

# STAIR IX

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

October 5–6, 2015  
Bethesda Pooks Hill Marriott  
Bethesda, Maryland

## "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*
- Implications: New standard of care? Impact on future study designs – *Jim Grotta*
- 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 Palesch*
- 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 —**

# STAIR IX

STROKE TREATMENT ACADEMIC INDUSTRY ROUNDTABLE

**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/ Kensington Rm.*  
Facilitators – Chair: *Tudor Jovin*    Co-chair: *David Liebeskind*

- 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 TO SELECT PATIENTS FOR ACUTE STROKE TREATMENT**  
*Montgomery/ 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/ Chesapeake Rm.*  
Facilitators – Chair: *Ken Lees*    Co-chair: *Pooja Khatri*

- Competition
- Collaboration
- Data Pooling
- Endpoint Selection
- Regulatory Issues

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

**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**

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## 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*
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