

# 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 2005

### 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>
Carmelo Graffagnino, Co-Medical Director	Gail Cook 684-0865	<a href="mailto:cook0007@mc.duke.edu">cook0007@mc.duke.edu</a>
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**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).**

### ACTIVE ENROLLING STUDIES

The NCRO currently supports **38** 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-12/31//05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 9
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 15

#### EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 8
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#### MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 16
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 464
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 54
SCOTT, Burt	Boston Life Sciences	Tremor	Altropane	Wyne 668-2837	20 / 8
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	15 / 16
STACY, Mark	Inst Neurodeg Disorder	Early PD	SPECT imaging	Gauger 668-1538	8 / 2
STACY, Mark	Boehringer Ingelheim	PD eye safety study	Pramipexole vs. Ropinirole	Field 668-2842	10 / 0

#### NEUROMUSCULAR

BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Grace 668-2844	15-20 / 20
BEDLACK, Rick	NEALS/CytRx Corp.	ALS	Arimoclomol	Grace 668-2844	10 / 0

#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 17
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 11
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 2
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 10
GRAFFAGNINO, C	Novo Nordisk	Acute intracerebral hemorrhage	F7ICH-1641	Stoner 668-5275	5 / 1
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 551
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 51
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 6

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

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

**R. Bedlack (PI) – Arimoclomol – Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) / CytRx Corporation  
“A Multicenter, Dose Ranging Safety and Pharmacokinetics Study of Arimoclomol in Amyotrophic Lateral Sclerosis”**

The primary objective of this phase IIa study is to assess the safety and tolerability of arimoclomol at three dosages over a 12 week treatment period in 80 ALS patients and to monitor pharmacokinetic levels in blood and CSF in half of the participating patients. This information will be correlated with safety measures and used to select study dosage for a followup phase IIb study. Minimum PHI used for screening includes: gender, age, medical history, medication history, disease duration, social history & vital capacity equal to or more than 60% of predicted value for gender, height & age. Eligible subjects will be randomized to receive either arimoclomol or placebo. Followup visits will occur at 2, 4, 6, 8, 10 & 12 weeks while receiving study drug with a 4 week post-study drug safety assessment by phone call. We estimate to recruit 10 subjects here at DUHS. Contact Dr. Rick Bedlack or Karen Grace (668-2844) if you have a patient who may be interested in this study.

**Duke University School of Medicine  
Clinical Trials Quality Assurance (CTQA)  
LUNCH AND LEARN SERIES  
2005/2006 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.

**\*Please note revisions to schedule**

<b>January 30*</b>	<b>Informed Consent*</b>	<b>Tammi Jaynes*</b>
<b>February 6</b>	<b>Investigational Drug Service</b>	<b>Sharon Ellison, R.Ph.</b>
<b>March 20</b>	<b>Clinical Trials Litigation</b>	<b>Kim Wilson, J.D.</b>
<b>April 6</b>	<b>Clinical Trials Billing*</b>	<b>Donna Morris*</b>
<b>May 12</b>	<b>Humanitarian Use Devices</b>	<b>John Falletta, M.D.</b>
<b>June 6</b>	<b>TBD</b>	<b>TBD</b>

THE CTQA LUNCH AND LEARN SERIES IS FREE AND OPEN TO THE PUBLIC – DUKE UNIVERSITY HEALTH SYSTEM AFFILIATION IS NOT REQUIRED. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

ALL SESSIONS ARE SCHEDULED FOR 12:00-1:00 PM IN ROOM 103 OF THE BRYAN RESEARCH BUILDING (NOT THE BRYAN CENTER). **SESSIONS HAVE BEEN APPROVED FOR 1.2 NURSING CONTACT HOURS AND 1.0 CONTINUING EDUCATION UNITS.**

PLEASE REGISTER FOR THE SERIES BY E-MAILING [CTQA@MC.DUKE.EDU](mailto:CTQA@MC.DUKE.EDU)  
BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!

\*\*\*NCRO Advisory Board Meeting\*\*\*

The next NCRO Advisory Board (AB) meeting is scheduled for January 11, 2006 in the 2<sup>nd</sup> floor conference room at Morreene Road Clinic at 5:30 p.m. Because of increasing emphasis on fiscal responsibility, the AB may have to make decisions regarding discontinuing poorly-enrolling trials or no longer accepting new trials. If you have a low enrolling trial or potentially new trial, consider contacting an AB member prior to this important meeting.

Because of increasing trial responsibilities, the regulatory department will no longer assume responsibility for updating faculty and coordinator CVs or Biographical statements. The AB will begin to evaluate a document responsibility policy, as time allows.