About ARISE

ARISE III: Roundtable Discussion with Industry and Stroke Experts

Stroke is a leading cause of death and serious long-term disability worldwide, with an estimated global prevalence of over 104.2 million people. With about 6.2 million deaths attributed to cerebrovascular diseases annually, ischemic and hemorrhagic strokes remain major threats to public health. There is no indication that these numbers changed significantly despite advances in modification of risk factors and specific preventive treatment of some etiologic factors. One major challenge is the highly heterogenous nature of potential causes of stroke, which require a concerted multidisciplinary approach to design and conduct of clinical prevention trials. Albeit well-designed successful clinical trials have led to significant advancement of management of stroke victims, there is the need for improvement and conduct. Newer data on the epidemiology of these diseases and innovative solutions must be integrated in the management of these patients through better collaboration among the major stakeholders: academia, government-based funding and regulatory organizations, and industry.

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*
- *TRANSARTERIAL ACCESS TO SUDURAL SPACE AND BRAIN SURFACE*
- *TRANSVENOUS ACCESS TO THE SUBDURAL SPACE & BRAIN SURFACE*

- *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*

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.