

Agenda

EXPANDING THE SCOPE OF INTRACRANIAL HEMORRHAGE (ICH), CEREBRAL VENOUS DISEASE (CVD) AND INTRACRANIAL ATHEROOCCLUSIVE DISEASE (ICAD) TREATMENT

New Perspectives on Epidemiology, Clinical Trials, Patient Selection, Evolving Therapies and Pre-clinical System Models_

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 am **FULL BREAKFAST PROVIDED**

Location: Metropolitan Galleries 4-6-Foyer **8:00 – 8:15 am** **ACADEMIA/INDUSTRY/FDA/NIH ROUNDTABLE ON ICH, CVD AND ICAD – OBJECTIVES** **Location: Metropolitan Galleries 1-3**

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

Introduction: Marc Fisher, BIDMC/Harvard Medical School, USA
8:15 – 11:00 am **SESSION 1: INTRACEREBRAL HEMORRHAGE (ICH) – NEW DATA, NEW LANDSCAPE, NEW APPROACHES**

Location: Metropolitan Galleries 1-3

Chairs: Mark Bain, Cleveland Clinic, USA
Christopher Kellner, Mount Sinai, USA

8:15-8:35

Intracerebral Hemorrhage epidemiology

8:15 – 8:27 Presentation by **Juhana Frösen**, Tampere University and University Hospital Tampere, Finland

8:27 – 8:35 Comments by **Jan- Karl Burkhardt**, University of Pennsylvania, USA

8:35-8:55

Major ICH clinical trials

8:35 – 8:47 Presentation by **Gustavo Pradilla**, Emory University, USA

8:47 – 8:55 Comments by **David Fiorella**, Stony Brook University, USA

8:55-9:15

Current MIS Evacuation Techniques

8:55 – 9:07 Presentation by **Christopher Kellner**, Mount Sinai, USA

9:07 – 9:15 Comments by **Brian Jankowitz**, JFK University Medical Center Edison, USA

9:15-9:35

Novel technologies

9:15 – 9:27 Presentation by **Mark Bain**, Cleveland Clinic, USA

9:27 – 9:35 Comments by **J Mocco**, Mount Sinai Health System, USA

09:35 – 11:00 ROUNDTABLE PANEL DISCUSSION

Panelists:

Mark Bain, Cleveland Clinic, USA; **Christophehr Kellner**, Mount Sinai, USA; **J Mocco**, Mount Sinai Health System, USA; **David Fiorella**, Stony Brook University, USA; **Jan- Karl Burkhardt**, University of Pennsylvania, USA; **Juhana Frösen**, Tampere University and University Hospital Tampere, Finland; **Babu Welch**, UT Southwestern Medical Center, USA **11:00 – 11:15**

amREFRESHMENT BREAK

Location: Metropolitan Galleries 4-6-Foyer **11:15 am– 1:30 pm**
SESSION 2: CEREBRAL VENOUS DISEASES: NEW DATA, NEW LANDSCAPE, NEW APPROACHES **Location: Metropolitan Galleries 1-3**

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

Felipe Albuquerque, Barrow Neurological Institute, USA

11:15 -11:35

Overview of cerebral Venopathies

11:15 – 11:27 Presentation by **Felipe Albuquerque**, Barrow Neurological Institute, USA

11:27 – 11:35 Comments by **Dorothea Altschul**, The Valley Hospital, USA

11:35-11:55

Cerebral Phlebography – what should we be looking for?

11:35 – 11:47 Presentation by **Omar Choudhri**, University of Pennsylvania, USA

11:47 – 11:53 Comments by **Waleed Brinjikji**, Mayo Clinic, USA

11:55- 12:15

Cerebral Venopathies – management options

11:55 – 12:07 Presentation by **Vitor Pereira**, University of Toronto and St. Michael's Hospital, Canada

12:07 – 12:15 Comments by **Peter Kan**, The University of Texas Medical Branch, USA

12:15 – 12:35

Clinical trial designs – what is next?

12:15 – 12:27 Presentation by **Kyle Fargen**, Atrium Health Wake Forest Baptist Medical Center, USA

12:27 – 12:35 Comments by **Athos Patsalides**, North Shore University Hospital, USA

12:35 – 1:30 ROUNDTABLE PANEL DISCUSSION

Vitor Pereira, University of Toronto and St. Michael's Hospital, Canada; **Felipe Alburquerque**, Barrow Neurological Institute, USA; **Gabor Toth**, Cleveland Clinic, USA; **David Liebeskind**, UCLA, USA; **Pierre Gobin**, Cornell University, USA; **Athos Patsalides**, North Shore University Hospital, USA; **Waleed Brinjikji**, Mayo Clinic, USA; **Ferdinand Hui**, University of Hawaii, USA; **1:30 – 2:30 pm LUNCH PROVIDED**

Location: Metropolitan Galleries 4-6-Foyer 2:30 – 5:00 pm
SESSION 3: INTRACRANIAL ATHEROCCLUSIVE DISEASE (ICAD): NEW DATA, NEW LANDSCAPE, NEW APPROACHES
Location: Metropolitan Galleries 1-3

Chairs: **Brian Hoh**, University of Florida, USA

Raul Nogueira, University of Pittsburgh, USA

2:30- 2:50

Do we know more after SAMMPRIS/VISSIT what went right, what went wrong?

2:30 – 2:42 Presentation by **Sam Zaidat**, Mercy Health St

Vincent, USA

2:42 – 2:50 Comments by **Raul Nogueira**, University of Pittsburgh, USA

2:50-3:10

Role of surgery in ICAD

2:50 – 3:02 Presentation by **Sepideh Amin-Hanjani**, University Hospitals Cleveland Medical Center, USA

3:02 – 3:10 Comments by **Giuseppe Lanzino**, Mayo Clinic, USA

3:10-3:30

Endovascular Management of ICAD

3:10 – 3:22 Presentation by **Pedro Lylyk**, University of Buenos Aires, USA

3:22 – 3:30 Comments by **Demetrius Lopes**, Advocate Aurora Health, USA

3:30-3:50 Imaging of ICAD

3:30 – 3:42 Presentation by **Matthew J Gounis**, UMass Chan Medical School, USA

3:42 – 3:50 Comments by **Edgar Samaniego**, University of Iowa, Iowa City, USA

3:50-4:10

Modern Management of ICAD – What we know and what we must learn

3:50 – 4:02 Presentation by **Brian Hoh**, University of Florida, USA

4:02 – 4:10 Comments by **Fawaz Al-Mufti**, New York Medical College, USA

4:10 – 5:00 ROUNDTABLE PANEL DISCUSSION

Brian Hoh, University of Florida, USA; **Raul Nogueira**, University of Pittsburgh, USA; **Sepideh Amin-Hanjani**, University Hospitals Cleveland Medical Center, USA; **Fawaz Al-Mufti**, New York Medical College, USA; **Satoshi Tateshima**, UCLA,

USA; **Italo Linfante**, Miami Neuroscience Institute, USA; **Ali Sultan**, Harvard Medical School, USA; **Geoffrey Colby**, University of California, US;

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 **DINNER – FOLLOWED BY SPECIAL PRESENTATION**

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

Bioinspired Breakthroughs in Medicine: From Shear-Targeted Stroke Therapeutics to Human Organ Chips

Donald E. Ingber, Harvard University, USA **7:00 – 8:00 am****FULL BREAKFAST PROVIDED**

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

amWORKSHOPS 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: MOST PROMISING APPROACHES TO IMPROVE THE TREATMENT OF INTRACRANIAL HEMORRHAGE

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

Felipe Albuquerque, Barrow Neurological Institute, USA

Matthew Amans, University of California, USA

Location: Dupont

Workshop #2

MOST PROMISING APPROACHES TO IMPROVE THE TREATMENT OF CEREBRAL VENOUS DISEASES

Moderators: Mark Bain, Cleveland Clinic, USA

Christopher Kellner, Mount Sinai, USA

Ricardo Hanel, Baptist Health, USA

Location: Dupont

Workshop #3

MOST PROMISING APPROACHES TO IMPROVE THE TREATMENT OF INTRACRANIAL ATHEROOCCLUSIVE DISEASE

Moderators: Brian Hoh, University of Florida, USA

Stavropoula Tjoumakaris, Thomas Jefferson University, USA

Guilherme Dabus, Miami Cardiac and Vascular Institute and
Baptist Neuroscience Institute, USA **10:45 – 11:00**
am **REFRESHMENT 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**