"Acute Stroke Trials: Advancing Design, Regulation and Implementation"

STAIR IX Program

Monday Morning, October 5

Maryland Suites – Main Floor of Hotel – Opposite Grande Ballroom
7:00 – 8:00 Full Breakfast Provided

Grande Ballroom – Main Floor of Hotel – Location of all General Sessions
8:00 – 8:15 MISSION, GOALS AND OBJECTIVES OF STAIR IX
STAIR IX Chairman: Greg Albers

8:15 – 10:15 SESSION 1: ACUTE STROKE TRIALS: NEW DATA, NEW LANDSCAPE, NEW DESIGNS
Session Chairs: Marc Fisher and Jeff Saver

- Update on endovascular trial results – Diederik Dippel, Michael Hill, Jeff Saver, Bruce Campbell, Tutor Jovin, Pooja Khatri
- Ongoing studies – Wade Smith
- Getting the right patients to the right places – Lee Schwamm

ROUNDTABLE PANEL DISCUSSION: Chairs, Speakers, Peter Rasmussen, J Mocco, Raul Nogueira, Pat Lyden, Sam Zaidat and Industry Representative

10:15 – 10:30 Refreshment Break -- Foyer Outside of Grande Ballroom

10:30 – 12:15 SESSION 2: HARNESSING CRITICAL MASS TO STRENGTHEN DATA COLLECTION/ANALYSIS AND INFLUENCE GUIDELINES/REGULATORY
Session Chairs: Joe Broderick and Tony Furlan

- StrokeNet: Rationale, Overview, Objectives, Priorities, Status – Joe Broderick and Yuko Paleschcy
- Insights from large national registries (GWTG-Stroke, SITS, Canada) – Eric Smith
- Data pooling in Acute Stroke Trials: Academic viewpoint – Ken Lees

ROUNDTABLE PANEL DISCUSSION: Chairs, Speakers, Ralph Sacco, Phil Gorelick, David Hess, Dawn Kleindorfer, Randy Marshall and Industry Representative

12:15 – 1:00 LUNCH PROVIDED – Maryland Suites – Main Floor
Monday Afternoon, October 5

Grande Ballroom – Main Floor of Hotel

1:00 – 2:15 SESSION 3: STIR IMAGING SESSION 1: ROLE OF IMAGING IN RECENT CLINICAL TRIALS
Session Chairs: Maarten Lansberg and David Liebeskind

- STIR I and STIR II Roadmap Summary – Steve Warach
- Comparison of imaging selection criteria and imaging outcomes in the recent endovascular trials:
  - MR-CLEAN – Charles Majoie
  - EXTEND-IA – Bruce Campbell
  - ESCAPE – Bijoy Menon
  - SWIFT-PRIME – Greg Albers
  - REVASCAT – Tudor Jovin
  - THERAPY – Albert Yoo

ROUNDTABLE PANEL DISCUSSION: Session Chairs, Speakers and Industry Representative

2:15 – 3:30 SESSION 4: STIR IMAGING SESSION II: IMAGING CONSIDERATIONS FOR TRIAL DESIGN
Session Chairs: Max Wintermark and Tudor Jovin

- Pooled clinical trial data: opportunities and limitations for imaging analysis – Pooja Khatri
- Imaging questions in need of addressing – Bruce Campbell
- Example of a clinical trial testing stroke imaging – Keith Muir

ROUNDTABLE PANEL DISCUSSION: Session chairs, Speakers, Soren Christenson and Industry Representative

3:30 – 3:45 Refreshment Break -- Foyer Outside of Ballroom

3:45 – 5:00 SESSION 5: REGULATORY PERSPECTIVE ON CLINICAL TRIAL ISSUES: IMAGING-BASED SELECTION, REGULATIONS AND RELEVANT POLICIES
Session Chairs: Billy Dunn FDA-CDER and Carlos Pena FDA-CDRH

- CDER Presentation Trial Design
  - Trial Efficiency and Regulations: Update on New Guidance
  - CDER Discussion on Companion Diagnostics
- CDRH Presentation on Neurothrombectomy
  - Device Review
  - Approaches to Trial Design
  - Considerations for Data Pooling
- Joint Discussion on how CDER and CDRH work together – Dunn and Pena
  - Device and Drug packaged together
  - Separate Drug and Device tested in combination (Add-on)
  - Drug and Device each effective alone and used at times concomitantly
  - Guidance for Future Studies

ROUNDTABLE PANEL DISCUSSION: Helmi Lutsep, Andrei Alexandrov, Michael Marks, Larry Wechsler Industry and FDA – Including CDRH and CDER Representative

Foyer Outside of Grande Ballroom- Main Floor

6:30 – 7:00 SPONSORED RECEPTION

Grande Ballroom- Main Floor

7:00 – 9:00 DINNER BANQUET -- FOLLOWED BY SPECIAL GUEST PRESENTATION

“The NINDS StrokeNet and Other Initiatives – The Status and Implications”

— Walter Koroshetz, Acting Director NINDS —
Tuesday Morning, October 6

7:00 – 8:00
FULL BREAKFAST PROVIDED – Maryland Suites – Main Floor

All Participants: Please Report Directly to Your Assigned Workshop at 8 AM

8:00 – 10:30
WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS
Participants are divided into three groups – each to develop recommendations

WORKSHOP 1: THE NEXT GENERATION OF ENDOVASCULAR TRIALS
Pooks Hill/Facilitators – Chair: Tudor Jovin Co-chair: David Liebeskind
Kensington Rm. • Next steps following the initial positive endovascular trials: key unanswered questions
• How to get the right patient to the right places
• How to preserve penumbra while waiting for reperfusion

WORKSHOP 2: IMAGING WORKSHOP: ORGANIZE A TRIAL TO COMPARE IMAGING MODALITIES
Montgomery/To select patients for acute stroke treatment
Democracy Rm. Facilitators – Co-chairs: Max Wintermark, Steve Warach and Marie Luby
• Which key imaging questions remain to be answered?
• Which of these questions could be answered from pooling available data?
• Which of these questions require a prospective trial?
• Should we randomize patients or compare sites with different selection techniques?
• How can the academic, drug, device and imaging industry work together?
• How can a trial testing imaging selection be funded?

WORKSHOP 3: ACADEMIC AND INDUSTRY SPONSORED TRIALS
Annapolis/Facilitators – Chair: Ken Lees Co-chair: Pooja Khatri
Chesapeake Rm. • Competition
• Collaboration
• Data Pooling
• Endpoint Selection
• Regulatory Issues

10:30 – 10:45
Refreshment Break - Foyer Outside of Grande Ballroom

10:45 – 12:00
WORKSHOP CHAIRS PRESENT RECOMMENDATIONS TO FULL ASSEMBLY
Grande Ballroom Drafting of consensus statement is initiated – Chaired by Greg Albers

12:00 – 12:15
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