

# NCRO HIGHLIGHTS

**Duke  
Neuroscience**

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



August 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	<a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>
Ron Beauvais, Administrator	Joanne Field 668-2842	<a href="mailto:joanne.field@duke.edu">joanne.field@duke.edu</a>
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Cathy O'Neill, Finance Manager	Peggy Perry-Trice 684-0865	<a href="mailto:peggy.perrytrice@duke.edu">peggy.perrytrice@duke.edu</a>
Jackie Woody, Clinical Trials Assistant	Sarah Wyne 668-2837	<a href="mailto:wyne0001@mc.duke.edu">wyne0001@mc.duke.edu</a>

**We are pleased to announce Peggy Perry-Trice has joined the NCRO as the newest member of our Study Coordinator Team! Please join us in welcoming Peggy to our group. She is located in Rm. 213 at Morreene Road.**

### 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-8/31/07
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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#### 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	Boehringer Ingelheim	PD tx'd with Mirapex / other anti-PD agents	BI 248.619 Dominion	Field 668-2842	75-225 / 102
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 / 6
STACY, Mark	Novartis	PD	Quest PD(CELC200AUS11)	Field 668-2842	10 / 2
STACY, Mark	Ceregene	Idiopathic PD	Cere-120-02	Gauger 668-1538	12 / 12
STACY, Mark	Merz Pharmaceuticals	Blepharospasm	MRZ 60201-0433	Heydt 668-2843	10 / 0
STACY, Mark	Solvay Pharmaceuticals	PD exp. motor fluctuations	SLV308 (S308.3.002)	Beck 668-2278	4 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	Physician Funded	ALS, Myopathy & Healthy Controls	HDAC Expression in Muscle	N/A	12 / 12
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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 / 787
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 4

#### GERIATRICS

WHITE, Heidi	Amgen	Observational-Anemia & Chronic Kidney Ds	20050239	Perry-Trice 684-0865	25 / 14
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**NON-NCRO TRIALS**

BROWNDYKE, Jeff	Ortho-McNeil Neurologics, Inc.	Mild AD	GAL-EMR-4026	Wyne 668-2837	36 / 4
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 / 1

**\*\*\*\*STUDY SPOTLIGHT\*\*\*\***

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

**M. Skeen (PI) – Novartis (CFTY720D2309)****“A 24-Month, Double-Blind, Randomized, Multicenter, Placebo-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 0.5 mg and 1.25 mg Fingolimod (FTY720) Administered Orally Once Daily Versus Placebo in Patients with Relapsing-Remitting Multiple Sclerosis”**

The primary objective of this study is to provide efficacy, safety and tolerability data of fingolimod (FTY720) compared to placebo in patients with relapsing-remitting multiple sclerosis (RRMS). Subjects will be randomized to receive a fixed dose of fingolimod (0.5 mg/ day or 1.25 mg/ day) or placebo. The study will consist of two phases: a pre-randomization phase (lasting up to 45 days) and a double-blind treatment phase (lasting up to 24 months). Subjects completing this study and who remain eligible will have the option of participating in an extension study and those wishing to participate will sign a separate consent form. Eligible subjects must be between 18-55 years of age and have at least one documented relapse during the previous year or two documented relapses during the previous two years prior to randomization. This study will recruit approximately 960 patients with RRMS. We anticipate recruiting 5 subjects here at Duke. You may contact Dr. Mark Skeen or Sarah Wyne (668-2837) for more information about this study.

**M. Stacy (PI) – Solvay (S308.3.002)****“A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of SLV308 as Adjunct Therapy to Levodopa in Patients with Parkinson’s Disease Experiencing Motor Fluctuations”**

The primary objective of this study is to determine the efficacy of SLV308 compared to placebo in reducing “OFF” time in Parkinson’s disease (PD) patients on levodopa therapy characterized by motor fluctuations based on subject home diaries. Subjects will be randomized to receive either SLV308 (maintenance doses of 12-42 mg/day) or placebo. The study will consist of the following periods: a one week minimum screening period, a four to seven week titration period, a two week stabilization period, a 12 week maintenance period and a one-week followup period (only for subjects who terminate the study). Subjects completing the study and who remain eligible will have the option of participating in an open-label safety extension study and those wishing to participate will sign a separate consent form. Eligible subjects must be 30 years of age or older and must be on stable treatment with levodopa for at least 28 days prior to randomization, requiring at least three but not more than seven dose periods of levodopa per day. This study will recruit approximately 280 subjects. We anticipate recruiting 4 subjects here at Duke. You may contact Dr. Mark Stacy 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**  
**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.

**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](mailto: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](mailto:jones018@mc.duke.edu).**