

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.

May 2006

Who's Who in the NCRO

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Mark Stacy, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
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ACTIVE ENROLLING STUDIES

The NCRO currently supports **42** 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-5/31/06
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 / 17

MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 17
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 502
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 61
SCOTT, Burt	Teva Pharmaceuticals	Early PD	Rasagiline (Adagio)	Field 668-2842	8-10 / 2
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	NIH, MDA, ALS Assoc.	ALS-motor neuron diseases	DNA Banking Repository	Heydt 668-2843	50 / 0
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 5

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 / 11
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	M. Scism 668-1429	700 / 638
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 52
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	M. Scism 668-1429	25 / 0
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	M. Scism 668-1429	100 / 6

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.

Cerebrovascular disorders

1. Roubin G., Clark W, Chakhtoura E, Brooks W, Hye RJ, Howard V, Hughes S, Tom M, Roberts J, **Goldstein LB**, Britt T, Hobson RW. Low complication rates for carotid artery stenting in the credentialing phase of the Carotid Revascularization Endarterectomy vs. Stenting Trial. *Stroke* 2006; 37: 620.
2. The SPARCL Investigators. The Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) Study. *Cerebrovascular Diseases* 2006; 21 (suppl 4): 1.
3. **Goldstein LB**, Lennihan L, Rabadi M, AESR Investigators. Amphetamine-Enhanced Stroke Recovery Trial: No relationship between comorbidity and stroke severity at the start or end of rehabilitation. *Neurology* 2006 (IN PRESS).
4. **Cheryl D Bushnell**, Jeffrey Griffin, L Kristin Newby, Larry B Goldstein, Kenneth W Mahaffey, Carmelo A Graffagnino, Robert A Harrington, Harvey D White, R John Simes, Robert M Califf, Eric J Topol, and J Donald Easton. Statin Use and Sex-Specific Outcomes in Patients with Vascular Disease. *Stroke* 2006; in press.

Movement Disorders

1. Lang, AE, Gill S, Patel NK, Lozano A, Nutt JG, Penn R, Brooks DJ, Hotton G, Moro E, Heywood P, Brodsky MA, Burchiel K, Hutchinson M, Kelly P, Dalvi A, Scott B, **Stacy M**, Turner D, Wooten VGF, Elias WJ, Laws ER, Dhawan V, Stoessl AJ, Matcham J, Coffey RJ, Traub M. A multicenter, randomized, double-blind, placebo controlled trial of liatermin (r-metHuGDNF) administered by bilateral Intraputamin infusion to patients with idiopathic Parkinson's disease. *Ann Neurol* 2006;59:459-66.
2. Ondo WG, Jankovic J, Connor GS, Pahwa R, Elble R, **Stacy M**, Koller WC, Schwarzman L, Wu S-C, Ph.D., Hulihan JF on behalf of the Topiramate Essential Tremor Study Investigators. Topiramate in essential tremor: A double-blind, placebo-controlled trial. *Neurology* 2006;66:672-7.
3. Kolls B, **Stacy M**. Apomorphine: A rapid rescue agent for motor and non-motor fluctuations in advanced Parkinson's disease. *Clinical Neuropharmacol* 2006;(in press)
4. Brin et al. A randomized, multicenter, double-blind, placebo-controlled study of botulinum toxin type A (BOTOX®) for the treatment of cervical dystonia. *Neurology* 2006 (in press)
5. Hancock DB, Martin ER, Fujiwara K, **Stacy MA**, Scott BL, Stajich JM, Jewett R, Li Y-L, Hauser MA, Vance JM, Scott WK. iNOS and the modulating effect of cigarette smoking in Parkinson disease. *Ann Neurol* (in press)
6. **Stacy M**, Hauser R, Oertel W, Schapira A, Sethi K, Stocchi F, Tolosa E. End of Dose Wearing-Off in Parkinson's Disease: a 9-question survey assessment. *Clin Neuropharm* (in press)
7. Parkinson Study Group. Randomized placebo-controlled study of the nicotinic agonist SIB-1508y in Parkinson's disease. *Neurology* 2006;66:408-10.
8. Parkinson Study Group. A randomized controlled trial of Etilevodopa in Parkinson's disease patients with motor fluctuations. *Arch Neurol* 2006;63:210-6.
9. Biglan KM for the Parkinson Study Group. Rasagiline improves quality of life in early Parkinson's disease. *Mov Disord* 2006;616-23.
10. Pankratz N for the Parkinson Study Group. Presence of an APOE4 allele results in significantly earlier onset of Parkinson's disease. *Mov Disord* 2006 Jan;21(1):45-9.
11. Goetz C for the Parkinson Study Group. Safety of rasagiline in elderly Parkinson's disease patients. *Neurology* 2006;66:1427-9.

Neuro-oncology

1. Reardon, D.A., Akabani, G., Coleman, R.E., Friedman, A.H., Friedman, H.S., Herndon, J.E., II, McLendon, R.E., Pegram, C.N., Provenzale, J.M., **Quinn, J.A.**, Rich, J.N., Vredenburgh, J.J., Desjardins, A., Guruangan, S., Badruddoja, M., Dowell, J.M., Wong, T.Z., Zhao, X.-G., Zalutsky, M.R., and Bigner, D.D.: Salvage radioimmunotherapy with murine 131I-labeled anti-tenascin monoclonal antibody 81C6 for patients with recurrent primary and metastatic malignant brain tumors: Phase II study results. *J. Clin. Oncol.* 24(1):115-122, 2006.
2. McLaughlin, C., Gururangan, S., Provenzale, J., Coleman, R.E., Halperin, E., Fuchs, H., George, T., Watral, M.A., Reardon, D., **Quinn, J.**, Rich, J.N., Vredenburgh, J., and Friedman, H.S.: Neuraxis metastasis in children with diffuse pontine glioma. *J. Neurooncology*, in press, 2006.
3. Reardon, D.A., **Quinn, J.A.**, Desjardins, A., Vredenburgh, J.J., Gururangan, S., Sathornsumetee, S., Herndon II, J.E., Dowell, J.M., McLendon, R.E., Provenzale, J.M., Sampson, J.H., Abey, R.D., Ochs, J.S., Lyons, P., Tourt-Uhlig, S., Friedman, A.H., Bigner, D.D., Friedman, H.S., and Rich, J.N.: Phase I trial of gefitinib plus sirollimus in adults with recurrent malignant glioma. *Clin. Cancer Res.*, in press, 2006.

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.

Next session scheduled for July 17, 2006.

Look for the new schedule to be posted in an upcoming issue of the newsletter once the CTQA office finalizes.

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!!