

## NCRO HIGHLIGHTS

### Neuroscience Clinical Research Organization

Duke  
Neuroscience



Division of Neurology  
Department of Medicine  
Duke University Health System

*The mission of the NCRO is to foster the development of a world-class neuroscience clinical trials center.*

December 2004

#### Who's Who in the NCRO

Management	Coordination	Email:
Carmelo Graffagnino, Medical Director	Kate Beck 668-2278	<a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a>
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JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	<a href="mailto:wyne0001@mc.duke.edu">wyne0001@mc.duke.edu</a>

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

#### New Approved Studies Ready for Recruitment!!

If you have patients who may be interested in participating in the below-referenced studies, please contact the individuals listed below – Thank you for your Support!

#### M. Stacy (PI) – Novartis / Orion Pharma (STRIDE-PD)

**“A long-term, double-blind, randomized, parallel-group, carbidopa/levodopa controlled, multi-center study to evaluate the effect of Stalevo™ in patients with Parkinson’s disease requiring initiation of levodopa therapy”**

Study will examine whether the use of Stalevo™, at the time that levodopa therapy is warranted, will result in significant prolongation in the time to development of incident dyskinesia when compared to standard formulation carbidopa/levodopa in Parkinson’s disease. Minimum PHI used for screening includes: gender, date of birth, medical history, social history, and medications. Subjects will be randomized to receive either Stalevo™ or carbidopa/levodopa. Study drug will be taken for up to 3 years. Trial participation will last up to 3 years. We estimate to recruit 10 subjects here at Duke. Contact Mark Stacy or Kate Beck (668-2278) if you have a patient who may be interested in this study.

#### M. Stacy (PI) – Institute for Neurodegenerative Disorders – (InSPECT)

**“InSPECT – Investigating effects of short-term treatment with pramipexole or levodopa on [<sup>123</sup>]β-CIT and SPECT imaging in early Parkinson’s disease”**

Study will assess the short-term effect of levodopa and pramipexole on [<sup>123</sup>]β-CIT and SPECT imaging on the dopamine transporter (DAT). Minimum PHI used for screening includes: gender, date of birth, diagnosis, medications, medical and social histories. After examination by a movement disorders neurologist during screening/baseline, subjects will travel to IND for imaging. Subjects will then be equally randomized to one of three arms: 1) no treatment; 2) treatment with levodopa; 3) or treatment with pramipexole. Subjects will undergo treatment for a period of 12 weeks. Subjects will return to IND for imaging after 12 weeks of treatment and withdraw from medication following the scan. Eight to 12 weeks after medication withdrawal, a final imaging scan will be performed at IND. We estimate to recruit 8 subjects here at Duke. Contact Mark Stacy or Lisa Gauger (668-1538) if you have a patient who may be interested in this study.

#### M. Stacy (PI) – Merck KGaA – (PADDY-1)

**“A double-blind, placebo-controlled, multicenter, multinational, Phase III study to evaluate the safety and efficacy of Sarizotan HCl 1 mg b.i.d. in patients with Parkinson’s disease suffering from treatment-associated dyskinesia”**

Study will examine the efficacy of 1 mg Sarizotan HCl b.i.d. after 12 weeks and after 24 weeks (maintenance of efficacy) in the treatment of dyskinesia in Parkinson’s disease. Minimum PHI used for screening includes: gender, date of birth, diagnosis, medications, medical and social histories. Subjects will be randomized to receive either Sarizotan or placebo. Study drug will be taken for 24 weeks. At the end of this study, eligible subjects will be offered the choice to enter a long-term open-label safety follow-up study. Trial participation may last up to 34 weeks. We estimate to recruit 12 subjects here at Duke. Contact Mark Stacy or Lisa Gauger (668-1538) if you have a patient who may be interested in this study.

**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.**

**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).

**DEMENCIA STUDIES**

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-12/31//04
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Linney 668-2843	15 / 3
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 4

**EPILEPSY**

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 1
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**GENERAL**

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Wyne 668-2837	15 / 5
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**MOVEMENT DISORDERS**

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 3
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 433
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 43
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Gauger 668-1538	5 / 1
SCOTT, Burt	Wyeth Pharm	PD-ERT	POEMS	Gauger 668-1538	38 / 27
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 3
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	10 / 0
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 0
STACY, Mark	Merck KgaA	PD with tx dyskinesias	Sarizotan	Gauger 668-1538	12 / 0

**NEUROMUSCULAR**

BEDLACK, Rick	Carolinas Med Ctr	ALS	ALS-Creatine	Choi 668-2844	15 / 23
BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Choi 668-2844	15-20 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 7

**PSYCHIATRY**

GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Wyne 668-2837	30 / 7
GOLI, Veeraindar	Elan	Chronic severe pain	Chronic Pain-ZEST	Linney 668-2843	4 / 3
GOLI, Veeraindar	UCB Pharma	Postherpatic neuralgia	Levetiracetam PHN	Linney 668-2843	5 / 0
GOLI, Veeraindar	UCB Pharma	Fibromyalgia syndrome	Keppra	Wyne 668-2837	60 / 7

**VASCULAR**

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	140 / 123
CHILUKURI, Vani	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 3
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 5
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 8
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 1
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 409
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 41
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 5

**CTQA LUNCH AND LEARN SERIES  
2004-2005 Schedule**

The lunch and learn series are one hour **coordinator centric educational sessions** with the primary goal of providing useful, hands on knowledge to build a stronger research work force. These sessions will also provide the members of the CTQA office an opportunity to present themselves as a resource to the research community.

**February 14, 2005**

**Handling Monitoring Visits**

March 14, 2005

Preparing Research Budgets

April 11, 2005

Basics of INDS

May 09, 2005

TBA

June 6, 2005

TBA

ALL SESSIONS ARE FROM 12:00-1:00pm AND HELD IN ROOM 103 BRYAN RESEARCH BUILDING. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

**PLEASE REGISTER FOR THE SERIES BY E-MAILING CTQA@MC.DUKE.EDU  
BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!**