

# NCRO NEWS

Duke  
Neuroscience

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System

*The mission of the NCRO is to foster the development of a world-class neuroscience clinical trials center.*



February 2009

### Who's Who in the NCRO

Management	Coordination	Email:
Mark Stacy, Medical Director	Kate Beck 668-2278	<a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>
Ron Beauvais, Administrator	Joanne Field 668-2842	<a href="mailto:joanne.field@duke.edu">joanne.field@duke.edu</a>
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Jessica Kesler, Clinical Trials Assistant	Karen White-Tong 668-2905	<a href="mailto:white044@mc.duke.edu">white044@mc.duke.edu</a>
Sandy Pendergraph, Financial Manager	Sarah Wyne 668-2837	<a href="mailto:sarah.wyne@duke.edu">sarah.wyne@duke.edu</a>

### ACTIVE ENROLLING STUDIES

The NCRO currently supports **37** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

### DEMENTIA

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-02/24/09
BURKE, Jim	Eli Lilly	Mild to Moderate Alzheimer's Disease	LY450139 (H6L-MC-LFAN)	Heydt 668-2843	20 / 3
BURKE, Jim	Toyama Chemistry Co, Ltd	Mild to Moderate Alzheimer's Disease	T-817MAa (AA4437420)	Heydt 668-2843	13 / 5

### EPILEPSY

HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP902)	Beck 668-2278	6 / 4
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### GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	20 / 15
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### MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 31
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 20
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharma.	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 5
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 5
SCOTT, Burt	Acadia Pharmaceuticals	Psychosis in PD	ACP-103-014	Perry-Trice 684-0865	10 / 0
STACY, Mark	Novartis	Non-motor symptoms in idiopathic PD	CEL200AUS14 (Stalevo vs. IR carbidopa/levodopa)	Field 668-2842	8 / 0
STACY, Mark	Weill Cornell	Parkinson's Disease	Coenzyme Q10 (QE3)	Field 668-2842	12 / 3

### NEUROMUSCULAR

BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	12 / 11
BEDLACK, Rick	Amyotrophic Lateral Sclerosis Assoc (ALSA)	ALS – Lithium in combination w/Riluzole	LALS-001	Grace 668-2844	10 / 0
BEDLACK, Rick	Amyotrophic Lateral Sclerosis Assoc (ALSA)	Validation of ALS Biomarkers	BIO ALS-01	Grace 668-2844	36 / 31

## VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	White-Tong 668-2905	55 / 38
GOLDSTEIN, Larry	Schering Plough	Atherosclerotic Disease	SCH 530348 w/standard of care (TRA 2°P – TIMI 50)	White-Tong 668-2905	75 / 0
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 2
GRAFFAGNINO, C	Johns Hopkins U / NIH-NINDS	Spontaneous ICH	MISTIE	Stoner 668-5275	12 / 1
KOLLS, Bradley	Astute Medical, Inc.	Biomarker for AKI in ICU patients	Prot AST-103	E. Bennett 668-1429	300 / 43
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 886
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin – ALIAS study	E. Bennett 668-1429	25 / 6

## NON-NCRO TRIALS

MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 1
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### \*\*\*STUDY SPOTLIGHT\*\*\*

**New Approved Studies Ready for Recruitment!!**  
Please see further details below – Thank you for your Support!

#### **Carmen Graffagnino (PI) – Johns Hopkins University / supported by grant from NIH-NINDS**

##### **“Minimally Invasive Surgery plus rt-PA for ICH Evacuation – MISTIE”**

The purpose of this study is to determine the safety of using a combination of minimally invasive surgery and clot lysis with rt-PA to remove ICH. The procedure is to use image-based surgery (MRI or CT) to provide catheter access to ICH for the intervention, which is a one-time clot aspiration followed by instillation of rt-PA over approximately 72 hours. Sponsor proposes to test if this intervention facilitates more rapid and complete recovery of function and decreased mortality from this condition compared to conventional medical management without subjecting the patient to craniotomy. We anticipate enrolling up to 12 subjects at Duke, with the total study population being 119. All patients presenting to the Emergency Dept at Duke or admitted to Duke Hospital with a diagnosis of an acute intracerebral hemorrhage and meeting the inclusion/exclusion criteria will be offered participation in this study. You may contact Dr. Carmen Graffagnino or Joanna Stoner (668-5275) for more information.

#### **Burton Scott (PI) – Acadia Pharmaceuticals**

##### **“A Multi-Center, Placebo-Controlled, Double-Blind Trial to Examine the Safety and Efficacy of ACP-103 in the Treatment of Psychosis in Parkinson’s Disease”**

The purpose of this study is to demonstrate the antipsychotic efficacy of ACP-103 in subjects with PD Psychosis as measured by a decrease in the severity and/or frequency of hallucinations and/or delusions. This study will be conducted as a six-week, multi-center, randomized, double-blind, placebo-controlled study. Study drug (ACP-103) will be given at 2 dose levels and each active arm will be compared to a single placebo arm. The study will be conducted on an outpatient basis with visits performed at Screening, on Study Day 1 (Baseline), Study Day 8, Study Day 15, Study Day 29, and Study Day 42 with a follow-up visit (Study Day 70) 4 weeks after the last regular study visit for those subjects who do not continue into the open-label extension study. We anticipate enrolling up to 10 subjects at Duke, with the total study population being 280. You may contact Dr. Burton Scott or Peggy Perry-Trice (684-0865) for more information.

#### **Richard Bedlack (PI) – Amyotrophic Lateral Sclerosis Association (ALSA)**

##### **“A Multicenter, Double-Blind, Placebo-Controlled, Study to Investigate the Safety and Efficacy of Lithium in Combination with Riluzole in Volunteers with Amyotrophic Lateral Sclerosis (ALS)”**

This is a double-blind, randomized, placebo-controlled crossover trial evaluating the safety and efficacy of lithium and riluzole compared to placebo and riluzole. All subjects enrolled in this study will be taking a stable dose of riluzole 50 mg PO BID for at least 30 days and have an ALS disease duration (from symptom onset) of no more than 36 months at enrollment. An interim analysis will occur once the 84<sup>th</sup> subject has been accrued. Based on the available data the DSMB may decide to stop the study for efficacy or futility or stop accrual and request that follow-up continue on the 84 subjects enrolled or continue accrual. We anticipate enrolling up to 10 subjects at Duke. After screening and randomization, subjects will be followed every 4 weeks for the first 12 weeks. Subsequent visits will then occur every 8 weeks with a final visit at Week 52. You may contact Dr. Richard Bedlack or Karen Grace (668-2844) for more information.

## *IRB Tips to Remember*

 An *Adverse Event* must be reported to the IRB if it:

- ✓ Is more likely than not related to study activities; and
- ✓ Represents a new risk; and
- ✓ Is unanticipated.

In addition, an expected event that is occurring at a frequency or intensity greater than originally anticipated must be reported to the IRB.

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 A *Protocol Deviation/Violation* must be reported to the IRB if it:

- ✓ Affects subject rights and welfare; or
  - ✓ Affects subject safety; or
  - ✓ Affects the integrity of study data; or
  - ✓ Affects the subject's willingness to continue in the study; or
  - ✓ Is specifically requested by a government agency, internal/external auditor, medical monitor, or the IRB.
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 A sponsor's waiver of inclusion criteria also requires IRB approval prior to implementation.

## New requirements for Human Subjects Protection Certification

As of January 1, 2009, Duke Medicine adopted the web-based modules from the Collaborative Institutional Training Initiative (CITI) website ([www.citiprogram.org](http://www.citiprogram.org)) for certification in Human Subjects Protection (HSP) Training. To date, more than 500 research personnel have completed the Duke Medicine requirements within the CITI system. Please go to the CRSO website for more information ([www.crso.som.duke.edu](http://www.crso.som.duke.edu)).

Duke University School of Medicine  
Clinical Research Support Office (CRSO)  
"Things You Need To Know"

**"Things You Need To Know" sessions are held the 1<sup>st</sup> Wednesday of each Month**

Time: Noon - 1:00 pm

School of Nursing

Room 1014 (Peter and Ginny Nicholas Auditorium and Learning Center)

307 Trent Drive

No registration necessary

Beverages and desserts are provided. Please feel free to bring your lunch.

If you have questions, please contact the CRSO at [CRSO.Help@notes.duke.edu](mailto:CRSO.Help@notes.duke.edu) or 681-6665.

We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: Donna Carnes @ [donna.carnes@duke.edu](mailto:donna.carnes@duke.edu).