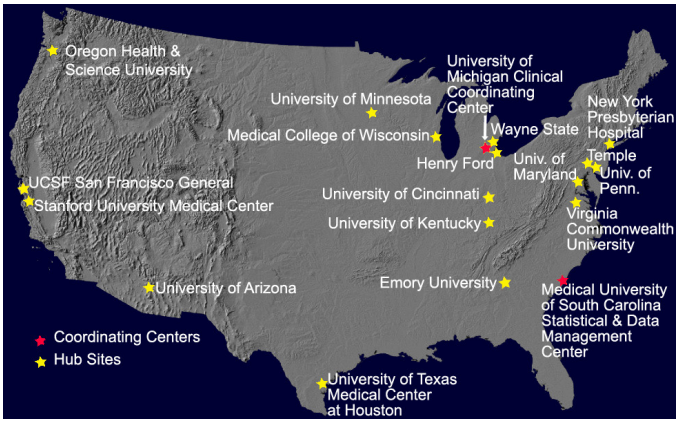
NETT-WORKINGS

NEUROLOGICAL EMERGENCIES TREATMENT TRIALS (NETT) NETWORK

AUGUST 2011

Emory University
David Wright, MD
Henry Ford Health System
Christopher Lewandowski, MD
Medical College of Wisconsin
Tom Aufderheide, MD
New York Presbyterian Hospital
Stephan Mayer, MD
Oregon Health & Science University
Robert Lowe, MD, MPH
Stanford University
James V. Quinn, MD
Temple University
Nina Gentile, MD
University of Arizona
Kurt Denninghoff, MD

PARTICIPATING HUBS AND INVESTIGATORS



University of California, SF
J. Claude Hemphill, III, MD
University of Kentucky
Roger Humphries, MD
University of Cincinnati
Arthur Pancioli, MD
University of Maryland
Barney J. Stern, MD
University of Minnesota
Michelle Biros, MD, MS
University of Pennsylvania
Jill Baren, MD, MBE
University of Texas
Elizabeth Jones, MD
Virginia Commonwealth University
Joseph P. Ornato, MD
Wayne State University
Robert Welch, MD

CLINICAL COORDINATING CENTER (CCC)
University of Michigan
William Barsan, MD

National Institute of Neurological Disorders and Stroke (NINDS)
Clinical Trial Group
Robin Conwit, MD and Scott Janis, PhD

STATISTICAL & DATA MANAGEMENT CENTER (SDMC)
Medical University of South Carolina
Yuko Palesch, PhD

Enrollment Update: as of 8/31/11 at 12pm (EDT)	ALIAS	ProTECT	POINT
Arizona	5	12	3
Cincinnati	22	41	13
Emory	24	35	8
HFH	11	6	21
Kentucky	25	7	13
Maryland	12	<5	8
Minnesota	18	27	15
NYP	24	<5	9
Oregon	47*	13	9
Stanford	18	29	15
Temple	23	14	11
Texas	28	35	8
UCSF	20	10	10
UPenn	32	24	37
VCU	9	8	<5
Wayne State	22	6	32
Wisconsin	7	45	12
NETT TOTAL	347	314	227

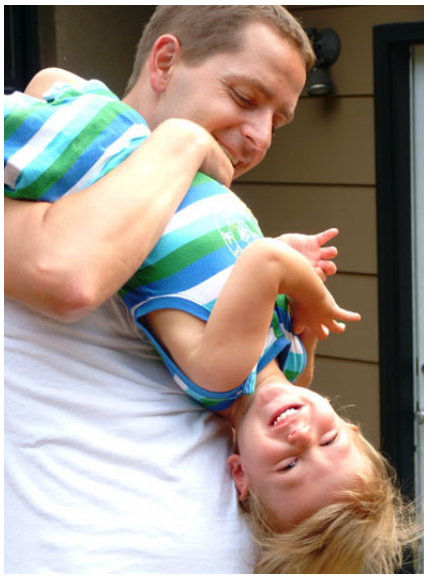
*OHSU WAS AN ORIGINAL SITE IN THE ALIAS I TRIAL AND CONTINUES IN THE ALIAS II TRIAL UNDER THE SAME CONTRACTUAL ARRANGEMENT WITH THE UNIVERSITY OF MIAMI STUDY CHAIR SITE.

Pleased to meet you...

Allison Kade, CCRC
SHINE Site Manager
ProTECT III and ALIAS2 Project Monitor
NETT Clinical Coordinating Center - University of Michigan

Allison (Allie) Kade is the SHINE Site Manager at the NETT CCC, as well as a monitor for both the ProTECT III and ALIAS2 trials. She has worked in clinical research for over five years, and has experience both in managing and monitoring multi-site trials and coordinating trials locally at the University of Michigan (U of M). She has also worked as a contractor conducting software training sessions for multinational clinical trials. Allie received her bachelor's degree from U of M and is currently pursuing an MS in Quality Management, where her interests are designing efficient research process flows and improving healthcare delivery systems. Outside of work and class, she is an active volunteer with her Red Cross chapter's Event Medical Services. In her free time, she enjoys spending time outdoors, photography, and travel.

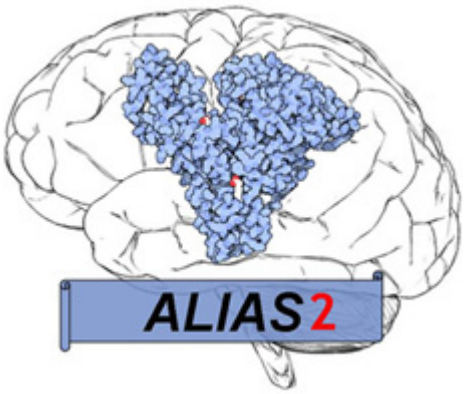
Aaron Perlmutter, MPH, LMSW
POINT Data Manager
Statistical Data Management Ctr. - Medical University of South Carolina



Aaron graduated from the Honors College at the University of South Carolina, where he continued on to receive a Masters in Public Health and a Masters in Social Work. After working as a social worker at an elder service agency in Boston, he moved to North Carolina to evaluate National Science Foundation and Department of Education grants. In January 2011, Aaron returned to his hometown of Charleston and joined the Data Coordination Unit at MUSC. He's the Data Manager for the POINT trial, where he helps maintain the POINT database in WebDCU™ and assists study team members with database-related issues. Aaron enjoys working at an academic institution and addressing the interesting issues that arise during clinical trials. In his free time, he loves being on the water, fishing and wakeboarding. Aaron recently completed his first triathlon, and he and his wife Karen also do a lot of running after their toddler Isaiah (Zayah) and dogs Solomon and Henry.

Shirley Frederiksen, RN, MS
ADAPT-IT Site Manager
POINT and SHINE Project Monitor
NETT Clinical Coordinating Center - University of Michigan

Shirley Frederiksen has worked in emergency medicine for the past 15 years, and prior to that has had lots of experience as a clinical nurse, educator and administrator. She received her Bachelor's in Nursing from the University of Michigan and an MS in Nursing from the University of Colorado. When she's not working, she enjoys time with her family, espeically her two grandchildren, Emma (8) and Ryan (5). Shirley and her husband also keep busy attending to their "hobby farm", with 2 dogs, 3 cats, 30 chickens, 150 quail and 400 pheasants. She says, "It's a zoo around here."



High-Dose Albumin Therapy For Neuroprotection In Acute Ischemic Stroke

Principal Investigator: Myron Ginsberg, MD

We would like to request agenda items for the next ALIAS Regional Meeting, scheduled to take place on September 18 and 19, 2011 at Niagara-on-the-Lake in Ontario, Canada. Current ideas for topics include:

* Study procedures for subjects who are transferred between institutions, e.g. “Ship and Drip” subjects
* Administration of study drug during interventional procedures
* Review of newly configured study drug kit
* Common protocol deviations and how to avoid them

The regional meetings are an excellent opportunity to discuss issues pertaining to subject recruitment, quality of patient care, and data-quality with the ALIAS PI, Project Management team, other NETT hubs/spokes, and non-NETT sites. Please feel free to respond with any topic of interest to ALIAS by September 9, 2011, even if you will not be attending the meeting. Outcomes of these discussions will be disseminated during subsequent Steering Committee and Study Coordinator teleconferences.

-Sam Mawocha (smawocha@umich.edu)

---

point

Platelet-Oriented Inhibition in New TIA Trial

Principal Investigator: Clay Johnston, MD

Thank you to all of our sites for your continued work on POINT! Three new sites were activated this month bringing the total number to 58! **Congratulations to Austin Brackenridge, one of the new spokes, for enrolling two subjects this month, and also to Wisconsin and Wayne State who each enrolled four!** Please make a goal to enroll at least one subject per month, as this will help keep us on track with the POINT study timeline!

Look for a new POINT FAQ regarding PPIs and enrollment coming soon!

-Tess Bonham (tbonham@umich.edu)

SHINE

Mark Your Calendars: Please reserve the week of January 9-13, 2012. The SHINE Investigator Kick-Off Meeting will be scheduled some time during that week in Atlanta, GA. Finalized dates and times will be announced within the next couple of months.

-Alllie Kade (akade@umich.edu)

ProTECT Progesterone for the Treatment of Traumatic Brain Injury

ProTECT™ III Principal Investigator: David Wright, MD

Tips to Minimize ProTECT Protocol Deviations

Eligibility

Common deviation: Study drug infusion begins outside of four-hour window.
Reason: Stat lab orders not placed in time.
Solution: Ensure all materials are available ahead of time. Create an enrollment packet complete with: Eligibility criteria checklist, Informed Consent Form, pre-completed lab forms for EOH and pregnancy tests, BioProTECT kit and form, pharmacy order form, and important numbers (e.g., ProTECT hotline, social work, etc.).

Eligibility

Common deviation: EMS/flight pre-hospital data is discrepant from initial data collected.
Reason: EMS/flight record not available at time of randomization.
Solution: Ensure that interview with EMS and flight team includes: time and cause of injury, index GCS, systolic BPs and times, whether the patient was hypoxic, and whether the event was witnessed. Get contact number for EMS and flight team and identify plan to obtain report as soon as possible.

Study drug infusion

Common deviation: Study drug infusion lasts >96 hours.
Reason: Taper error
Solution: Utilize the study drug infusion card (available in the ProTECT Toolbox), which will pre-populate change times. Maintain ongoing communication with the nursing staff. Ensure daily checks are completed on schedule. Check the medical record system to ensure the order times are accurate and based on the study drug infusion card. Follow up with nursing staff promptly to confirm the change was completed at the scheduled time.

-Erin Zaleski (ezajaros@umich.edu)

WebDCU™ Clinical Trial Data Management System

We have added several questions to the [people] table in the WebDCU NETT database to identify whether a team member is a physician, and if so, what their specialties are. Please take some time over the next two months to update the [people] table with this new information for team members within your hub/spokes. This information will help the NETT operations committee to identify the specialties of investigators at your sites.

-Cassidy Conner (connerc@musc.edu)

NETT Journal Club is Back! Join us on September 21st at 1:00 pm EDT

The NETT Journal Club encourages thoughtful discussion of current issues in emergency medicine with a special emphasis on neurological emergencies. The Journal Club meets the **3rd Wednesday of every month at 1:00 PM EDT** in the NETT virtual conference room. Journal topics for each month can be found on the NETT website at:

http://sitemaker.umich.edu/nettjournalclub

Do you have a new study team member?

The NETT website has a webpage with information that each new study team member will need:

http://www.nett.umich.edu/nett/new_team_member_information

Direct your new team members to this page to find the basic resources needed to get started in any NETT trial.