

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.

March 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
Sharon Dowell, Administrative Manager	Debra Heydt 668-2843	debra.heydt@duke.edu
Lisa Gauger, Clinical Research Administrator	Rene Link 970-1648	link0002@mc.duke.edu
JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

Please join us in welcoming Debra Heydt as the newest addition to our clinical research coordinator team. Debra has in over 16 years at Duke and we're excited to welcome her aboard!

NCRO OPERATIONS

Operations Update: Over the last year we have made a number of changes in NCRO operations to make investigator participation easier. This process has allowed me to assemble a collection of pet peeves: most have to do with a lack of investigator attention to process. When approached by a sponsor for potential participation in a clinical trial, just say "yes." With that comment a **Confidentiality Agreement (CDA)** should be FAXed to you – do not sign this. Duke Legal must review it. Please send the document to JoAnn Jones, and she will forward (and the sooner she is involved – the happier you will be...). Once a fully executed CDA is processed, the sponsor will determine site selection. Once sites are selected, **IRB and Regulatory Packages** will be shipped to sites. As soon as you receive this, it should be forwarded to JoAnn, if you plan to utilize the NCRO for Administrative services. JoAnn will then request the following documents: 1) Request for Clinical Trial Support; 2) Research Summary and 3) Memorandum of Understanding. Once these documents are returned to JoAnn, the study will be placed on the next NCRO Administrative agenda and subsequently sent for Advisory Board review. Once fully approved, the NCRO Regulatory staff will process the IRB and Regulatory Start-Up Packages.

Contracts: If you request administrative support from the NCRO, the contract should be sent to JoAnn who will process this with Duke Legal until a fully executed contract is obtained. IRB will not release final approval on a study until there is a fully executed contract on file.

Budgets: The NCRO is happy to assist and advise for budget negotiation as much as an investigator wishes.

NCRO Visit Activity: Below is a 6-month summary of the visits conducted within the NCRO. The charges represent the activity billed on the physician encounter forms, and the payments reflect the discounted rates negotiated with the PDC. In real terms the 554 visits generated \$57,000 in revenue (\$100/v) and \$18,500 in payments (\$33/v). Outpatient visits often reflect a 99203 code; this may not truly capture physician activity. Please consider research coding more carefully in the future.

Hopefully this raises more questions than answers. If the Administrative Manager is not notified and encounter visits are not captured, payments cannot occur. For outpatient studies it is the investigators responsibility to complete the encounter form and the coordinators responsibility for a form to move through the PDC. The inpatient process remains to be defined.

	10/04	11/04	12/04	01/05	02/05	03/05	TOTALS
Number of visits	91	70	96	58	116	123	554
Total Charges (x \$1000)	14.2	4.8	7.9	4.2	16.8	9.3	\$57,286
Payments after discounts (x\$1000)	5.0	2.0	2.3	1.0	5.2	3.1	\$18,583

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 **46** 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-3/31/05
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Heydt 668-2843	15 / 3
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 6

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 3
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GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Wyne 668-2837	15 / 10
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MOVEMENT DISORDERS

MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 6
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 / 2
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 4
SCOTT, Burt	Boston Life Sciences	Altropane	PD – tremors	Wyne 668-2837	20 / 2
STACY, Mark	Novartis	PD requiring levodopa	Stride PD (Stalevo)	Beck 668-2278	10 / 5
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 / 7

NEUROMUSCULAR

BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Choi 668-2844	15-20 / 3
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 / 9

PSYCHIATRY

GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Wyne 668-2837	30 / 10
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

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 12
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 / 9
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 / 460
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 44
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.

April 11, 2005

May 09, 2005

Basics of INDs

What To Do When You Have Issues with Research Misconduct

Guest speaker: Rich Malloy

June 6, 2005

Clinical Contracts

Guest speaker: Marti Salguero

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!!