



American Society for Experimental Neurotherapeutics

12th Annual Meeting Program

(subject to change)

March 4-6, 2010 • Bethesda, Maryland

Thursday, March 4, 2010

Challenges in Conducting Clinical Research

Co-Chairs: Miroslav Backonja, MD, Robin Elliott, MA, Mark Corrigan, MD, Martha Morrell, MD

8:00 a.m.-9:30 a.m. Challenges in Conducting Drug Trials

- *Clinical Trial Methods*, Dave Zuckerman, Customized Improvement Strategies, LLC
- *IRB, Contract and Recruitment Issues*, Joyce Cramer, Yale University School of Medicine
- *Trial Design*, Including Ethics of Placebo Controls, Ken Getz, MBA, Tufts Center for the Study of Drug Development
- *Panel Discussion: When Good Trials Go Bad – Why Do Good Trials Fail to Determine an Outcome?*

9:30 a.m.-9:45 a.m. Break

9:45 a.m.-10:30 a.m. Challenges in Conducting International Trials

- *Clinical Trial Methods and Trial Design: Differences from U.S.-based Trials*, Virinder Nohria, MD, PhD
- *Trans-Regional Regulatory Issues*, Gene Wright, PharmD, PhD, Neuromed Pharmaceuticals, Inc.

10:30 a.m.-11:30 a.m. Post-Marketing Trials

- *What Are the New Requirements for Post-Marketing Trials for Safety and Efficacy?*, Danica Marinac-Dabic, MD, PhD, CDRH, Food and Drug Administration
- *Industry Perspective and Response*, Nancy Santilli, BSN, MSN, Endo Pharmaceuticals, Inc.

11:30 a.m.-1:00 p.m. Lunch (on your own)

1:00 p.m.-2:15 p.m. Challenges in Conducting Device Trials

- *How Are Device Trials Different than Pharma Trials?*, Nina Graves, Medtronic
- *Panel Discussion: What Does the Future Hold for Device Trials in Neurology?*, Nina Graves, Medtronic; Andres Lozano, MD, Toronto Western Hospital; Michael Rogawski, MD, PhD, University of California, Davis

2:15 p.m.-2:30 p.m. Break

2:30 p.m.-3:15 p.m. Special Issues in Conducting Drug Trials: Suicide Risk Associated with Neurological Therapies – Point/Counterpoint

- *There is a Significant Risk*, Russell Katz, MD, FDA
- *The Risk is Overstated*, Dale Hesdorffer, PhD, Gertrude H. Sergievsky Center

3:15 p.m.-4:45 p.m. Conducting Trials in Vulnerable Populations

- *Ethical Considerations in Conducting Trials in Vulnerable Populations*, Barbara Karp, MD, NINDS, National Institutes of Health
- *Panel Discussion*, Dale Hesdorffer, PhD, Gertrude H. Sergievsky Center; John Messenheimer, MD, GlaxoSmithKline; Brigitta Robertson, MD

5:00 p.m.-6:30 p.m. Information Exchange and Poster Presentation Reception

6:30 p.m.-8:30 p.m. Dinner Session — Drug Development: Overcoming Challenges in the Road Ahead

Chair: Kitty Clarence-Smith, MD, PhD

- *What Does It Really Cost to Develop a Treatment?*, Kenneth Kaitin, PhD, Tufts Center for the Study of Drug Development
- *Alleviating Burdens in Drug Development: The Clinical Trials Transformation Initiative*, Alberto Grignolo, PhD, PAREXEL Consulting
- *Innovative Strategies for Drug Development in Small Target Populations*, Frank Douglas, MD, PhD, Austen BioInnovation Institute

Friday, March 5, 2010

Select One of Two Morning Concurrent Sessions

A. Drug Development: Challenges, Consortia and CROs

Co-Chairs: Wilson Bryan, MD, Bernard Ravina, MD

8:00 a.m.-8:05 a.m. Introduction

8:05 a.m.-8:50 a.m. Review of Development

Kenneth Kaitin, PhD, Tufts Center for the Study of Drug Development

8:50 a.m.-9:30 a.m. Contract Research Organizations: How to Select, Problems and Experiences

Christopher Gallen, MD, Neuromed Pharmaceuticals, Ltd.

9:30 a.m.-9:45 a.m. Break

9:45 a.m.-10:15 a.m. Academic CROs

John March, MD, MPH, Duke Clinical Research Institute

10:15 a.m.-10:45 a.m. Consortia: An Academic Perspective

Karl Kieburz, MD, University of Rochester

10:45 a.m.-11:15 a.m. Consortia: An Industry Perspective

TBD

11:15 a.m.-11:30 a.m. Break

11:30 a.m.-12:15 p.m. Panel Discussion: Questions and Answers Focusing on Consortia

Or

B. Spectrum of Mitochondrial Dysfunction in Neurological Disease

Co-Chairs: Bennett Lavenstein, MD, Jill Rasmussen, MD

8:30 a.m.-9:10 a.m. Mitochondria in Health and Disease Across the Lifespan

W. Davis Parker Jr., MD, University of Virginia School of Medicine

9:10 a.m.-9:40 a.m. Mitochondrial Dysfunction in Pediatric Disorders

Andrea Gropman, MD, Children's National Medical Center

9:40 a.m.-10:20 a.m. Genetic Mechanisms of Mitochondrial Disease

Eric Schon, PhD, Columbia University

10:20 a.m.-10:30 a.m. Break

10:30 a.m.-11:00 a.m. Mitochondrial Dysfunction in Neurodegenerative Disease: Focus on Parkinson's Disease

Peter Riederer, PhD, University of Wurzburg

11:00 a.m.-11:30 a.m. Therapeutic Strategies in Mitochondrial Disorders

Michio Hirano, MD, Columbia University Medical Center

11:30 a.m.-12:15 p.m. Panel Discussion

12:15 p.m.-2:00 p.m. Lunch (on your own)

2:00 p.m.-6:00 p.m. Pipeline Session

Co-Chairs: Philip Perera, MD, Michael Rogawski, MD, PhD

Investigators in academia, government, industry and advocacy present an update on research and development progress on a specific project in the broad area of neurotherapeutics. Such projects may address neurological disorders, psychiatric disorders, pain, neurooncology, neurological infections or any other disorder affecting the central or peripheral nervous systems.

Saturday, March 6, 2010

Symposium: Comparative Effectiveness

Co-Chairs: Jacqueline French, MD, Karen Johnston, MD, MSC

9:00 a.m.-9:15 a.m. Introduction: The Trials of Comparative Trials

Jacqueline French, MD, New York University Comprehensive Epilepsy Center

9:15 a.m.-9:45 a.m. Active Control Equivalence: Getting it Right

Susan Ellenberg, PhD, University of Pennsylvania

9:45 a.m.-10:15 a.m. Regulatory Aspects of Comparative Trials

Russell Katz, MD, FDA

10:15 a.m.-10:30 a.m. Break

10:30 a.m.-11:00 a.m. Guidelines and Comparative Trials

Gary Gronseth, MD, University of Kansas Medical Center

11:00 a.m.-11:30 a.m. Health Economic Implications of Comparative Effectiveness: Will It Affect Who Will Pay for What and What Will Be Available?

Walter Koroshetz, MD, NINDS, National Institutes of Health

11:30 a.m.-12:00 p.m. Panel Discussion

12:00 p.m.-12:30 p.m. Questions and Answers