

NCRO HIGHLIGHTS

Neuroscience Clinical Research Organization

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.

Duke
Neuroscience



January 2005

Who's Who in the NCRO

Management	Coordination	Email:
Carmelo Graffagnino, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
Mark Stacy, Director of Operations	Yong Choi 668-2844	choi0001@mc.duke.edu
Ron Beauvais, Administrator	Gail Cook 684-0865	cook0007@mc.duke.edu
Donna Carnes, Regulatory Assistant	Joanne Field 668-2842	joanne.field@duke.edu
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Lisa Gauger, Clinical Research Administrator	Kristen Linney 668-2843	linne003@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

****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!

J. Massey (PI) – Aspreva Pharmaceuticals Corp.

“A prospective, randomized, double-blind, placebo-controlled, parallel group, multicenter, 36-week trial to assess the efficacy and safety of adjunct mycophenolate mofetil (MMF) to maintain or improve symptom control with reduced corticosteroids in subjects with myasthenia gravis”

Study will assess efficacy, safety, and tolerability of MMF therapy compared to placebo in myasthenia gravis (MG) patients receiving prednisone and assess steroid-sparing effect while maintaining or improving symptom control in MG patients. Minimum PHI used for screening includes: date of birth, gender, diagnosis, medical history, medications, and social behavior. Subjects will be randomized to receive either MMF or placebo. Trial participation will last up to 36 weeks. We estimate to recruit 6 subjects here at Duke. Contact Janice Massey or Rachel Suddarth (684-5422) if you have a patient who may be interested in this study.

R. Bedlack (PI) – Dainippon Pharmaceutical Co., Ltd.

“A multicenter, randomized, double-blind, placebo-controlled multiple dose study of the efficacy and safety of AS-3201 in patients with diabetic sensorimotor polyneuropathy”

Study will assess safety, efficacy, and determine the best dose of AS-3201 compared to placebo for 52 weeks to prevent progression or possibly reverse the course of sensorimotor polyneuropathy in patients with diabetes. Minimum PHI used for screening includes: diagnosis, medications, date of birth, medical history, and social behavior. Subjects will be randomized to receive either AS-3201 or placebo. Trial participation will last up to 58 weeks. We estimate to recruit 20 subjects here at Duke. Contact Rick Bedlack or Yong Choi (668-2844) if you have a patient who may be interested in this study.

Clinical Trial Flowsheet:

Task	Response	Time Requirement
1 st contact	Request Confidentiality Agreement (CDA) from sponsor	2 days
CDA to Regulatory	To Duke Legal for review	1 day
CDA finalized	Negotiation completed between Duke/Sponsor	1 month
Fully executed CDA to Sponsor	Await Site Selection	Sponsor determined
Receive Regulatory Package	Request to PI for SOP, MOU, Research Summary	1 day
Receipt of documents from PI	Assigned NCRO Admin. Meeting date	varies by PI
Assigned NCRO Admin. Mtg. Agenda	NCRO internal review	1 st & 3 rd Tuesdays
Submit for Advisory Board (AB) review	Advisory Board comments/approval	5 days allowed
NCRO prepares IRB	Submit to IRB	3 wks (includes 1 wk obtaining signatures)
NCRO prepares Regulatory package	Submit to Sponsor	3 wks
Budget negotiation	NCRO negotiates with Sponsor	1 wk
Contract negotiation	To Duke Legal to negotiate with Sponsor	4-6 wks
Final IRB Approval of study	Released only with fully executed contract	6-8 wks

Above time requirements are based on PI, Sponsor/CRO, IRB turnaround times to NCRO.

Time to completion 2004: Range: 2 - 5 months Goal: 2 ½ months

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 **45** 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-1/31/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Linney 668-2843	15 / 7
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 / 4
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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 / 4
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 / 38
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 / 1
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 / 24
BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Choi 668-2844	15-20 / 0
BEDLACK, Rick	Dainippon AS-3201-253	Diabetic sensorimotor polyneuropathy	AS-3201	Choi 668-2844	20 / 0
MASSEY, Janice	Hoffman LaRoche-Aspreva	Myasthenia Gravis	Mycophenolate mofetil	Provided by Physician	6 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 8

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 / 6

VASCULAR

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	140 / 136
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 3
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 10
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
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 / 419
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 43
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.

March 14, 2005

April 11, 2005

May 09, 2005

June 6, 2005

Preparing Research Budgets

Basics of INDs

TBA

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!!