

**STAIR IV**  
STROKE TREATMENT  
ACADEMIC INDUSTRY ROUNDTABLE

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

***Marriott Waterfront Hotel, Baltimore, Maryland***

***April 1<sup>st</sup> & 2<sup>nd</sup>, 2004***

**STAIR IV Program**

***Thursday, April 1<sup>st</sup> 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***

***Laurel Room STAIR CONFERENCES – Marc Fisher, Conference Chair***

***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”***  
***S. Davis, J. Saver, P. Michel, C. Johnston, S. Warach, L. Caplan, E. Barnathan***

***1:00—2:00 LUNCH PROVIDED Harborside Ballroom Salon D***

# STAIR IV

STROKE TREATMENT  
ACADEMIC INDUSTRY ROUNDTABLE

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

*Thursday, April 1<sup>st</sup> 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”**  
*R. Katz, C. Peck, H. Adams, M. Pontecorvo, D. Easton, R. Urbanski, S. Liang, C. Witten, D. Hanley*

**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*

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*Neurological Magical Mystery Tour – L. Brass, Yale*

**S T A I R I V**  
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**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    G. Donnan & T. Furlan*  
*Red*

**Workshop 2: Recommendations for: Enhancing Government, Industry and Academic Cooperation  
in Acute Stroke Drug/Device Development**  
*Kent B & C    G. Albers, C. Kidwell & J. Broderick*  
*Blue*

**Workshop 3: Recommendations for: Regulatory Issues for Approving Therapeutic Interventions for Acute  
Stroke Treatment**  
*Waterview A    J. Grotta, R. Sacco & K. McKenna*  
*Green*

**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.**  
*Laurel Room    Chaired by M. Fisher*

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

————— ***Thank You for Your Participation*** —————