

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



July 2007

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
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Cathy O'Neill, Finance Manager	Rene Link 970-1648	link0002@mc.duke.edu
Jackie Woody, Clinical Trials Assistant	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

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-7/31/07
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD on Donepezil treatment	Rosiglitazone XR (REFLECT-2 102672)	Heydt 668-2843	15 / 0

EPILEPSY

HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 0
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MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 532
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 79
SCOTT, Burt	Boehringer Ingelheim	PD tx'd with Mirapex / other anti-PD agents	BI 248.619 Dominion	Field 668-2842	75-225 / 89
SCOTT, Burt	Merz Pharmaceuticals	Cervical Dystonia	MRZ 60201-0408	Heydt 668-2843	6-8 / 6
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 5
STACY, Mark	Novartis	PD	Quest PD(CEL200AUS11)	Field 668-2842	10 / 2
STACY, Mark	Ceregene	Idiopathic PD	Cere-120-02	Gauger 668-1538	6-8 / 11
STACY, Mark	GE Healthcare	Normal Human volunteers	TR0107 (99mTc-NC100697 Injection)	Field 668-2842	15 / 7
STACY, Mark	Merz Pharmaceuticals	Blepharospasm	MRZ 60201-0433	Heydt 668-2843	10 / 0

NEUROMUSCULAR

BEDLACK, Rick	Physician Funded	ALS, Myopathy & Healthy Controls	HDAC Expression in Muscle	N/A	12 / 6
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VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	40 / 25
GRAFFAGNINO, C	CoAxia, Inc.	Acute ischemic stroke	SENTIS-CD-0125	Stoner 668-5275	10 / 0
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1000 / 786
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 3

GERIATRICS

WHITE, Heidi	Amgen	Observational-Anemia & Chronic Kidney Ds	20050239	Cook 684-0865	25 / 13
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NON-NCRO TRIALS

BROWNDYKE, Jeff	Ortho-McNeil Neurologics, Inc.	Mild AD	GAL-EMR-4026	Wyne 668-2837	36 / 3
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 4
GRAFFAGNINO, C	PhotoThera	Acute Ischemic Stroke	NEST-2-NeuroThera Laser System	Stoner 668-5275	12 / 0

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

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

A. Husain (PI) – EISAI (E2080-A001-301)**“A Double-Blind, Placebo-Controlled, Parallel-Group Study of Rufinamide Given as Adjunctive Therapy in Patients with Refractory Partial Seizures”**

The primary objective of this study is to evaluate the effect of rufinamide on total partial seizure frequency in adolescent & adult patients (only adults 18-80 will be enrolled at Duke) with refractory partial onset seizures who are maintained on a maximum of three stable antiepileptic drugs (AEDs). The NIH has noted that rufinamide exhibits broad-spectrum anticonvulsant properties at non-toxic doses by elevating seizure threshold and preventing seizure spread during a recent anticonvulsant profile. The study consist of three phases: a 56-day prospective baseline (screening) phase (in which a seizure diary is maintained and patients with ≥ 6 seizures during the 56-day period will be eligible for randomization into the double-blind aspect of the study) prior to randomization; a 12-day, double-blind titration phase, followed by a 12-week, double-blind maintenance phase. At the end of the maintenance phase, eligible subjects will have the option of enrolling into an open-label extension study of rufinamide (E2080-A001-302). We anticipate recruiting 6 subjects here at Duke. You may contact Dr. Aatif Husain or Kate Beck (668-2278) for more information on this study.

**Duke University School of Medicine
Clinical Research Support Office (CRSO)
LUNCH AND LEARN SERIES
2007 Schedule
CHANGES NOTED BELOW**

The Clinical Research Support Office (CRSO) is now in charge of the Lunch/Learn Series. More information will follow as the schedule is updated.

Lunch & Learn Series

All Lunch & Learns are held in Room 103 of the Bryan Research Building on Research Drive (not Bryan Center) from Noon until 1:00 PM with no registration necessary. Beverages and desserts are provided - please feel free to bring your lunch.

August 13, 2007 **Topic: The Clinical Trials Networks Best Practices: NIH Roadmap**
Presenters: Buddy West and Renee Pridgen, CTN Project Team – DCRI

September 10, 2007 **Topic: Overview of the Clinical Research Support Office (CRSO)**
Presenters: Jennifer Holcomb, Ricky Byrd and Lynda Szczech, M.D., CRSO Leadership

If you have questions, please contact Pam Riley at pam.riley@duke.edu or 668-5928.

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.