

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



July 2006

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

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
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JoAnn Jones, Regulatory Administrator	Rene Link 970-1648	link0002@mc.duke.edu
Tina Long, Regulatory Assistant	Sarah Wyne 668-2837	wyne0001@mc.duke.edu
Cathy O'Neill, Financial Manager		

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-7/31/06
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 / 19

GENERAL

Hurwitz, Barrie	Serono	RR-Multiple Sclerosis	25643 (Cladribine)	Wyne 668-2837	9 / 0
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MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 18
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 / 4
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
STACY, Mark	GE Healthcare	Parkinsonian Syndrome	99mTc-NC100697 Injection	Field 668-2842	4-6 / 0

NEUROMUSCULAR

BEDLACK, Rick	NIH, MDA, ALS Assoc.	ALS-motor neuron diseases	DNA Banking Repository	Heydt 668-2843	50 / 43
BEDLACK, Rick	UCB Pharma	Motor neuron disease	Levetiracetam	Heydt 668-2843	20 / 14

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 17
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
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 / 668
LASKOWITZ, Danny	Merck & Phys Funded	Aneurysmal SAH	Simvastatin-SAH	M. Scism 668-1429	120 / 58
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	M. Scism 668-1429	25 / 0

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.

****INVESTIGATOR-INITIATED STUDIES****

Registering Investigator-Initiated Studies on ClinicalTrials.gov website

Jacqueline Dougherty, Administrator for Dr. Ross McKinney, will register Duke investigator-initiated studies onto the ClinicalTrials.gov website for you. Her phone number is 684-0831 and her Lotus Notes Address is: Jacqueline C Dougherty/MCAdmin/mc/Duke@mc.

****STUDY SPOTLIGHT****

New Approved Study Ready for Recruitment!!

Please see further details below– Thank you for your Support!

B. Hurwitz (PI) – Serono Cladribine 25643

“A Phase III, Randomized, Double-Blind, Three-Arm, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Oral Cladribine in Subjects with Relapsing-Remitting Multiple Sclerosis (RRMS)”

The primary objective of this study is to evaluate the efficacy of cladribine vs. placebo in the reduction of qualifying relapse rate during 96 weeks of study drug in subjects with RRMS. This study will include a pre-study evaluation period (up to 28 days prior to the start of study drug); an initial treatment period (cladribine vs. placebo) during Year 1; with a re-treatment period (cladribine vs. placebo) during Year 2. For all subjects, there will be a rescue option of treatment with Rebif®. Potential participants will be inpatients or outpatients on the neurology service at DUHS. Minimum PHI used for screening includes: DOB, diagnosis, medical history, weight, and medication history. We expect to recruit 9 subjects here at DUHS. Contact Dr. Barrie Hurwitz or Sarah Wyne (668-2837) if you have a patient who may be interested in this study.

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.

Date	Topic	Speaker
September 18	Consent with Special Populations and Legally Authorized Representatives	Warren Taylor, M.D.
October 16	Making the Protocol Your Guide	Sheda Moori
November 20	Angiogenesis and Gene Therapy	Debra Hunt
December 18	Monitoring	TBD
January 8	E-IRB and IRB Forms	Mina Pak Debbie Reddoch
February 12	TBD	TBD
March 12	TBD	TBD
April 9	TBD	TBD
May 14	TBD	TBD
June 11	TBD	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 .10 CONTINUING EDUCATION UNITS.**

BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!

FOR THOSE WHO WILL BE COMING FROM OFF CAMPUS, DRIVING DIRECTIONS AND PARKING INFORMATION CAN BE FOUND AT THE FOLLOWING LINK: <http://neuro.duke.edu/Links/map.htm>

PLEASE REGISTER FOR THE SERIES BY E-MAILING CTQA@MC.DUKE.EDU

CHECK OUR WEB SITE FOR UPDATES: <http://medschool.duke.edu/compliance>