

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



September 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
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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
Sandy Pendergraph, Financial Manager		

ACTIVE ENROLLING STUDIES

The NCRO currently supports **40** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

DEMENTIA

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-9/30/08
BURKE, Jim	Eli Lilly	Mild to Moderate Alzheimer's Disease	LY450139 (H6L-MC-LFAN)	Heydt 668-2843	20 / 0
BURKE, Jim	Toyama Chemistry Co, Ltd	Mild to Moderate Alzheimer's Disease	T-817MAa (AA4437420)	Heydt 668-2843	13 / 0

EPILEPSY

HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 6
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	5-6 / 1

GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	20 / 6
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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 / 28
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 8
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 / 8
BEDLACK, Rick	Amyotrophic Lateral Sclerosis Association (ALSA)	Validation of ALS Biomarkers	BIO ALS-01	Grace 668-2844	36 / 4

VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	White-Tong 668-2905	55 / 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 / 844
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

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

We are pleased to announce the arrival of Sandy Pendergraph, our new NCRO Financial Manager.
Please join us in making her feel welcome!

We are also sorry to announce that JoAnn Jones, Regulatory Administrator, has accepted an opportunity to work in grants and contracts with the ORA. We will miss her expertise, but wish her great success.

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

New Approved Studies Ready for Recruitment!!

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

J. Burke (PI) – Eli Lilly and Company (H6L-MC-LFAN)

“Effect of γ -Secretase Inhibition on the Progression of Alzheimer’s Disease: LY450139 versus Placebo”

The primary objective of this study is to test the hypothesis that the gamma secretase inhibitor LY450139 given orally (and compared to placebo) will slow the decline of Alzheimer’s disease. Eligible subjects will be randomized to one of three groups: 1) LY450139 100 mg, 2) LY450139 140 mg or 3) placebo. Subjects randomized to placebo will begin receiving LY450139 (escalating to 140 mg/day) at or after visit 14 (64 weeks on study drug) and to continue for the remainder of the study so it may be determined whether there is a disease modifying effect of LY450139. This delayed-start design will evaluate whether subjects originally receiving placebo only will improve such that their cognitive scores subsequently approximate those of subjects initially randomized to LY450139. We anticipate recruiting 20 subjects here at DUHS. You may contact Dr. Jim Burke or Deb Heydt (668-2843) for more information.

J. Burke (PI) – Toyama Chemical Company, Ltd. (AA4437420)

“A Phase 2a Multi-center, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of T-817MAa in Patients with Mild to Moderate Alzheimer’s Disease”

The primary objective of this study is to evaluate the efficacy of T-817MAa in treating dementia in patients who have mild to moderate Alzheimer’s Disease (AD). The Alzheimer’s Disease Assessment Scale-cognitive portion (ADAS-cog) will be used to measure cognitive function to assess T-817MAa efficacy. Eligible subjects will be randomized to one of two groups: 1) T-817MAa 224 mg or 2) placebo. We anticipate recruiting 13 subjects here at DUHS. You may contact Dr. Jim Burke or Deb Heydt (668-2843) for more information.

**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

November 10, 2008

Topic: Vulnerable Populations – Best Practices when Consenting, Use of Interpreter, and Legalities
Presenter: Donna Cookmeyer, Ph.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: Donna Carnes @ donna.carnes@duke.edu.