STAIR IV
STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

“Acute Stroke Treatment Trials: Enhancing Development, Cooperation and Approval”
Marriott Waterfront Hotel, Baltimore, Maryland
April 1st & 2nd, 2004

STAIR IV Program

Thursday, April 1st Morning
7:00—8:00 CONTINENTAL BREAKFAST
Essex Room Fourth Floor

All Sessions for the day are in the Laurel Ballroom on the Fourth Floor

8:00—8:30 WELCOME, OVERVIEW OF THE CONFERENCE GOALS & IMPACT OF PRIOR STAIR CONFERENCES – Marc Fisher, Conference Chair
Laurel Room
Opening Remarks – M. Kaste
Current Status of Acute Stroke Drug Therapy – W. Hacke

8:30—10:30 SESSION 1: STROKE TRIAL DESIGN: STATISTICAL & ENDPOINT CONSIDERATIONS
T. Furlan & T. Odergren
• Novel Approaches to Data Analysis and Evaluation in Stroke Trials – D. Berry
• Traditional Approaches to Data Analysis and Evaluation in Stroke Trials – G. Howard
• Acute Stroke Trial Endpoints – M. Krams, J. Weaver
• Innovative Approaches to Stroke Trial Design – K. Lees
• ROUNDTABLE PANEL DISCUSSION: “Stroke Trial Design”
  D. Berry, G. Howard, M. Krams, K. Lees, P. Duncan, J. Weaver, W. Long, L. Schwartz

10:30—11:00 Refreshment Break
Laurel Ballroom Foyer

11:00—1:00 SESSION 2: IMPROVING STROKE TRIALS
P. Gorelick & W. Söehngen
• Mega Trials vs. Focused Trials – S. Davis
• Applying Lessons Learned from Prior Stroke Trials to Future Trials – J. Saver
• Current Status and Future Directions for Imaging Directed Patient Selection – P. Michel
• Standardizing Patient Management: Physiological Parameters, Concomitant Medications, Post-Acute Care – C. Johnston
• ROUNDTABLE PANEL DISCUSSION: “Improving Stroke Trials”

1:00—2:00 LUNCH PROVIDED Harborside Ballroom Salon D
“Acute Stroke Treatment Trials: Enhancing Development, Cooperation and Approval”

Thursday, April 1st Afternoon
Laurel Ballroom

2:00—4:00 SESSION 3: REGULATORY CHALLENGES AND INSIGHTS
J. Zivin & D. Levy
- Facts and Myths about the FDA Approval Process – R. Katz, FDA
- Regulatory Approval for Devices and Device/Drug Combinations – C. Witten, FDA
- Applying FDAMA to Stroke Drug Development – C. Peck
- The Role of FDA Advisory Panels – H. Adams
- ROUNDTABLE PANEL DISCUSSION: “Regulatory Challenges and Insights”

4:00—4:15 Refreshment Break
Laurel Ballroom Foyer

4:15—6:00 SESSION 4: ACADEMIC—INDUSTRY—GOVERNMENT COOPERATION
L. Goldstein & J. LeClerc
- Future Prospects for Stroke Clinical Trial Consortia – A. Buchan
- Prospects for Organizing Industry and Government Sponsored Trials – J. Marler
- Engendering Cooperation Amongst Investigators, Industry and Government to Enable Better Trials
  V. Hachinski
- Fostering Cooperation between Device and Pharmaceutical Companies in Drug/Device Development
  J. Broderick
- ROUNDTABLE PANEL DISCUSSION: “Academic-Industry-Government Cooperation”
  A. Buchan, J. Marler, V. Hachinski, M. Bozik, M. Brainin, J. Broderick

6:30—7:00 COCKTAIL RECEPTION SPONSORED BY CEREMEDIX, INC.
Waterview Ballroom Foyer – First Floor

7:00—9:00 DINNER  Keynote Address Following Dinner – R. Atkinson
Waterview Ballroom

Neurological Magical Mystery Tour – L. Brass, Yale
**STAIR IV**
**STROKE TREATMENT**
**ACADEMIC INDUSTRY ROUNDTABLE**

“Acute Stroke Treatment Trials: Enhancing Development, Cooperation and Approval”

**Day 2**

*Friday April 2 Morning*

7:30—8:30 **BREAKFAST PROVIDED**

Essex Room

_All Participants: Please Convene in the Laurel Room Prior to Going to Your Workshop_

8:30 – 10:30 **WORKSHOPS TO DEVELOP CONSENSUS RECOMMENDATIONS**
Participants will be divided into three groups – each to develop recommendations

**Workshop 1:** Recommendations for: *Designing Stroke Trials to Maximize Success*

Laurel Room

Red

G. Donnan & T. Furlan

**Workshop 2:** Recommendations for: *Enhancing Government, Industry and Academic Cooperation in Acute Stroke Drug/Device Development*

Kent B & C

Blue

G. Albers, C. Kidwell & J. Broderick

**Workshop 3:** Recommendations for: *Regulatory Issues for Approving Therapeutic Interventions for Acute Stroke Treatment*

Waterview A

Green

J. Grotta, R. Sacco & K. McKenna

10:30 – 11:00 **Refreshment Break**

Laurel Ballroom Foyer

11:00—12:15 **WORKSHOP CHAIRS PRESENT RECOMMENDATIONS** from their group with general discussion. Drafting of consensus statement is initiated.

_Chaired by M. Fisher_

12:15—12:30 **CLOSING COMMENTS AND ADJOURNMENT**

--- Thank You for Your Participation ---