

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



August 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
Ron Beauvais, Administrator	Joanne Field 668-2842	joanne.field@duke.edu
Monica Bryant, Clinical Trials Assistant	Karen Grace 668-2844	karen.grace@duke.edu
Donna Carnes, Clinical Trials Assistant	Debra Heydt 668-2843	debra.heydt@duke.edu
Lisa Gauger, Clinical Research Administrator	Peggy Perry-Trice 684-0865	peggy.perrytrice@duke.edu
JoAnn Jones, Regulatory Administrator	Karen White-Tong 668-2905	white044@mc.duke.edu
Jessica Kesler, Clinical Trials Assistant	Sarah Wyne 668-2837	sarah.wyne@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).

EPILEPSY

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-8/31/08
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 5
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 / 6
-------------	-------------------------	------------------------	---------------------	---------------	-------

MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 91
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 25
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 7
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharmaceuticals	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 1
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 0
STACY, Mark	Novartis	Non-motor symptoms in idiopathic PD	CEL200AUS14 (Stalevo vs. IR carbidopa/levodopa	Field 668-2842	8 / 0
STACY, Mark	Weill Cornell	Parkinson's Disease	Coenzyme Q10 (QE3)	Field 668-2842	12 / 0

NEUROMUSCULAR

BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	8-10 / 6
BEDLACK, Rick	Amyotrophic Lateral Sclerosis Association (ALSA)	Validation of ALS Biomarkers	BIO ALS-01	Grace 668-2844	36 / 0

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	White-Tong 668-2905	45 / 38
GOLDSTEIN, Larry	Schering Plough	Atherosclerotic Disease	SCH 530348 with standard of care (TRA 2°P – TIMI 50)	White-Tong 668-2905	75 / 0
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 5
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 2
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 822
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

NON-NCRO TRIALS

MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 1
----------------	---------	------------------------	------------	-------------------	-------

******NEW NCRO STAFF******

We are pleased to announce the addition of three new staff members to the NCRO: Monica Bryant and Jessica Kesler (regulatory) and Karen White-Tong (coordinator). We are happy to have them on board. Please join us in making them feel welcome!

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

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

R. Bedlack (PI) – Amyotrophic Lateral Sclerosis Association (BIO_ALS-01)
“A Multicenter Study for the Validation of ALS Biomarkers”

The purpose of this study is to identify biomarkers in the blood and CSF that correlate with ALS diagnosis and progression of ALS. Preliminary studies designed to look for ALS biomarkers identified a number of significant metabolites that distinguish healthy controls from ALS patients. Although unlikely physicians will have difficulty distinguishing ALS from healthy controls, but rather difficulty distinguishing ALS from other neuromuscular disorders with similar presentations. Due to preliminary studies not having enough disease mimic participants to make any meaningful statistical comparisons, in this study (to increase the specificity and clinical utility of the biomarkers) we propose to study metabolomic signatures in a new subset of subjects with ALS early in the disease course, off riluzole and other non-essential medications, compared to age and gender-matched disease controls with other neuromuscular diseases. Four subject groups will be recruited for this study across 18 study sites: early ALS, suspected ALS, motor neuron disease mimics and healthy controls. We anticipate recruiting 36 subjects at DUHS. You may contact Dr. Rick Bedlack or Karen Grace (668-2844) for more information about this study.

Duke University School of Medicine
Clinical Research Support Office (CRSO)
LUNCH AND 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:

October 13, 2008

Topic: Adverse Events and Unanticipated Problems
Presenter: John Kessler, Pharm.D.
Vice-Chair, Institutional Review Board

If you have questions, please contact the CRSO at CRSO.Help@notes.duke.edu or 681-6665.

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.