

NCRO HIGHLIGHTS

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.

March 2006

Who's Who in the NCRO

Management	Coordination	Email:
Mark Stacy, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
Carmelo Graffagnino, Co-Medical Director	Gail Cook 684-0865	cook0007@mc.duke.edu
Ron Beauvais, Administrator	Joanne Field 668-2842	joanne.field@duke.edu
Donna Carnes, Regulatory Assistant	Karen Grace 668-2844	karen.grace@duke.edu
Lisa Gauger, Clinical Research Administrator	Debra Heydt 668-2843	debra.heydt@duke.edu
JoAnn Jones, Regulatory Administrator	Rene Link 970-1648	link0002@mc.duke.edu
Cathy O'Neill, Financial Manager	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

We are pleased to announce Cathy O'Neill has joined the NCRO as our trial Financial Manager! Please join us in welcoming her to our group. She is located in Rm. 206 at Morreene Road.

ACTIVE ENROLLING STUDIES

The NCRO currently supports **43** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

DEMENTIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-3/31/06
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 11
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 16

MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 16
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 499
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 63
SCOTT, Burt	Teva Pharmaceuticals	Early PD	Rasagiline (Adagio)	Field 668-2842	8-10 / 0
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 3
STACY, Mark	Ovation Pharmaceuticals	Psychosis in PD	Melperone OV-1003	Gauger 668-1538	6 / 0
STACY, Mark	Novartis	PD	Quest PD(CELC200AUS11)	Field 668-2842	10 / 0

NEUROMUSCULAR

BEDLACK, Rick	NEALS/CytRx Corp.	ALS	Arimoclomol	Grace 668-2844	10 / 9
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VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 17
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 12
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 10
GRAFFAGNINO, C	Novo Nordisk	Acute intracerebral hemorrhage	F7ICH-1641	Stoner 668-5275	5 / 1
GRAFFAGNINO, C	CoAxia, Inc.	Acute ischemic stroke	SENTIS-CD-0125	Stoner 668-5275	10 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 603
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 51
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

REMINDER

The next NCRO Advisory Board meeting is scheduled for 4/12/06 @ 5:30 p.m. at Morreene Road Clinic - 2nd floor conference room.

We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: JoAnn Jones @ jones018@mc.duke.edu.

STUDY SPOTLIGHT

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

M. Stacy (PI) – Quest PD

“A Prospective, Multi-Center, Randomized, Open-Label Study with Blinded Raters to Evaluate the Effects of Immediate Versus Delayed Switch to Stalevo® On Motor Function and Quality of Life in Patients with Parkinson’s Disease With End-Of-Dose Wearing Off”

The primary objective of this study is to assess changes in motor function and quality of life in patients with Parkinson’s Disease who are experiencing end-of-dose wearing off. The study will consist of three phases: a Pretreatment Phase (includes a screening period & baseline visit), a Treatment Phase (randomization into one of two groups: a) immediate-switch group or b) delayed-switch group), and an 8 week Extension Phase. We expect to recruit 10 subjects here at DUHS. Minimum PHI used for screening includes: DOB, diagnosis, medications, and medical history. Contact Dr. Mark Stacy or Joanne Field (668-2842) if you have a patient who may be interested in this study.

C. Graffagnino (PI) – SENTIS NeuroFlo™ Catheter

“SENTIS Stroke Trial Protocol – Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke”

The primary objective of this study is to demonstrate the safety and efficacy of the NeuroFlo treatment plus medical management relative to medical management alone in improving neurologic outcome in ischemic stroke patients. The study is a prospective, controlled, randomized, multicenter study of NeuroFlo treatment plus standard medical management versus standard medical management alone. Randomization will be 1:1 and stratified to ensure equivalent subject distribution between treatment and control for the following key parameters: NIHSS at baseline (stratify ≤ 10 , 11-18) and time from symptom onset to time of baseline NIHSS evaluate (stratify <5 hrs, 5-8 hrs). We expect to recruit 10 subjects here at DUHS. Minimum PHI used for screening includes: DOB, diagnosis, NIHSS, time of symptom onset, and medical history. Contact Dr. Carmen Graffagnino or Joanna Stoner (668-5275) if you would like more information regarding this study. A stroke pager is in place and carried by a stroke research attending. When an acute stroke code is activated, the attending will call the neurology resident to obtain information sufficient to decide if the stroke attending should screen the patient. If so, the stroke attending and/or the stroke research nurse will go to the ER.

**Duke University School of Medicine
Clinical Trials Quality Assurance (CTQA)
LUNCH AND LEARN SERIES
2005/2006 Schedule**

The lunch and learn series are one hour **coordinator centric educational sessions** with the primary goal of providing useful, hands on knowledge to build a stronger research work force. These sessions will also provide the members of the CTQA office an opportunity to present themselves as a resource to the research community.

**May 12
June 6**

**Humanitarian Use Devices
TBD**

**John Falletta, M.D.
TBD**

THE CTQA LUNCH AND LEARN SERIES IS FREE AND OPEN TO THE PUBLIC – DUKE UNIVERSITY HEALTH SYSTEM AFFILIATION IS NOT REQUIRED. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

ALL SESSIONS ARE SCHEDULED FOR 12:00-1:00 PM IN ROOM 103 OF THE BRYAN RESEARCH BUILDING (NOT THE BRYAN CENTER). **SESSIONS HAVE BEEN APPROVED FOR 1.2 NURSING CONTACT HOURS AND 1.0 CONTINUING EDUCATION UNITS.**

PLEASE REGISTER FOR THE SERIES BY E-MAILING CTQA@MC.DUKE.EDU
BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!

Bushnell CD. **Hormone replacement therapy and stroke: the current state of knowledge and directions for future research.** *Semin Neurol.* 2006 Feb;26(1):123-30. Review.

Goldstein LB. **Improving the clinical diagnosis of stroke.** *Stroke.* 2006 Mar;37(3):754-5.

Goldstein LB, Hankey GJ. **Advances in primary stroke prevention.** *Stroke.* 2006 Feb;37(2):317-9.

Goldstein LB. **Is there a causal relationship between the amount of alcohol consumption and stroke risk?** *Stroke.* 2006 Jan;37(1):1-2.

Lang AE, Langston JW, Stoessl AJ, Brodsky M, Brooks DJ, Dhawan V, Elias WJ, Lozano AM, Moro E, Nutt JG, Stacy M, Turner D, Wooten GF. **GDNF in treatment of Parkinson's disease: response to editorial.** *Lancet Neurol.* 2006 Mar;5(3):200-2.

Lang AE, Gill S, Patel NK, Lozano A, Nutt JG, Penn R, Brooks DJ, Hotton G, Moro E, Heywood P, Brodsky MA, Burchiel K, Kelly P, Dalvi A, Scott B, Stacy M, Turner D, Wooten VG, Elias WJ, Laws ER, Dhawan V, Stoessl AJ, Matcham J, Coffey RJ, Traub M. **Randomized controlled trial of intraputamenal glial cell line-derived neurotrophic factor infusion in Parkinson disease.** *Ann Neurol.* 2006 Mar;59(3):459-66.

Ondo WG, Jankovic J, Connor GS, Pahwa R, Elble R, Stacy MA, Koller WC, Schwarzman L, Wu SC, Hulihan JF; Topiramate Essential Tremor Study Investigators. **Topiramate in essential tremor: a double-blind, placebo-controlled trial.** *Neurology.* 2006 Mar 14;66(5):672-7.

Parkinson Study Group. **A randomized controlled trial of etilevodopa in patients with Parkinson disease who have motor fluctuations.** *Arch Neurol.* 2006 Feb;63(2):210-6.

Parkinson Study Group. **Randomized placebo-controlled study of the nicotinic agonist SIB-1508Y in Parkinson disease.** *Neurology.* 2006 Feb 14;66(3):408-10.

Warner DS, Laskowitz DT. **Changing Outcome from Aneurysmal Subarachnoid Hemorrhage: Another Step Closer.** *Anesthesiology.* 2006 Apr;104(4):629-630.