

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.

October 2005

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
	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

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.

ACTIVE ENROLLING STUDIES

The NCRO currently supports **41** 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-10/31/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 9
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 13

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 8
---------------	---------	---------------------------	------------------	---------------	-------

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 / 464
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 54
SCOTT, Burt	Wyeth Pharm	PD-post-menopausal women	POETRY	Gauger 668-1538	5 / 4
SCOTT, Burt	Boston Life Sciences	Tremor	Altropane	Wyne 668-2837	20 / 7
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	15 / 13
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 1
STACY, Mark	Boehringer Ingelheim	PD eye safety study	Pramipexole vs. Ropinirole	Field 668-2842	10 / 0

NEUROMUSCULAR

BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Grace 668-2844	15-20 / 19
---------------	------------------	-----	-------------	----------------	------------

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 / 11
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 2
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 10
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 2
GRAFFAGNINO, C	Novo Nordisk	Acute intracerebral hemorrhage	F7ICH-1641	Stoner 668-5275	5 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 543
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 50
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

*****STUDY SPOTLIGHT*****

New Approved Study Ready for Recruitment!!

**Patients will be selected from Duke ER admissions and direct transfers to the ICU through the Neurology Service at DUHS.
Please see further details below– Thank you for your Support!**

C. Graffagnino (PI) – NovoNordisk F7ICH-1641

“Randomized, Double-Blind, Placebo Controlled, Multicenter, Parallel Groups Confirmatory Efficacy and Safety Trial of Activated Recombinant Factor VII (NovoSeven®/Niastase®) in Acute Intracerebral Hemorrhage”

Study will evaluate the efficacy and safety of recombinant activated factor FVII (rFVIIa/ NovoSeven® / Niastase®) in reducing disability and improving clinical outcome by preventing early hematoma growth in patients with acute intracerebral hemorrhage (ICH). Minimum PHI used for screening includes: age, diagnosis, time of symptom onset, medical history, and medication history. Patients will undergo a baseline head CT scan within 3 hours of symptom onset to determine whether the patient has an ICH. Eligible subjects must be administered study drug within 4 hours of symptom onset and no later than 1 hour after baseline CT scan. CT scan will be repeated 24 hours after study drug administration and Day 3 post-study drug administration. Subjects will have follow-up evaluations at Day 15 or discharge (whichever comes first) and Day 90. We estimate to recruit 5 subjects here at Duke. Contacts for further details regarding the study are Carmen Graffagnino or Joanna Stoner (668-5275). A stroke research pager will be carried by the stroke research attending physician. When an acute stroke code is activated, the attending physician will call the neurology resident to obtain information sufficient to decide if the patient should be screened. If the patient should be screened, the attending physician or stroke research nurse will see the patient in the ER.

**Duke University School of Medicine
CTQA LUNCH AND LEARN SERIES
2005 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.

December 8

AE Reporting

Ken Mahaffey

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 1.0 NURSING CONTACT HOURS AND .08 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!!