

STAIR XI

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

October 1–2, 2020

"The Transparent Time Window" *New Perspectives on Reperfusion, Neuroprotection and Imaging*

CYBER STAIR XI Program

Thursday Morning, October 1 (All Times are US Eastern Daylight Time)

WELCOME
9:00-9:15

SETTING THE STAGE: Ramifications of a Transparent Window
STAIR XI Chairman – *Greg Albers*

SESSION 1
9:15-11:15

SESSION 1: ACUTE STROKE TRIALS: New Data, New Landscape, New Designs
Session Chairs: *Ralph Sacco and Marc Fisher*

- Update on Neuroprotective Trial Results: What did we learn from ESCAPE NAI?
– *Mike Tymianski*
- Update on Collateral Enhancement – *Jeff Saver*
- Update on Thrombectomy Trials and New Devices – *Raul Nogueira*
- Detection of Stroke in the Ambulance – *Wade Smith*
- Pre-Hospital Trials – *Jim Grotta*

ROUNDTABLE PANEL DISCUSSION – *Tudor Jovin, Michael Marks, Josef Parvizi and Stacey Pugh*

11:15 – 11:30 **REFRESHMENT BREAK**

SESSION 2
11:30-1:00

SESSION 2: NEUROPROTECTION: Preclinical and Clinical Evaluation in 2020
Session Chairs: *Walter Koroshetz and Eng Lo*

- NINDS Pre-Clinical Assessment Network (SPAN): Rationale, overview, objectives, priorities – *Pat Lyden*
- Revisiting the Original Pre-Clinical STAIR Criteria: Do they still apply in 2020?
– *Marc Fisher*
- STAIR Consensus Statement Proposal: Standardized nomenclature for mRS outcomes
– *Jeff Saver*
- Neuroprotection Prior to Reperfusion – *Sean Savitz*
- Neuroprotection in ICH / Prevention of Edema in LHI – update on current trials
– *Chitra Venkat*

ROUNDTABLE PANEL DISCUSSION – *Kevin Sheth, Jaren Landen and Ana Krtolica*

1:00 – 2:00 **LUNCH BREAK GUEST PRESENTATION – COVID-19: Stroke Risk and
Impact on Research** – *Babak Navi*

STAIR XI

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

Thursday Afternoon, October 1

SESSION 3 2:00-3:15

SESSION 3: ROLE OF IMAGING IN RECENT AND FUTURE CLINICAL TRIALS

Session Chairs: *Pooja Khatri and David Liebeskind*

- **Imaging Advancements in Recent Thrombectomy and Thrombolysis Trials**
– *Bruce Campbell*
- **Role of Collateral Imaging in Testing Neuroprotectants** – *Maarten Lansberg*
- **Advanced Imaging SHOULD Be Performed at Primary Centers** – *Steve Warach*
- **Advanced Imaging SHOULD NOT Be Performed at Primary Centers** – *Michael Hill*

ROUNDTABLE PANEL DISCUSSION – *Taylor Kimberly, Amrou Sarraj and Eva Mistry*

SESSION 4 3:15-4:30

SESSION 4: INTRAVENOUS THROMBOLYSIS / TRIAL DESIGN

Session Chairs: *Andrei Alexandrov and Larry Wechsler*

- **Expanding the Window for IV Thrombolysis** – *Lee Schwamm*
- **How to Enhance the Efficacy of tPA?** – *Opeolu Adeoye*
- **NIH Rationale for Platform Trials of Thrombectomy** – *Clinton Wright and Scott Janis*
- **Introduction and Presentation of STEP Platform:**
 - **Overview of STEP Platform** – *Jeffrey Saver*
 - **Design & Opportunities for Academic Investigators and Industry**
 - **Expansion Indication Trials** – *Raul Nogueira*
 - **Innovative Drug & Device Trials: Optimized Concomitant Care, Novel Systems and Systems of Care** – *J Mocco*
 - **Adaptive Platform Design and Analysis: Efficiency and Rigor** – *Caitlyn Meinzer*

ROUNDTABLE PANEL DISCUSSION – *Barbara Purdon, Joe Broderick, Phil Gorelick, Pooja Khatri and Walter Koroshetz*

4:30 – 4:45 REFRESHMENT BREAK

SESSION 5 4:45-6:15

SESSION 5: REGULATORY PERSPECTIVE ON KEY CLINICAL TRIAL ISSUES

Session Chairs: *Carlos Peña and Greg Albers*

- **Points to Consider in Advancing Medical Device Studies** – *Xiaolin Zheng*
- **When is an IDE Required?** – *John Marler*
- **Looking Ahead: Registry vs. IDE Trials, Expanding Indications for Use and Engaging FDA**
– *Carlos Peña*
- **FDA; CDER and CDRH Panel – Overview of Important Regulatory Topics**– *Billy Dunn, Heather Fitter, Nick Kozauer, Xiaolin Zheng and John Marler*

STAIR XI

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

Friday Morning, October 2

10:00-12:30
Please Report
to Your
Workshop

WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS

Participants are divided into three groups – each to develop recommendations — **Please report to your workshop by 10:00 AM.**

WORKSHOP 1

TOP PRIORITIES FOR NEUROPROTECTIVE STUDIES

Facilitators: Chair – *Pat Lyden* Co-Chair – *Eng Lo*

- Optimal designs for future neuroprotective studies
- What did we learn from ESCAPE NAI?
- Optimizing pre-clinical evaluation criteria

WORKSHOP 2

IMAGING WORKSHOP – THE TIME WINDOW GETS TRANSPARENT

Facilitators: Chair – *Bruce Campbell* Co-Chair – *Maarten Lansberg*

- Which key imaging questions remain to be answered?
- How much imaging should be done at the primary center?
- Best designs to clarify optimal imaging

WORKSHOP 3

HOW TO ESTABLISH THE “OUTER LIMITS” OF REPERFUSION THERAPIES

Facilitators: Chair – *Larry Wechsler* Co-Chair – *Tudor Jovin*

- Time, Core, Penumbra, Vessel, Posterior Circulation, Microvascular Reperfusion, Platform vs RCTs

12:30 – 12:45 **REFRESHMENT BREAK**

12:45-2:00
WORKSHOP
REPORTS
ALL
PARTICIPANTS

WORKSHOP CHAIRS PRESENT RECOMMENDATIONS TO FULL ASSEMBLY

Drafting of consensus statements is initiated – Chaired by *Greg Albers*

CLOSING COMMENTS AND ADJOURNMENT

STAIR MISSION STATEMENT

The STAIR Consensus Conferences, via a collaboration of medical academia, the healthcare industry and government agencies, are intended to advance and accelerate stroke research to ultimately result in improved stroke acute treatment, care and prevention. To achieve this goal, STAIR will:

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