

## NCRO HIGHLIGHTS

Duke  
Neuroscience

### Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



October 2004

*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:   |
|--|-------------------------|--|
| Carmelo Graffagnino, Medical Director        | Kate Beck 668-2278      | <a href="mailto:beck0002@mc.duke.edu">beck0002@mc.duke.edu</a> |
| Mark Stacy, Director of Operations           | Yong Choi 668-2844      | <a href="mailto:choi0001@mc.duke.edu">choi0001@mc.duke.edu</a> |
| Ron Beauvais, Administrator                  | Gail Cook 684-0865      | <a href="mailto:cook0007@mc.duke.edu">cook0007@mc.duke.edu</a> |
| Donna Carnes, Regulatory Assistant           | Rene Link 970-1648      | <a href="mailto:link0002@mc.duke.edu">link0002@mc.duke.edu</a> |
| Sharon Dowell, Administrative Manager        | Kristen Linney 668-2843 | <a href="mailto:linne003@mc.duke.edu">linne003@mc.duke.edu</a> |
| Lisa Gauger, Clinical Research Administrator | Sarah Moore 668-2842    | <a href="mailto:moore016@mc.duke.edu">moore016@mc.duke.edu</a> |
| JoAnn Jones, Regulatory Administrator        | Sarah Wyne 668-2837     | <a href="mailto:wyne0001@mc.duke.edu">wyne0001@mc.duke.edu</a> |

#### 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!

#### R Bedlack (PI) – Columbia / NINDS (Minocycline / ALS)

##### “A multicenter, phase III, randomized, double-blind, placebo-controlled clinical trial of minocycline in 400 subjects with ALS”

Study will examine the use of minocycline to determine if it slows the progressive deterioration of global function in patients with amyotrophic lateral sclerosis. Minimum PHI used for screening includes: medical history; respiratory status including FVC; diagnosis and onset; date of birth; medications; social history. Subjects will be randomized to receive either minocycline or placebo. Study drug will be taken for 9 months. Trial participation may last up to 13 months. We estimate to recruit 15-20 subjects here at Duke. **NOTE: In the last 2 years more than 1017 visits for ALS were recorded by the PDC. Contact Rick Bedlack or Yong Choi (668-2844) if you have a patient who may be interested in this study.**

#### C Graffagnino (PI) – AstraZeneca – (CHANT – SA-NXY-0012)

##### “A double-blind, randomized, placebo-controlled, parallel group, multicenter, phase IIb study to assess the safety and tolerability of intravenous NXY-059 in adult patients with acute intracerebral hemorrhage”

Study will evaluate the safety and tolerability of NXY-059 compared to placebo when given to patients who present within six hours of onset of symptoms consistent with a diagnosis of intracerebral hemorrhage. Minimum PHI used for screening includes: date of birth; diagnosis; time of symptom onset; medical history; social history; medications. Subjects will be randomized to receive either NXY-059 (intravenous loading dose of 2270 mg followed by a 71 hour infusion at 960 mg/h: adjusted according to creatinine clearance) or similarly applied placebo infusion. Subjects will be followed clinically while in the hospital and return back to clinic for 90 day follow-up. We estimate to recruit 3-6 subjects here at Duke. **NOTE: In the last 2 years more than 1800 visits for intracerebral hemorrhage were recorded by the PDC. Contact Carmen Graffagnino or Joanna Stoner (668-5275) if you have a patient who may be interested in this study.**

#### V Chilukuri (PI) – NIH (COSS)

##### “Carotid Occlusion Surgery Study”

Study will compare the incidence of stroke in surgery versus standard, non-surgical, medical practice. The surgery arm of this study is an “extracranial-intracranial bypass”. Minimum PHI used for screening includes: date of birth; diagnosis of unilateral carotid occlusion by vascular imaging (doppler ultrasound, magnetic resonance angiography, CT angiography or intraarterial catheter angiography). Patients will then be eligible for PET. If PET meets criteria for ipsilateral increased oxygen extraction, then arteriographic criteria must be met for randomization eligibility. Subjects will be randomized to undergo bypass surgery versus treatment with standard medications recommended by the study physician to prevent stroke. Subjects will return to clinic in one month, two months and every three months thereafter for a minimum of two years and as long as six years. We estimate to recruit 31 subjects here at Duke. **NOTE: In the last 2 years nearly 200 visits for carotid occlusion were recorded by the PDC. Contact Vani Chilukuri or Sarah Moore (668-2842) 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 **42** 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-9/30/04 |
|--------------|-----------------|----------------------|--------------------|-----------------|---------------------------------|
| BURKE, Jim   | GlaxoSmithKline | Mild to Moderate AD  | Rosiglitazone XR   | Linney 668-2843 | 15 / 0                          |
| WHITE, Heidi | NIH             | Mild cog. Impairment | Nicotine Tr of MCI | Cook 684-0865   | 25 / 1                          |

**EPILEPSY**

|               |         |                           |                  |               |       |
|---------------|---------|---------------------------|------------------|---------------|-------|
| HUSAIN, Aatif | Schwarz | Epilepsy-partial seizures | SPM 927 (SP 754) | Beck 668-2278 | 5 / 0 |
|---------------|---------|---------------------------|------------------|---------------|-------|

**GENERAL**

|                 |        |                       |        |               |        |
|-----------------|--------|-----------------------|--------|---------------|--------|
| Hurwitz, Barrie | Berlex | RR-Multiple Sclerosis | Beyond | Wyne 668-2837 | 15 / 4 |
|-----------------|--------|-----------------------|--------|---------------|--------|

**MOVEMENT DISORDERS**

|                 |                      |                                 |                       |                |                 |
|-----------------|----------------------|---------------------------------|-----------------------|----------------|-----------------|
| HUSAIN, Aatif   | Boehringer Ingelheim | Restless Legs                   | RLS                   | Beck 668-2278  | 8 / 2           |
| MORGENLANDER, J | Private Investors    | Restless Legs                   | RLS                   | N/A            | 20 / 0          |
| SCOTT, Burt     | Physician Funded     | Movement disorder               | Visual Documentation  | N/A            | No Target / 433 |
| SCOTT, Burt     | Physician Funded     | Movement disorder               | Tetabenazine          | N/A            | No Target / 43  |
| SCOTT, Burt     | Wyeth Pharm          | PD-ERT                          | POETRY                | Moore 668-2842 | 5 / 0           |
| SCOTT, Burt     | Wyeth Pharm          | PD-ERT                          | POEMS                 | Moore 668-2842 | 20 / 6          |
| SCOTT, Burt     | Kyowa                | PD-motor response complications | KW-6002 (6002-US-018) | Cook 684-0865  | 8 / 0           |

**NEUROMUSCULAR**

|                |                   |                   |              |                       |           |
|----------------|-------------------|-------------------|--------------|-----------------------|-----------|
| BEDLACK, Rick  | Carolinas Med Ctr | ALS               | ALS-Creatine | Choi 668-2844         | 15 / 18   |
| 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 / 5 |
| GOLI, Veeraindar | Elan       | Chronic severe pain    | Chronic Pain-ZEST | Linney 668-2843 | 4 / 2  |
| GOLI, Veeraindar | UCB Pharma | Postherpatic neuralgia | Levetiracetam PHN | Linney 668-2843 | 5 / 0  |
| GOLI, Veeraindar | UCB Pharma | Fibromyalgia syndrome  | Keppra            | Wyne 668-2837   | 60 / 1 |

**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 | Moore 668-2842       | 30 / 0    |
| GOLDSTEIN, Larry | AGA Med Corp         | Cryptogenic stroke     | RESPECT                  | Link 970-1648        | 10 / 0    |
| GOLDSTEIN, Larry | Boehringer Ingelheim | Recurrent strokes      | PRoFESS                  | Link 970-1648        | 30 / 0    |
| GRAFFAGNINO, C   | AstraZeneca-         | Acute ischemic stroke  | Stroke-SA-NXY-0007       | Stoner 668-5275      | 10 / 7    |
| GRAFFAGNINO, C   | Centocor             | Acute ischemic stroke  | AbESTT II                | Stoner 668-5275      | 12 / 0    |
| 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 / 379 |
| LASKOWITZ, Danny | Merck & Phys Funded  | Aneurismal SAH         | Simvastatin-SAH          | B. Blessing 970-4888 | 120 / 38  |
| 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.

|                   |   |
|-------------------|---|
| November 1, 2004  | Subject Recruitment                           |
| December 06, 2004 | The Consenting Process                        |
| January 10, 2005  | Recognizing and Reporting Research Misconduct |
| 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!!