

NCRO HIGHLIGHTS

Neuroscience Clinical Research Organization

Duke
Neuroscience



February 2005

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.

Who's Who in the NCRO

Management	Coordination	Email:
Carmelo Graffagnino, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
Mark Stacy, Director of Operations	Yong Choi 668-2844	choi0001@mc.duke.edu
Ron Beauvais, Administrator	Gail Cook 684-0865	cook0007@mc.duke.edu
Donna Carnes, Regulatory Assistant	Joanne Field 668-2842	joanne.field@duke.edu
Sharon Dowell, Administrative Manager	Rene Link 970-1648	link0002@mc.duke.edu
Lisa Gauger, Clinical Research Administrator	Kristen Linney 668-2843	linne003@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

STUDY SPOTLIGHT

New Approved Study Ready for Recruitment!!

If you have patients who may be interested in participating in the below-referenced study, please contact the individuals listed below – Thank you for your Support!

B. Scott (PI) – Boston Life Sciences

“Evaluation of the Efficacy and Safety of ALTROPANE for Differentiating Parkinsonian Syndromes from Non-Parkinsonian Syndromes in Patients with Tremors”

Study will assess the efficacy of ALTROPANE for differentiating Parkinsonian Syndromes (PS) from Non-Parkinsonian Syndromes (NPS) in patients with tremor as well as assess the safety of ALTROPANE in patients with tremor. Minimum PHI used for screening includes: age, diagnosis, medical history, social history, and medication history. Eligible subjects will undergo ALTROPANE injection and SPECT imaging and assessment by a movement disorders specialist. Trial participation will involve three clinic visits and consist of an approximate one-month screening window and two days on-study (Visit 2 & Visit 3). We estimate to recruit 20 subjects here at Duke. Contact Burt Scott or Sarah Wyne (668-2837) if you have a patient who may be interested in participating in this study.

ALS NEWS

CONGRATULATIONS To Rick Bedlack & the Duke ALS Clinic!!

The Duke ALS Clinic has been invited to join the Northeast ALS Consortium (NEALS). NEALS is an independent, non-profit consortium of clinical and scientific investigators who conduct research at their affiliated institutions. NEALS is committed to the cooperative planning, implementation and satisfactory completion, analysis and reporting of controlled clinical trials, and of other research studies aimed at improving patient care and disease understanding of Amyotrophic Lateral Sclerosis (ALS). NEALS will work with other professional organizations, and with government and industry sponsors, to develop substantive treatments for patients with ALS.

Rick would like to thank everyone who helped recruit for the “Creatine in Amyotrophic Lateral Sclerosis” study, as this success was a major factor in being selected to join NEALS. Currently, there are 23 subjects who enrolled out of a target recruitment goal of 15 here at Duke. Duke was the #2 recruiting center in the country for this study.

Rick is currently recruiting for the minocycline study and is hoping to have two other ALS trials up and running this year.

Please join us in congratulating the Duke ALS Clinic for their efforts and commitment to patient care and improved treatments for those suffering with ALS.

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 **44** 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-2/28/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Linney 668-2843	15 / 2
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 6

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 3
---------------	---------	---------------------------	------------------	---------------	-------

GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Wyne 668-2837	15 / 5
-----------------	--------	-----------------------	--------	---------------	--------

MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 6
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 433
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 43
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Gauger 668-1538	5 / 2
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 3
SCOTT, Burt	Boston Life Sciences	Altropane	PD – tremors	Wyne 668-2837	20 / 0
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	10 / 3
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 0
STACY, Mark	Merck KgaA	PD with tx dyskinesias	Sarizotan	Gauger 668-1538	12 / 2

NEUROMUSCULAR

BEDLACK, Rick	Carolinas Med Ctr	ALS	ALS-Creatine	Choi 668-2844	15 / 23
BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Choi 668-2844	15-20 / 0
BEDLACK, Rick	Dainippon AS-3201-253	Diabetic sensorimotor polyneuropathy	AS-3201	Choi 668-2844	20 / 0
MASSEY, Janice	Hoffman LaRoche-Aspreva	Myasthenia Gravis	Mycophenolate mofetil	Provided by Physician	6 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 8

PSYCHIATRY

GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Wyne 668-2837	30 / 7
GOLI, Veeraindar	Elan	Chronic severe pain	Chronic Pain-ZEST	Linney 668-2843	4 / 3
GOLI, Veeraindar	UCB Pharma	Postherpatic neuralgia	Levetiracetam PHN	Linney 668-2843	5 / 0
GOLI, Veeraindar	UCB Pharma	Fibromyalgia syndrome	Keppra	Wyne 668-2837	60 / 6

VASCULAR

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	140 / 136
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 3
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 10
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 / 8
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 1
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 444
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 44
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 5

CTQA LUNCH AND LEARN SERIES

2004-2005 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.

March 14, 2005

April 11, 2005

May 09, 2005

June 6, 2005

Preparing Research Budgets

Basics of INDs

TBA

TBA

ALL SESSIONS ARE FROM 12:00-1:00pm AND HELD IN ROOM 103 BRYAN RESEARCH BUILDING. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

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