

# NCRO HIGHLIGHTS

Duke  
Neuroscience

## Neuroscience Clinical Research Organization

Division of Neurology  
Department of Medicine  
Duke University Health System



May 2008

*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

Mark Stacy, Medical Director  
Ron Beauvais, Administrator  
Donna Carnes, Clinical Trials Assistant  
Lisa Gauger, Clinical Research Administrator  
JoAnn Jones, Regulatory Administrator  
Cathy O'Neill, Finance Manager  
Jackie Woody, Clinical Trials Assistant

#### Coordination

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### ACTIVE ENROLLING STUDIES

The NCRO currently supports **37** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

#### EPILEPSY

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-5/31/08
HUSAIN, Aatif	EISAI	Refractory partial seizures	Rufinamide (E2080-A001-301)	Beck 668-2278	6 / 3
HUSAIN, Aatif	Schwarz Biosciences	Partial onset seizures	Lacosamide monotherapy (SP 902)	Beck 668-2278	5-6 / 0

#### GENERAL

SKEEN, Mark	Novartis (CFTY720D2309)	Relapsing Remitting MS	Fingolimod (FTY720)	Wyne 668-2837	5 / 2
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#### MOVEMENT DISORDERS

SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 548
SCOTT, Burt	Physician Funded	Movement disorder	Tetrabenazine	N/A	No Target / 91
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 21
SCOTT, Burt	HP Therapeutics	Huntington's Disease	Observational (COHORT)	Wyne 668-2837	25 / 2
SCOTT, Burt	Juvantia Pharma Ltd / Santhera Pharmaceuticals	Parkinson's Disease	Fipamezole oromucosal tablet (SNT-11-004)	Gauger 668-1538	12 / 0
SCOTT, Burt	Mass General (NINDS)	Huntington's Disease	Coenzyme Q10 (2CARE)	Wyne 668-2837	8 / 0
STACY, Mark	Schering Plough	Moderate-to-severe PD	SCH420814 (P04501)	Perry-Trice 684-0865	5-6 / 4

#### NEUROMUSCULAR

BEDLACK, Rick	Avanir Pharmaceuticals	Tx of pseudobulbar affect in ALS	AVP-923 (Zenvia) 07-AVR-123 (STAR)	Grace 668-2844	8-10 / 3
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#### VASCULAR

GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Gauger 668-1538	45 / 38
GRAFFAGNINO, C	NIH / Wash Univ	Carotid occlusion - COSS	Surgery vs stan med care	Stoner 668-5275	30 / 5
GRAFFAGNINO, C	The Medicines Company	Acute hypertension & ICH	Clevidipine IV infusion (TMC-CLV-07-02)	Stoner 668-5275	6 / 0
LASKOWITZ, Danny	Physician funded	Biomarker-brain injury	Stroke Panel of Biomarkers	E. Bennett 668-1429	1200 / 803
LASKOWITZ, Danny	NINDS	Acute ischemic stroke	Human Albumin	E. Bennett 668-1429	25 / 6

#### NON-NCRO TRIALS

MASSEY, Janice	NIH/UAB	Myasthenia w/o thymoma	Thymectomy	Lipscomb 684-5422	6 / 0
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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).

**REGULATORY NEWS**

**\*\*\*REMINDER\*\*\***

**CONFIDENTIAL DISCLOSURE AGREEMENTS / NON-DISCLOSURE AGREEMENTS**

Please remember to send these agreements to JoAnn Jones in the NCRO ([jones018@mc.duke.edu](mailto:jones018@mc.duke.edu)) for processing (along with contact information at CRO/Sponsor level for negotiations). Do not sign and return to CRO/Sponsor. These agreements are to be with the University and not the PI.

Duke OCRC must review these agreements to make sure the terms are consistent with Duke policies and also to place the obligation of confidentiality on the University instead of the PI alone.

Feel free to contact JoAnn for any questions (668-2847).

**Duke University School of Medicine  
Clinical Research Support Office (CRSO)  
LUNCH AND LEARN SERIES**

***Lunch & Learn Series***

**Lunch and Learns are held the 2nd Monday of each Month**

Time: Noon - 1:00 pm

**NEW LOCATION:** School of Nursing

Room 1014 (Peter and Ginny Nicholas Auditorium and Learning Center)  
307 Trent Drive

No registration necessary

Beverages and desserts are provided. Please feel free to bring your lunch.

**Scheduled Topics:**

**June 9, 2008**

**Topic: Compliance Office and CTQA**

**Presenter: Tina Tyson, JD**

**SOM Chief Compliance Officer**

If you have questions, please contact Sue Avery at [sue.avery@duke.edu](mailto:sue.avery@duke.edu) or 668-8685.