

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



February 2008

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	Peggy Perry-Trice 684-0865	peggy.perrytrice@duke.edu
Jackie Woody, Clinical Trials Assistant	Sarah Wyne 668-2837	sarah.wyne@duke.edu

ACTIVE ENROLLING STUDIES

The NCRO currently supports **37** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

EPILEPSY

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-2/29/08
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 2
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	5-6 / 0

GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	5 / 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	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 15
STACY, Mark	Merz Pharmaceuticals	Blepharospasm	MRZ 60201-0433	Heydt 668-2843	10 / 0
STACY, Mark	Schering Plough	Moderate-to-severe PD	SCH420814 (P04501)	Perry-Trice 684-0865	5-6 / 2

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	45 / 35
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 5
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 798
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

NON-NCRO TRIALS

GRAFFAGNINO, C	PhotoThera	Acute Ischemic Stroke	NEST-2-NeuroThera Laser System	Stoner 668-5275	12 / 5
MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 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.

STUDY SPOTLIGHT

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

A. Husain (PI) – Schwarz Biosciences, Inc. (SP 902)

“A Historical-controlled, Multicenter, Double-blind, Randomized Trial to Assess the Efficacy and Safety of Conversion to Lacosamide 400 mg/day Monotherapy in Subjects with Partial-Onset Seizures”

The trial objective is to demonstrate the efficacy and safety of conversion to Lacosamide (LCM) 400 mg/day monotherapy in subjects with partial-onset seizures (with or without secondary generalization) who are withdrawn from one to two marketed antiepileptic drugs (AEDS). In order to blind the treatment group, a LCM 300 mg/day arm will be added. Eligible subjects meeting inclusion criteria and taking stable doses of one or two marketed AEDs during the 8 week baseline phase, will be randomized to either LCM 400 mg/day or 300 mg/day. Trial participation for subjects is 30 weeks maximum duration with maximum study drug administration of 20 weeks. Eligible subjects must be between 18-70 years of age, have a diagnosis of simple partial seizures (motor component) and/or complex partial seizures (with or without secondary generalization), and have been maintained on a stable dose of one or two marketed AEDs for at least 28 days prior to Visit 1. The study will recruit approximately 357 subjects for randomization. We anticipate recruiting 6 subjects here at DUHS. You may contact Dr. Aatif Husain or Kate Beck (668-2278) for more information about this study.

**Duke University School of Medicine
Clinical Research Support Office (CRSO)
LUNCH AND LEARN SERIES**

Lunch & Learn Series

Lunch and Learns are held the 2nd Monday of each Month

Time: Noon - 1:00 pm

NEW LOCATION: School of Nursing

Room 1014 (Peter and Ginny Nicholas Auditorium and Learning Center)
307 Trent Drive

No registration necessary

Beverages and desserts are provided. Please feel free to bring your lunch.

Scheduled Topics:

March 10, 2008

Topic: Conflict of Interest (COI) and Financial Disclosure

Presenter: Michelle M. Evans, Administrative Manager, Duke School of Medicine Research, Integrity Office

If you have questions, please contact Sue Avery at <mailto:sue.avery@duke.edu> or 668-8685.