NETT-Workings

Neurological Emergencies Treatment Trials (NETT) Network

August 2014

Participating Hubs and Investigators

Emory University
David Wright, MD
Henry Ford Health System
Christopher Lewandowski, MD
Medical College of Wisconsin
Tom Aufderheide, MD
University of Kentucky
Roger Humphries, MD and Creed Pettigrew, MD
Oregon Health & Science University
Robert Lowe, MD, MPH and Craig Warden, MD
University of Pittsburgh
Clifton Callaway, MD, PhD and Jon Rittenberger, MD
Temple University
Nina Gentile, MD
University of Arizona
Kurt Denninghoff, MD
SUNY Downstate Medical Center
Steven Levine, MD
Massachusetts General Hospital
Joshua N. Goldstein, MD, PhD
Stanford University
James V. Quinn, MD

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

Clinical Coordinating Center (CCC)
University of Michigan
William Barsan, MD

Statistical & Data Management Center (SDMC)
Medical University of South Carolina
Yuko Palesch, PhD

University of California, San Francisco
J. Claude Hemphill, III, MD
New York Presbyterian Hospital
Stephan Mayer, 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
University of California, Los Angeles
Jeffrey Saver, MD and Sidney Starkman, MD
Ohio State University
Michel Torbey, MD

Enrollment Update: As of 8-29-14 at 8:39a (EDT)

	ATACH-II	POINT	SHINE
Arizona	<5	38	2
Cincinnati	<5	93	14
Emory	<5	51	50
HFH	5	46	<5
Kentucky	<5	38	30
Maryland	<5	32	9
Mass General	15	11	<5
Minnesota	21	97	7
NYP	24	44	62
Ohio State	<5	16 (Emmes/NETT)	36
OHSU	<5	47	<5
Pittsburgh	<5	12	15
SUNY Downstate	7	42	6
Stanford	9	70	13
Temple	6	60	22
Texas	8	73	23
UCLA	<5	21 (Emmes)	8
UCSF	<5	50	6
UPenn	28	205	14
VCU	<5	12	<5
Wayne State	<5	103	7
Wisconsin	<5	44	<5
Non NETT sites (ATACH-II only)	333	-	-
Emmes + Harrison (POINT only)	-	1115	-
Ancillary Sites (SHINE only)	-	-	106
TOTAL	612	2285	443

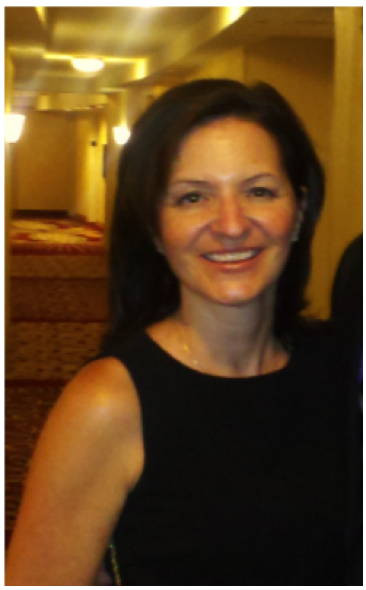
Pleased to Meet You NETT...

Will Meurer, MD, MS
NETT Co-Principal Investigator

Dr. Meurer is an Assistant Professor of Emergency Medicine and Neurology at the University of Michigan with fellowship training in Stroke and Cerebrovascular Disease, along with a Master's degree in Clinical Research Design and Statistical Analysis. He is also a Co-Investigator with the NETT, and one of the Principal Investigators for the NINDS Clinical Trials Methodology Course. His specific clinical and research focus is on adaptive trial design for the treatment of acute neurological illness. He has extensive experience in the design and conduct of clinical trials and provides expertise from the entire spectrum of trial development from idea, design, enrollment, analysis and interpretation. In his "free" time Dr. Meurer enjoys time with his wife and three children. He also is a very talented singer and actor, and has taken part in several local theater productions. And when he is at the University of Iowa with time to kill before a flight he is known to go on Herky explorations!

Allison DuRoss
NETT Research Assistant

Allison graduated from the University of Michigan in May of 2014 with a BSE in Chemical Engineering with a concentration in Biopharmaceutical Engineering. Her research career began her sophomore year when she obtained a research assistant position in a cancer and diabetes research lab at the University of Michigan. Eventually, she plans to return to school for a Ph.D. in Pharmaceutical Sciences. In addition to her work at the NETT, she also holds a part time position as Nanny for a 12 year old girl and a 9 year old boy. For fun and relaxation she loves to attend hot yoga classes, go on bike rides, attend Michigan football games with her boyfriend, and traveling!



Mickie Speers
NETT ATACH-II Project Monitor

Mickie has worked in research for over 25 years, with the last 14 years focused on clinical research. She earned two degrees from the University of Michigan; one of them in nursing. Mickie has been happily married to her husband, Ted, for 29 years! Mickie and Ted have two wonderful children, Lindsey and Willie, and a son-in-law, Trevor. She enjoys spending time with her family and friends, and working out. In addition her competitive spirit comes alive when playing golf, tennis, and euchre.

Stroke Hyperglycemia Insulin Network Effort Trial

Principal Investigators: Karen Johnston, MD, MSc, Askiel Bruno, MD, and Christiana Hall, MD

Remote Monitoring

The NETT is excited to introduce remote monitoring in the SHINE trial. Remote monitoring allows a monitor to access and review medical records from the site to verify CRF submitted data. The monitors will be able to complete the visit from their offices at the University of Michigan. The first remote monitoring visit will take place in September at the University of Kentucky. Donna will be reviewing CRF data from Enrollment through End of Treatment for several subjects.

The University of Virginia has remote monitoring access. West Virginia University and Georgia Regents Hospital are very close to having remote monitoring access.

In the near future you will receive a questionnaire requesting information about your ability to have remote monitoring access at your site. The NETT is very committed to initiating remote monitoring at every site and in all NETT trials. We will be establishing a working group including interested parties from IT, IRB and Privacy Officers to create a guidance document. Is there a key person at your site that might be interested in participating in this working group? If so, please contact Donna Harsh (dharsh@umich.edu).

Remote monitoring will NOT replace in-person monitoring visits but may lengthen the time between visits and reduce the amount of time at the in-person monitoring visit.

We are excited to travel down this new path with you.

SAEs

SAEs need to be reported within 24 hours of knowledge. Please complete all fields within the SAE CRF with data available at the time of reporting and include a detailed narrative describing SHINE enrollment, treatment, and discharge, and any other relevant event details. SAE narrative templates for most commonly seen events are located at https://sitemaker.umich.edu/nett/shine_toolbox#saetemplates. The site manager and monitors are also available to help with any SAE reporting questions that you may have.

Site IRB Renewal Approvals

Site IRB renewal approvals expire annually and continued renewal (CR) applications are required to be submitted by approximately 40-60 days prior to the expiration date for timely IRB review. Kindly upload the IRB acknowledgements of CR submissions under “SHINE Full study IRB submittal V 2.0” to help us track the current status of submission at your site. We really appreciate the timely CR submissions.

New Bravo Zulu Flag Recipient

Congratulations to ***Emory University*** who is now in possession of the Bravo Zulu Flag!

Platelet-Oriented Inhibition in New TIA Trial

Principal Investigator: Clay Johnston, MD

POINT Study Refresher Call: Getting Back on Track

Attention POINT Trial Project Managers, Study Coordinators, and Investigators...
There will be a POINT Trial Refresher review session focusing on POINT protocol highlights, study eligibility criteria, best practices, and FAQs. The review will end with a Q&A session. Please be sure to invite your POINT study team members to participate in this exciting engagement!

Date/Time: Tuesday, September 2, 2014 at 1:00 PM EDT.

Where: NETT virtual conference room

Dial in: 1-888-330-1716, password 7049083

Web address for virtual seminar room: https://connect.umms.med.umich.edu/nett_seminar/

Select "Enter as a Guest"- enter your name and join the call

POINT Study Drug Update

POINT study drug packages were shipped August 27th, and will continue through the rest of August and into September. You should receive a WebDCU notification once the drug has been released from the central pharmacy to your site.

Your Primary Drug Recipient should be the only study team member to receive POINT study drug into WebDCU. Please login to WebDCU as soon as shipment is received to confirm receipt. If your site was actively enrolling in WebDCU before the July Enrollment Hold, you may start enrolling immediately once you receive study drug.

Thank you to all our sites for your patience while POINT study drug is being restocked. The NETT is very excited for you to start enrolling subjects again!

-Gina Neshewat (neshewat@umich.edu)

ATACH-II

Antihypertensive Treatment of Cerebral Hemorrhage

Principal Investigator: Dr. Andnan Qureshi

Attention ATACH-II Study Coordinators: Don't miss out on a great opportunity!

We realize that Form 05 is a BIG task to complete. In appreciation for your hard work the CCC is going to present a $10 Target Gift Card for the first 15 form 05s that do NOT generate a query when monitored! If you would like to have your forms reviewed prior to your visit you can upload the de-identified data and let us know it is there for review. If you have any questions please contact Mickie Speers at LRAES@med.umich.edu or Angi Caveney at angif@med.umich.edu .

Please use this time to review your forms prior to your monitoring visit.

-Mickie Speers (lraes@med.umich.edu)