

**“Stroke Drug Development:
Bridging the Gap from Animal Research to Human Trials”**
Orlando (Lake Buena Vista) Florida
March 6-7 1999

———— *Dedicated to the Memory of Julio H. Garcia, MD* ————

Conference Agenda

Saturday, March 6th

8:00 AM *WELCOME AND OVERVIEW OF THE CONFERENCE GOALS – M.FISHER*

SESSION 1 – “INTRODUCTION AND OVERVIEW OF CURRENT STROKE MODELS”
W. PULSINELLI and G. FEUERSTEIN

8:15 – 8:30 *Mouse Stroke Models, Including Transgenics – P. Chan*

8:30 – 8:45 *Rat Stroke Models – C. Hsu*

8:45 – 9:00 *Cat Stroke Models – R. Traystman*

9:00 – 9:15 *Primate Stroke Models – G. del Zoppo*

9:15 – 9:30 *Embolic Stroke Models – M. Chopp*

9:30 – 10:30 *Discussion – Moderated by W. Pulsinelli and G. Feuerstein*

10:30 – 10:45 *Break*

**SESSION 2: “HOW TO BEST MAKE ANIMAL DRUG ASSESSMENT RELEVANT TO
CLINICAL STROKE THERAPY DEVELOPMENT”**
M. MOSKOWITZ, and J. CLEMENS

10:45 – 11:00 *Physiological Monitoring Standards and Recommendations on the Length of
Animal Survival – A. Buchan*

11:00 – 11:15 *Behavioral Outcome Measurements – What to use and When – D. Dietrich*

11:15 – 11:30 *The Therapeutic Time Window and Stroke Models – M. Ginsburg*

11:30 – 11:45 *Pharmacological Principles of Stroke Drug Development – A. Faden*

11:45 – 12:45 *Discussion – Moderated by M. Moskowitz and J. Clemens*

12:45 – 1:45 *Lunch*

SESSION 3: "HOW TO PROCEED FROM PRECLINICAL TO CLINICAL DRUG DEVELOPMENT" – J. ZIVIN and B. STEIGER

- 1:45 – 2:00** What Type of Preclinical Data would Clinical Stroke Neurologists like Demonstrated before beginning Clinical Trials – *R. Sacco, G. Albers*
- 2:00 – 2:15** How to Relate the Preclinical Pharmacological Profile to Clinical Drug Development – *J. McCulloch*
- 2:15 – 2:30** Lessons for Preclinical Drug Development from Recent Clinical Trials – *E. Hall*
- 2:30 – 2:45** What Type of Preclinical Data would Upper Management in the Pharmaceutical Industry like to help make Decisions about Clinical Development – *D. Levy*
- 2:45 – 3:00** An NINDS Perspective on Animal Modeling to Develop Acute Stroke Therapies – *J. Marler*
- 3:00-3:20** Are Surrogate Markers Useful in Preclinical and Clinical Stroke Drug Development – *M. Moseley, S. Warach*
- 3:20 – 4:00** Discussion – *Moderated by J. Zivin and B. Steiger*
- 4:00 – 4:15** Break

**SESSION 4: "RESTORATIVE THERAPY FOR ISCHEMIC STROKE"
L. GOLDSTEIN and J. BOGOUSLAVSKY**

- 4:15 – 4:30** Functional Recovery Following Brain Injury in Rats – Role of New Neuronal Sprouting – *T. Schallert*
- 4:30 – 4:45** Reorganization of Sensorimotor Cortex in Monkeys following Ischemic Injury – *R. Nudo*
- 4:45 – 5:00** Polypeptide Growth Factors in Stroke Recovery – their Role as potential Therapeutic Agents – *S. Finklestein*
- 5:00-5:15** Clinical Tools for Assessment of Stroke Recovery – *S. Cramer*
- 5:15 – 5:45** Discussion
- 7:00 – 9:00** Dinner (on site)
- 9:00 – 9:30** How does the Pharmaceutical Industry view the failure of Stroke Models to Predict Clinical Trial Outcome – *F. Marcoux (Park-Davis)*

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Sunday, March 7th

**8:00 – 10:00 WORKING BREAKFAST FOCUS GROUPS WITH PARTICIPANTS
DIVIDED INTO THREE GROUPS – EACH GROUP TO DEVELOP A
REPORT**

**GROUP 1: Recommendations for Standards Regarding Neuroprotective Drug
Development – *Chairmen: R. Traystman and M. Kaste***

**GROUP 2: Recommendations for how best to use Animal Modeling to Develop Restorative
Drug Therapy for Acute Ischemic Stroke – *Chairmen: P. Gorelick and
S. Finklestein***

**GROUP 3: Recommendations to Clinicians concerning how to assess the Relevance and
Appropriateness of Preclinical Stroke Drug Evaluations – *Chairmen: A. Furlan
and K. Lees***

10:00 – 10:30 Break – Reconvene All Attendees

**10:30 – 12:00 Presentation of the Recommendations from the Three Focus Groups and
General Discussion – *Chaired by M. Fisher, S. Finklestein and R. Traystman***

**12:00 – 2:00 Working Lunch. Begin to Draft a Consensus Document covering the Four
Main Charges of the Conference**

2:00 Adjournment

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