

STAIR V

STROKE TREATMENT
ACADEMIC INDUSTRY ROUNDTABLE

“Acute Stroke Treatment Trials: A New Era of Regulatory, Technology and Design Opportunities”

Arlington, VA

March 25th & 26th, 2006

STAIR V Preliminary Program

Saturday, March 25th Morning

7:00— 8:00 *CONTINENTAL BREAKFAST*

8:00— 8:40 **WELCOME — OVERVIEW OF CONFERENCE GOALS & IMPACT OF PRIOR STAIRS**
M. Walker & D. Easton

- Welcoming Remarks – Conference Chair – *Marc Fisher*
- Impact of Prior STAIR Conferences – *Kennedy Lees*

8:40—10:40 **SESSION 1: LESSONS AND IMPLICATIONS FROM SAINT TRIALS**
R. Sacco & W. Söehngen

- Detailed Overview of the *SAINT I* Results – *S. Davis*
- Lessons About Trial Design and Implementation from the *SAINT* Trails – *C. Diener*
- Shifting the Modified Rankin as a Primary Outcome Measure: Clinical Significance, Biological Relevance and Implications for Future Trials – *J. Saver*
- Impact on Future Stroke Trials if NXY-059 is Approved or Not Approved – *W. Hacke*
- ROUNDTABLE PANEL DISCUSSION: “Lessons and Implications”
S. Davis, C. Diener, J. Savor, W. Hacke, E. Barnathan, C. Kidwell, K. Lees, W. Wasiewski

10:40—11:00 Refreshment Break

11:00—12:45 **SESSION 2: TELEMEDICINE: POTENTIAL IMPACT ON ACUTE STROKE TRIALS
& THE MARKETING OF NEWLY APPROVED THERAPIES**
V. Hachinski & T. Odergren

- Telemedicine in Conjunction with a DPH Mandate for Primary Stroke Centers – *E. Smith*
- Enhancing IV-tPA use and newly approved stroke Therapies – *D. Hess*
- Models of Designing and Implementing Telemedicine-based Acute Stroke Trials – *P. Lyden*
- Can Telemedicine Networks Facilitate a National Stroke Consortium? – *G. Albers*
- ROUNDTABLE PANEL DISCUSSION: “Telemedicine Impact”
E. Smith, D. Hess, P. Lyden, G. Albers, M. Rosenberg, M. Rymer, N. Bornstein

12:45—1:45 *LUNCH PROVIDED*

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Saturday, March 25th Afternoon

1:45—4:15 SESSION 3: REGULATORY AND REIMBURSEMENT ISSUES

H. Adams & S. Liang

- **Pharmacological Therapies – Perspectives on the Acute Stroke Approval Process – *M. Walton FDA***
- **Device Therapies: Approvals beyond MERCI – *C. Pena, FDA***
- **FDA Regulation of Therapies and Trials Combining Drugs and Devices– *M. Kramer, FDA***
- **The Process for Changing the DRG tPA – *T. Curtis***
- **Harmonizing Drug and Device Approval -- *T. Furlan***
- **ROUNDTABLE PANEL DISCUSSION: “Regulatory Challenges and Insights”
*M. Walton, C. Pena, T. Furlan, J. Zivin, M. Kramer, T. Curtis, T. Zimmerman***

4:15—4:30 *Refreshment Break*

**4:30—6:00 SESSION 4: CURRENT STATUS AND FUTURE PROSPECTS FOR
INTERVENTIONAL DEVICES TO TREAT ACUTE STROKE**

J. Bogousslavsky & B. Skolnick

- **Endovascular Approaches to Clot Removal and Dissolution – *T. Tomsick***
- **Inducing Hypothermia and Enhancing Collateral Flow – *R. Atkinson***
- **Combining Intravenous and Intra-Arterial Delivery of Drugs and Devices: The Ultimate Future Combination Therapy? – *J. Broderick***
- **ROUNDTABLE PANEL DISCUSSION: “Devices to Treat Acute Stroke”
*T. Tomsick, R. Atkinson, J. Broderick, M. Kaste, A. Weiss, L. Wechsler, A. Wakhloo***

6:30—7:00 *SPONSORED COCKTAIL RECEPTION*

7:00—9:00 *DINNER*

Master of Ceremonies – *Rick Atkinson*

Keynote Address Following Dinner –STOP Stroke Bill** -- *Caya B. Lewis***

Deputy Staff Director for Health

Senate Health, Education, Labor and Pensions Committee

United States Congress

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Day 2

Sunday, March 26th Morning

7:30—8:30 BREAKFAST PROVIDED

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 Design:
Novel Approaches to Measuring Outcomes in Phase II & III Acute Stroke Trials
Red S. Warach, P. Gorelick, G. Howard

Workshop 2: Recommendations for Technology:
**Incorporating New Technology into Trials: Telemedicine, Electronic databases/CRFs,
and Population Kinetics in Acute Stroke Drug/Device Development**
Blue L. Goldstein, J. Marler, E. Jauch

Workshop 3: Recommendations for Regulatory:
Proceeding into the Combination Therapy Era of Drugs + Drugs and Drugs + Devices
Green D. Hanley, W. Smith, A. Quereshi

10:30 – 11:00 Refreshment Break

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*** —————