recommendations for clinical trial design, data reporting, preclinical research methods, endpoint definition and consensus formation to be published in a major neuroscience journal.

#### To achieve this goal, ARISE 2025 will:

- Develop new approaches to overcome barriers impeding drug and device development
- Identify, clarify, and communicate the implications of new research for cerebrovascular diseases
- Publish the consensus recommendations of ARISE participants which address these concerns
- Promote adoption of ARISE solutions by research, industry, clinical and government communities

### WHO IS INVOLVED:

ARISE architecture thus includes **3 major stakeholders research and practice in the treatment of cerebrovascular disease**: **academia** (leading international physicians/scientists from all involved disciplines), **industry** (scientists and executives from private sector pharmaceutical, device, and imaging companies), and **regulatory institutions** (executive managers, physicians and scientists from NIH and FDA).

## **PRELIMINARY AGENDA:**

The ARISE program begins with a full-day conference emphasizing the latest advancements in clinical and research methodologies. The sessions feature expert-led discussions on emerging techniques, novel therapeutic approaches, and regulatory frameworks. The agenda includes:

- **SESSION 1: MIDDLE MENINGEAL ARTERY (MMA): A PATHWAY TO INNOVATIVE TREATMENTS**
- > REFRACTORY MIGRAINE
- > ENDOVASCULAR ACCESS TO SUDURAL SPACE AND BRAIN SURFACE
- MMA INFUSIONS/EMBOLIZATION FOR HA
- > REQUIREMENTS FOR A NOVEL LIQUID EMBOLIC AGENT





- **SESSION 2: NON-CLINICAL REQUIREMENTS IN NEURO-IR**
- VALUE OF BIOLOGICAL SYSTEMS
- > VALUE OF SIMULATED USE EXPERIMENTATION
- NONCLINICAL EVIDENCE TO INFORM CLINICAL TRIAL DESIGN IMAGING, BIOLOGY
- **SESSION 3: AI & ROBOTICS**
- > THE EU AI ACT 2024: IMPLICATIONS FOR U.S. HEALTH CARE
- > ROBOTICS

#### **SECOND DAY WORKSHOPS:**

The second day of **ARISE** focuses on developing consensus recommendations through a collaborative process involving experts from **academia**, **industry**, **and regulatory institutions**. Here's how the day is structured:

Participants are divided into three thematic groups, focusing on:

- WORKSHOP 1: MIDDLE MENINGEAL ARTERY (MMA): A PATHWAY TO INNOVATIVE TREATMENTS
- **WORKSHOP 2: NON-CLINICAL REQUIREMENTS IN NEURO-IR**
- **WORKSHOP 3: AI & ROBOTICS**

#### **CONSENSUS STATEMENT PREPARATIONS:**

Each group is provided equal opportunity to engage in structured discussions. Initial recommendations from academic leaders in these fields are presented. These are then openly discussed, amended or expanded based on group input and replaced or refined as necessary. Each group presents their finalized recommendations to the entire assembly for broader input and validation. Writing Committees draft manuscripts summarizing the group recommendations.

Drafts are reviewed by all participants. Finalized articles are published to disseminate the recommendations widely.

This process ensures that the consensus reflects a balanced, multidisciplinary perspective, promoting evidence-based, actionable guidelines.





## **CORE ORGANISERS:**



**Prof Ajay K. Wakhloo, MD PhD FAHA FSNIS** Professor, TUFTS University School of Medicine, Boston, MA



Prof Adam S. Arthur, MD MPH FAANS FSNIS
Professor and chair of Neurosurgery at University of
Tennessee Health Science Center (UTHSC), Memphis, TN

#### **INVITATION:**

ARISE is a Roundtable where only invited faculty and companies can participate. The goal is to have companies from different fields involved. ARISE is then *inviting* your company to participate in this meeting by supporting this excellent platform that has a goal to foster consensus in areas of major relevance to ARISE and the networks needed to design/conduct successful trials in the field.

You have the possibility to bring your company's representatives, according to your support level. Please contact us to discuss the possibilities.

#### FOR FURTHER DETAILS, PLEASE CONTACT ME:



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