

THE 2ND ANNUAL TRAUMATIC BRAIN INJURY CONFERENCE

Challenges and Opportunities in Preclinical & Clinical Development
of New Diagnostics and Therapeutics

**MARCH 6-7, 2012
WASHINGTON, DC**

Treatment of TBI and especially acute TBI is still a major unmet medical need. Therapies that prove an ability to limit the damage done to the brain and improve clinical outcomes of patients of TBI will have a major impact on the global pharmaceutical market.

Although past clinical trials for new therapies have ended in failure, there is indeed renewed interest in this field and with recent initiatives from both the US Congress and Department of Defense to improve treatment options for TBI patients, the time has come for a rethinking of the potential for pharmaceutical management of this condition.



For more information about this conference, please contact us at 1-866-397-1376 or 1-312-244-3703, email: enquiries@tbiconference.com or visit www.tbiconference.com

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About this Conference

The 2nd Annual Traumatic Brain Injury Conference will address the challenges and opportunities in the development of new diagnostics and therapeutics for traumatic brain injury (TBI). Additionally, this conference will highlight strategies for clinical assessment of TBI and will address chronic outcomes of TBI, including post-traumatic stress disorder and neurodegeneration.

Speakers from academia, industry, the military and government will be addressing traumatic brain injury from a variety of perspectives in order to provide attendees with a holistic perspective on the diagnosis, treatment and outcomes associated with traumatic brain injury. To this end, presenters will be addressing the following issues:

- Advances in neuroimaging for TBI
- Clinical trial design for new TBI therapeutics
- Implementation of biomarkers for stratification, outcome prediction and therapeutics intervention monitoring
- Pre-clinical modeling and translating results to the clinic
- Drug delivery (blood-brain barrier) challenges facing development of new therapies
- Treatment of acute as well as post-acute/chronic neurorehabilitation
- Halting secondary injury in TBI
- Cell therapy potential for TBI
- Cognitive measures of TBI and outcomes
- Neuroprotection as a therapeutic intervention
- Regulatory perspectives on clinical trials and companion diagnostic development and commercialization

Key Questions Addressed

- How can animal model results translate to clinical research?
- What are the key patient populations for future clinical trials?
- What outcomes should new clinical trials measure?
- How can the blood-brain barrier be overcome in drug delivery?
- How can companion diagnostics and biomarkers improve therapeutic interventions and outcome prediction?
- What are the regulatory barriers facing developers of both companion diagnostics and new therapies?

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Speakers

The full list of speakers for this event has not yet been announced

Ramona Hicks, Ph.D., Program Director, Extramural Research Program, **NIH/NINDS**

Ramon Diaz-Arrastia, MD, Ph.D., Professor of Neurology, **Uniformed Services University of the Health Sciences**, Director of Clinical Research, **Center for Neuroscience & Regenerative Medicine**

Marie-Noelle Castel, Ph.D., Pharm.D., Head, Nervous System Disorders Development Unit, **sanofi-aventis**

David W. Wright, MD, FACEP, Associate Professor, Director, Emergency Neurosciences, Department of Emergency Medicine, **Emory University School of Medicine**

Larry Glass, Chief Executive Officer, **Neuren Pharmaceuticals**

Jeff Bazarian, MD, MPH, Associate Professor, Department of Emergency Medicine, **University of Rochester Medical Center**

Andreas Jeromin, Ph.D., Director, Business Development and Assay Core Services, **Banyan Biomarkers, Inc.**

David Poulsen, Ph.D., Research Associate Professor, **University of Montana**, Chief Scientific Officer, **Sinapsis Pharma**

Peter Como, Ph.D., Lead Reviewer, Neuropsychologist, Division of Ophthalmic, Neurological & Ear, Nose & Throat Devices (DONED), Neurodiagnostic and Neurotherapeutic Devices Branch (NNDB), **FDA**

Magali Haas, MD, Ph.D., Partner, Janssen R&D Innovation, **Johnson & Johnson**; Scientific Advisor, **OneMind**

Jordan Grafman, Ph.D., Director, Traumatic Brain Injury Research Laboratory, **Kessler Foundation Research Center**

Giulio Maria Pasinetti, MD, Ph.D., Professor of Psychiatry, Neuroscience, Geriatrics and Adult Development, Department of Psychiatry, **Mount Sinai School of Medicine**

Curtis Ponton, Ph.D., Chief Science Officer, **Neuro Assessment Systems**

Christine E. Marx, MD, Associate Professor, Department of Psychiatry and Behavioral Sciences, **Duke University Medical Center and Durham VA Medical Center**

Mikael Brönnegård, MD, Ph.D., Associate Professor, Chief Executive Officer, **NeuroVive Pharmaceutical AB**

Rachel Berger, MD, MPH, Associate Professor of Pediatrics, **University of Pittsburgh School of Medicine**

Thomas MacAllister, JD, Ph.D., Chief Executive Officer, **BHR Pharma**

Raymond Dionne, M.S., D.D.S., Ph.D., Scientific Director, Division of Intramural Research, National Institute of Nursing Research, **National Institutes of Health**

John Van Horn, Ph.D., Assistant Professor, Laboratory of Neuroimaging, **University of California Los Angeles**

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Agenda

DAY ONE Tuesday, March 6, 2012

8:30 Chair's Opening Remarks

Andreas Jeromin, Ph.D., Director, Business Development and Assay Core Services, **Banyan Biomarkers, Inc.**

8:40 Biomarkers in Pediatric TBI: Children Are Not Just Little Adults

In this presentation, we will discuss the current state of biomarker research in pediatric TBI with a focus on the differences between adults and children. This will include a discussion of biomarker-based diagnostics in pediatric TBI and how biomarkers are being used and may be used in the future to develop and test novel therapies for pediatric TBI.

Rachel Berger, MD, MPH, Associate Professor of Pediatrics, **University of Pittsburgh School of Medicine**

9:10 Evidence of Prolonged Deficits Using a Brain-Based Assessment of Symptoms Following Concussion

Topics to be discussed include:

- Overview of a novel medical technology development process: proprietary easy-to-use miniaturized electroencephalogram (EEG) platform
- Clinical Strategy: Domestic and international clinical studies of TBI for regulatory clearance and clinical acceptance
- Understanding the regulatory pathway for novel medical devices to reach the market

Curtis Ponton, Ph.D., Chief Science Officer, **Neuro Assessment Systems**

9:40 Biomarkers of Brain Injury: From Discovery to Diagnostics

Andreas Jeromin, Ph.D., Director, Business Development and Assay Core Services, **Banyan Biomarkers, Inc.**

10:10 Refreshment Break/Poster Viewing

10:40 Use of Serum S100B to Diagnose and Manage Mild Traumatic Brain Injury

Dr. Bazarian will review the use of serum S100B as a screening test for abnormal head CT scan after mild TBI in emergency department settings. He will also discuss the potential use of serum S100B as a diagnostic adjunct to mild TBI in sports settings and its potential role as a measure of blood-brain barrier damage after TBI.

Jeff Bazarian, MD, MPH, Associate Professor, Department of Emergency Medicine, **University of Rochester Medical Center**

11:10 The Role of Ectopically Expressed Olfactory Receptors in Traumatic Brain Injury-associated Tauopathy

Dr. Pasinetti will discuss studies from his laboratory suggesting for the first time that down regulation of certain ORs that are ectopically expressed in the brain may causally promote pathophysiological mechanisms underlying TBI clinical complications and, possibly, increase TBI patients' risk of developing Alzheimer's disease. He will also discuss clinically accessible biomarkers that might prove useful for assessing the likelihood of TBI subjects to develop clinical complications, which could provide more sensitive outcome measurements for clinical interventions and, ultimately, the characterization of potential novel therapeutic targets to prevent TBI-associated tauopathy.

Giulio Maria Pasinetti, MD, Ph.D., Professor of Psychiatry, Neuroscience, Geriatrics and Adult Development, Department of Psychiatry, **Mount Sinai School of Medicine**

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DAY ONE continued

11:40 **Novel Neuroimaging Biomarkers of Traumatic Brain Injury**

Ramon Diaz-Arrastia, MD, Ph.D., Professor of Neurology, **Uniformed Services University of the Health Sciences**, Director of Clinical Research, **Center for Neuroscience & Regenerative Medicine**

12:10 **Lunch**

1:20 **Patient-Focused Multimodal Neuroimaging Analysis of Cortical and Connectomic Traumatic Brain Injury**

In this presentation Dr. Van Horn will discuss emerging work from his multi-center team concerning multi-modal neuroimaging processing focused on brain image registration, segmentation, connectomics, and measurement from acute and chronic TBI patients of varying severity with a view toward treatment informatics and outcome prediction.

John Van Horn, Ph.D., Assistant Professor, Laboratory of Neuroimaging, **University of California Los Angeles**

1:50 **Panel Session: New Perspectives on Diagnosis, Diagnostic Development & Biomarkers for Traumatic Brain Injury**

Chair: **Andreas Jeromin, Ph.D.**, Director, Business Development and Assay Core Services, **Banyan Biomarkers, Inc.**
Rachel Berger, MD, MPH, Associate Professor of Pediatrics, **University of Pittsburgh School of Medicine**;
Curtis Ponton, Ph.D., Chief Science Officer, **Neuro Assessment Systems**; **Jeff Bazarian, MD, MPH**, Associate Professor, Department of Emergency Medicine, **University of Rochester Medical Center**; **Giulio Maria Pasinetti, MD, Ph.D.**, Professor of Psychiatry, Neuroscience, Geriatrics and Adult Development, Department of Psychiatry, **Mount Sinai School of Medicine**

2:40 **The Long Term Effects of Traumatic Brain Injury on Social Cognition**

Dr. Grafman will describe the long-term cognitive and social consequences of traumatic brain injury. He will then focus on the effects of location of brain injury and genetic polymorphisms on social ability and quality of life.

Jordan Grafman, Ph.D., Director, Traumatic Brain Injury Research Laboratory, **Kessler Foundation Research Center**

3:10 **Refreshment Break/Poster Viewing**

3:40 **SyNAPSe: A Phase 3, Multi-Center Trial for Severe TBI**

This presentation will cover the following:

- An overview of the history of progesterone as a neuroprotective agent as a backdrop leading to the current study.
- Discuss the SyNAPSe clinical trial – what BHR hopes to see and who they hope to help
- Discuss BHR Pharma's future plans, including a nasal formulation and how that will address an even broader segment of the population

Thomas MacAllister, JD, Ph.D., Chief Executive Officer, **BHR Pharma**

4:10 **The Neuroprotective Potential of Low Dose Methamphetamine for the Treatment of TBI**

Dr. Poulsen will describe preclinical results that show significant improvements in behavioral and cognitive assessments following treatment with methamphetamine up to 12 hours after severe TBI. He will also show histological and molecular data indicating potential methamphetamine-mediated mechanisms of neuroprotection. Finally, data describing the impact of methamphetamine treatment on the development of seizures after TBI will be shared.

David Poulsen, Ph.D., Research Associate Professor, **University of Montana**, Chief Scientific Officer, **Sinapsis Pharma**

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4:40 **Cyclosporin A and Cyclophilin Inhibitors in the Treatment of Acute Traumatic Brain Injury**

The long odyssey of cyclosporine is almost over. Since its strong neuroprotective properties in TBI were first discovered in the early 1990s, cyclosporine (CsA, also known as Cyclosporin A) has been progressing through various levels of study. Mikael Bronnegard, MD, PhD, will present the scientific evidence supporting NeuroVive's NeuroSTAT's (Cyclosporin A) significant positive impact on moderate to severe TBI and outline the path towards approval as a treatment for acute TBI within the next few years.

This presentation will cover the following:

- Cyclosporin A and cyclosporine analogues - preclinical and clinical data
- Phase II/III clinical trial with NeuroSTAT (CsA) in patients with moderate to severe TBI
- R&D and clinical strategy to develop a panel of cyclophilin inhibitors for treatment of acute neurological conditions
- Future path for NeuroSTAT towards approval

Mikael Brønnegård, MD., Ph.D., Associate Professor, Chief Executive Officer, **NeuroVive Pharmaceutical AB**

5:10 **Cocktail Reception**

DAY TWO Wednesday, March 7, 2012

8:30 **Chair's Opening Remarks**

8:40 **In Search of a Clinical Treatment for Acute Traumatic Brain Injury: The ProTECT III Clinical Trial**

This session will review the current state of clinical treatments for acute TBI and discuss a potential novel treatment. An update of the ProTECT III clinical trial will also be provided.

Objectives:

- Describe the impact of traumatic brain injury (TBI) in the US
- Discuss the current challenges that faces TBI research
- Describe the evidence for use of progesterone in acute TBI patients and the ProTECT III clinical trial progress

David W. Wright, MD, FACEP, Associate Professor, Director, Emergency Neurosciences, Department of Emergency Medicine, **Emory University School of Medicine**

9:10 **Development of a p75NTR Antagonist as an Acute Neuroprotective Treatment for Moderate to Severe TBI**

This presentation will cover discovery background on the target, pharmacology, preclinical data and provide some overview on the translational medicine approach for clinical development.

Marie-Noelle Castel, Ph.D., Pharm.D., Head, Nervous System Disorders Development Unit, **sanofi-aventis**

9:40 **Development of a Novel Neuroprotective Molecule for Mild TBI/Concussion**

In this presentation Mr. Glass will discuss the product development pathway for a neuroprotectant molecule from discovery through early-stage clinical trials. The presentation will cover discovery, pharmacology, oral formulation development, regulatory strategy and clinical trial considerations for NNZ-2566, a synthetic analog of the naturally occurring neuropeptide, IGF-1(1-3).

Larry Glass, Chief Executive Officer, **Neuren Pharmaceuticals**

10:10 **Refreshment Break/Poster Viewing**

10:40 **Biomarkers Driven Development of Experimental Therapeutics for Traumatic Brain Injury**

Raymond Dionne, M.S., D.D.S., Ph.D., Scientific Director, Division of Intramural Research, National Institute of Nursing Research, **National Institutes of Health**

11:10 **An Update on the Multi-Site DOD-Funded Injury and Traumatic Stress Consortium (INTRUST) and Related Projects Focusing on TBI and PTSD**

Christine E. Marx, MD, Associate Professor, Department of Psychiatry and Behavioral Sciences, Duke University Medical Center and Durham VA Medical Center

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Continued from previous page

11:40 **Panel Session: Research and Development of New Therapeutics for Traumatic Brain Injury**

Chair: Andreas Jeromin, Ph.D., Director, Business Development and Assay Core Services, **Banyan Biomarkers, Inc.**; **David Poulsen, Ph.D.**, Research Associate Professor, University of Montana, Chief Scientific Officer, **Sinapsis Pharma**; **Mikael Brönnegård, MD., Ph.D.**, Associate Professor, Chief Executive Officer, **NeuroVive Pharmaceutical AB**; **David W. Wright, MD, FACEP**, Associate Professor, Director, Emergency Neurosciences, Department of Emergency Medicine, **Emory University School of Medicine**; **Marie-Noelle Castel, Ph.D., Pharm.D.**, Head, Nervous System Disorders Development Unit, **sanofi-aventis**; **Thomas MacAllister, JD, Ph.D.**, Chief Executive Officer, **BHR Pharma**

Lunch

1:30 **Issues in the Development and Validation of Diagnostic Devices for Traumatic Brain Injury – A Regulatory Perspective**

The development of valid diagnostic devices for traumatic brain injury (TBI) poses numerous challenges with respect to proper study design, subject selection (e.g., severity of TBI), and clinical assessment. Currently, no single TBI diagnostic “gold standard” exists making validation of novel diagnostic devices for TBI problematic. Currently, there are no approved TBI diagnostic devices. This presentation will address some of the key issues in the validation of TBI diagnostic devices from a regulatory perspective, including the essential elements required for FDA approval of a TBI diagnostic device.

Peter Como, Ph.D., Lead Reviewer, Neuropsychologist, Division of Ophthalmic, Neurological & Ear, Nose & Throat Devices (DONED), Neurodiagnostic and Neurotherapeutic Devices Branch (NNDB), **FDA**

2:00 **Towards an International Collaboration for TBI Research**

The international research community has acknowledged the importance of working together to develop better diagnostics and treatments for traumatic brain injury (TBI). An important step toward this goal is the standardization of data elements and tools, and the development of a shared data repository. Another important step is the prioritization of research questions to ensure that future collaborative studies successfully test their hypotheses and achieve their specific aims.

This presentation will provide an overview of some of the major accomplishments and progress towards an international collaboration for TBI research, including updates on the TBI Common Data Elements Project, the Federal Interagency TBI Research (FITBIR) Informatics System, and the EU – USA – Canada Workshop on Comparative Effectiveness Research

Ramona Hicks, Ph.D., Program Director, Extramural Research Program, **NIH/NINDS**

2:30 **An Overview of the OneMind for Research Campaign**

Magali Haas, MD, Ph.D., Partner, Janssen R&D Innovation, **Johnson & Johnson**; Scientific Advisor, **OneMind**

3:00 **End of Conference**

Poster Session

The 2nd Annual Traumatic Brain Injury Conference Poster Session provides the opportunity for individuals to present their research and offers an excellent venue for extended informal discussion with meeting attendees.

Requirements

Abstracts should be no longer than 1000 words and follow a standard format (background, methods, results, and conclusion). Please include the following in your submission:

- Full name and affiliation
- Poster title
- Abstract

Deadlines/Other information

Please email your submission to enquiries@tbiconference.com by February 15, 2012.

Guidelines for Presenters

Information regarding physical dimensions/specifications for accepted submissions will be communicated to presenters via email.

* *Regular registration rates apply for all accepted poster session presenters*



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VENUE/LODGING

Crowne Plaza Old Town Alexandria
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Volunteers

If you are a student or are currently unemployed and wish to volunteer at the 2nd annual TBI Conference, please email us at enquiries@tbiconference.com to apply.

Volunteers receive free admission to the conference in exchange for on-site assistance and/or marketing support (eg. registration desk, attendee support, etc.) given to Arrowhead staff.

Substitution/Cancellation Policy

Your registration may be transferred to a member of your organization up to 24 hours in advance of the conference.

- Full refunds (minus a \$95 processing fee) are available if cancellation is received before February 10, 2012.
 - No cancellations can be accepted after this date, but voucher will be issued for attendance at a future Arrowhead event.
- Please fax, email or mail notice of cancellation to: Arrowhead Publishers & Conferences, 5412 Irving Avenue South, Minneapolis, MN 55419; fax: 312-244-3703; email: enquiries@tbiconference.com

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