Tue, Dec 27, 2016 at 11:31 AM

University of Minnesota - Department of Emergency Medicine

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Introduction

Michelle Biros, MD, MS
Minnesota Hub PI

Dear colleagues,

It is hard to believe that the Minnesota Hub of the Neurological Emergencies Treatment Trials (NETT) network has been in existence for nine and one half years. Since its inception in 2007, NETT has launched seven diverse clinical trials including 3 using exception from informed consent for emergency research. Four of the seven studies have been completed resulting in several distinct original research reports, and the potential to improve the care of patients with acute neurologic illness or injury.

In This Issue

Our Minnesota NETT Hub has been a great contributor to the success of the national NETT. We have been involved in all studies performed within the network and have included from 3 to 11 Spoke sites as enrollment centers for our various studies. We are always above NETT averages in terms of ongoing recruitment, and often end up among the top NETT enrolling Hubs once a study has run its course. We have maintained an incredibly high retention rate of enrolled subjects in all of our studies (95-100%) and have consistently been among the top tier of Hubs when it comes to responding to coordinating center requests, maintaining regulatory documents, completion of study reports, timeliness to milestones, and contributions to other aspects of NETT. These great achievements are a testament to the hard work of all of the NETT infrastructure staff as well as all of the site investigative teams.

The NETT, for me, has provided a great deal of professional and personal satisfaction, as well as an excellent learning experience. I'm very humbled by the opportunity to interact with such great colleagues as all of our Spoke and Hub staff and clinician providers. I am extremely grateful for having had this opportunity.

As we enter the last six months of the NETT, we look forward to continued research efforts, and collaboration to improve patient well-being in advance. This final stretch is opening up even broader research opportunities and involvement in other exciting research networks. Please stay tuned, and we will be updating all of you shortly.

Thank you again for all of your hard work and your support of the Minnesota NETT Hub.

Announcements

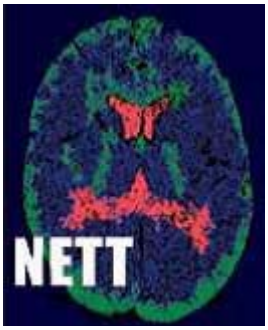
Kathleen Miller, BSN, CCRC

Minnesota Hub Manager

We can't thank you enough for all the great work done by spoke staff this year. POINT enrollments really picked up in the past six months! As a group, we remain in fourth place compared to other NETT Hubs. Many thanks to the five spokes that helped us launch the ESETT study earlier this year. Each enrollment is a learning opportunity for all to share.

Research studies involving technology: ipads (POINT), laptops (SHINE) and ipods (ESETT) present additional challenges for research and clinical teams. The coordinators are key to keeping not only study materials up to date but also equipment fully charged and ready to go.

Speaking of keeping up to date…a reminder to keep all study staff in compliance with Human Subjects Protection training, NIHSS and other trainings. Marinda Bland, our Regulatory Documents specialist sends out notices to coordinators in advance of documents expiring. With tracking over 400 research team members (over the past 5 years), this can feel like a full time job!



NETT in 2017

All NETT studies will continue after "NETT" sunsets and the new "SIREN" network takes shape. We expect that we will receive frequent communication from the University of Michigan in the next few months regarding winding down activities in the network. The official end date of the NETT Grant award is May 31, 2017.

Until NIH/NINDS announcements are made regarding the new SIREN Clinical Coordinating Center (CCC) and the SIREN Hubs, we will operate business as usual. If you have questions about contracts or contract extensions, we will facilitate getting your concerns addressed either internally here or at University of Michigan. Our goal is to make this a seamless transition.

Changes to WebDCU

Both NETT and StrokeNet use the Data Coordinating Unit at Medical College of South Carolina as the repository for clinical trial data and regulatory documents. As a result, if one network changes, it affects the other. Recently, StrokeNet moved to using “eDOA” (electronic Delegation of Authority logs). Coordinators no longer need signatures on paper logs for each research team member. This transition certainly will have some advantages.

With the POINT trial, it has additional advantages of cleaning up information as it is converted into the electronic format. Marinda has been helping to correct outdated information by working with the NETT project managers. Moving forward, spokes can elect to have us continue to manage your DOA or you can make the changes when you change personnel. Just let us know your preference for POINT, and we will be in contact to train you in. The Hub will continue to provide oversight authority.

The Hub will maintain responsibility for uploading regulatory documents for all sites.

ESETT

Established Status Epilepticus Treatment Trial

ESETT Study Lead Coordinator: Abbey Staugaitis, RN (staug002@umn.edu)

Version 2 of the protocol has been released. There is a nice table on page 2 that summarizes the changes to the protocol.

CRFs:

Pay special attention to the CRF completion timetable (14.3 in the CRF guidelines - may require UM Friends login to access). The timelines for CRF completion are much tighter than we were used to for POINT and SHINE. Many CRFs need to be started and/or completed within 8 hours of randomization!

On January 13th we'll be doing a database freeze to generate an upcoming DSMB report. Please enter any late CRF data and respond to queries in the coming weeks in preparation for the freeze.

Consent notes & LARs:

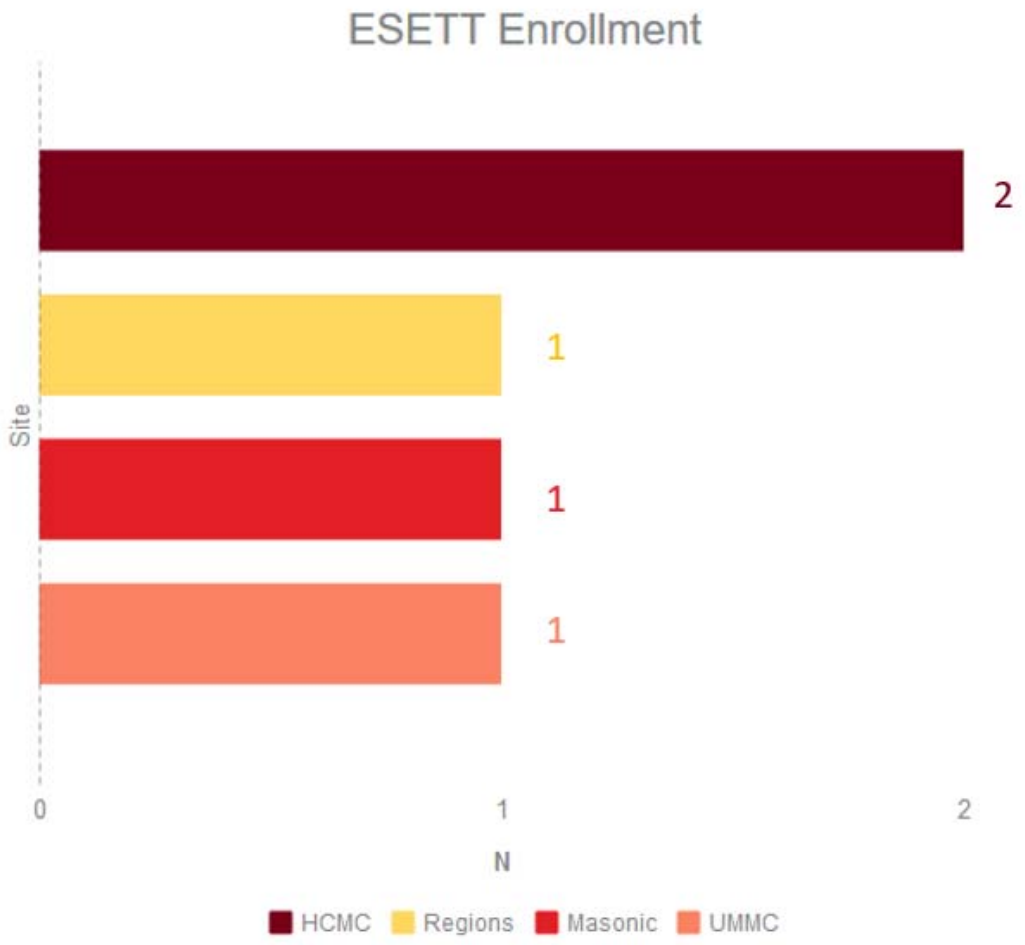
1. Please fill out the paper informed consent log before putting the info in Web DCU (as there is a particular order to the attempts in Web DCU).
2. 1st consent log entry should always document A) if there is an LAR present or not upon START of the study drug AND B) if the LAR offered objection (even if the coordinator isn't there, he/she should find out this information upon their arrival).
3. The very last consent log entry should be the successful consent (if we get one). *It should also be documented WHY a subject can't give consent for themselves if we only consent from the LAR. *If you are able to get a consent from the subject AFTER you've obtained consent from the LAR, document that in the COMMENTS section. The last entry in the

log should still be the 1st successful consent with the LAR.

*It is expected that we should obtain consent from an LAR within 24 hours (and all attempts should be documented).
*Use the code “other” when documenting attempts at consent with anyone other than the LAR (for example: you speak to a charge nurse who is trying to locate the LAR).

Protocol assist devices:
A friendly reminder to keep the iPods charged. Checking them weekly would be ideal. This is something that the ESETT monitor will check when they come to review CRFs. Another lesson learned is that the iPOD device does not record data. It helps to track time since the dose is given and can remind the clinical team to perform assessments at 20 minutes and 60 minutes. It is important that the clinical team use the paper form to document study information and also document in the medical record.

Michigan will soon be releasing an update to the ESETT app for the protocol assist devices, so stay tuned. Also, the device is a great BACK UP but save yourself more work later on and have the ED team complete the paper data collection guide, too.

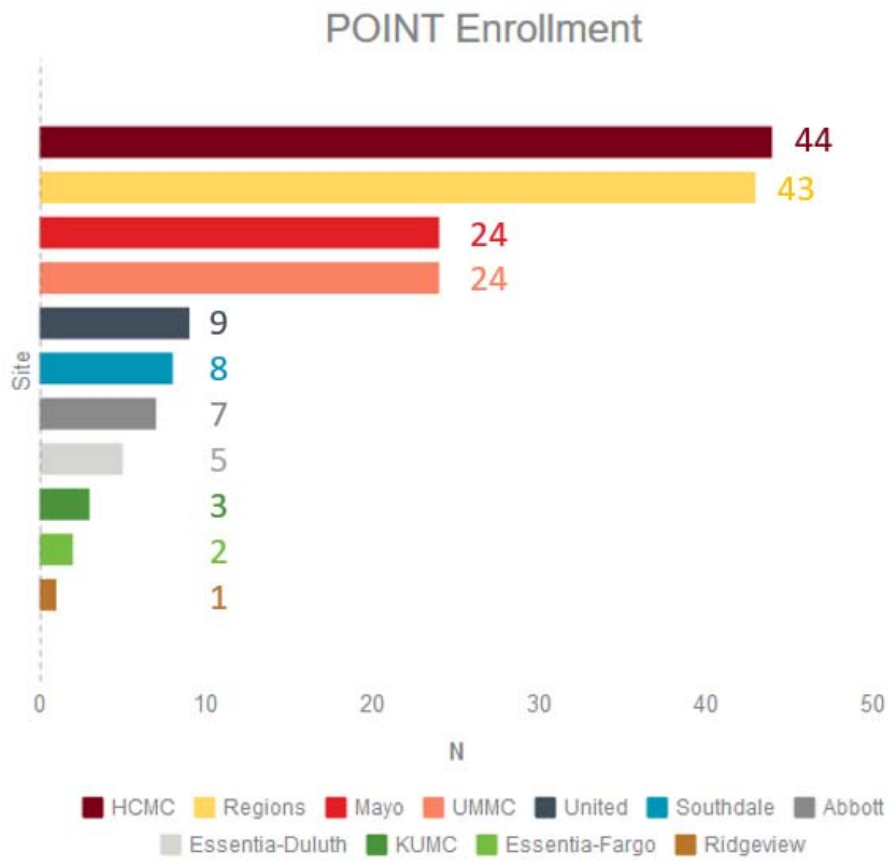


POINT

Platelet Oriented Inhibition in New TIA and minor ischemic stroke

POINT Study Lead Coordinator: Abbey Staugaitis, RN (staug002@umn.edu)

There are new updated FAQs available (requies UM Friends login). They help to answer some tricky questions about the study. Please let me or Marinda know if you would prefer to keep your eDOA current for POINT.

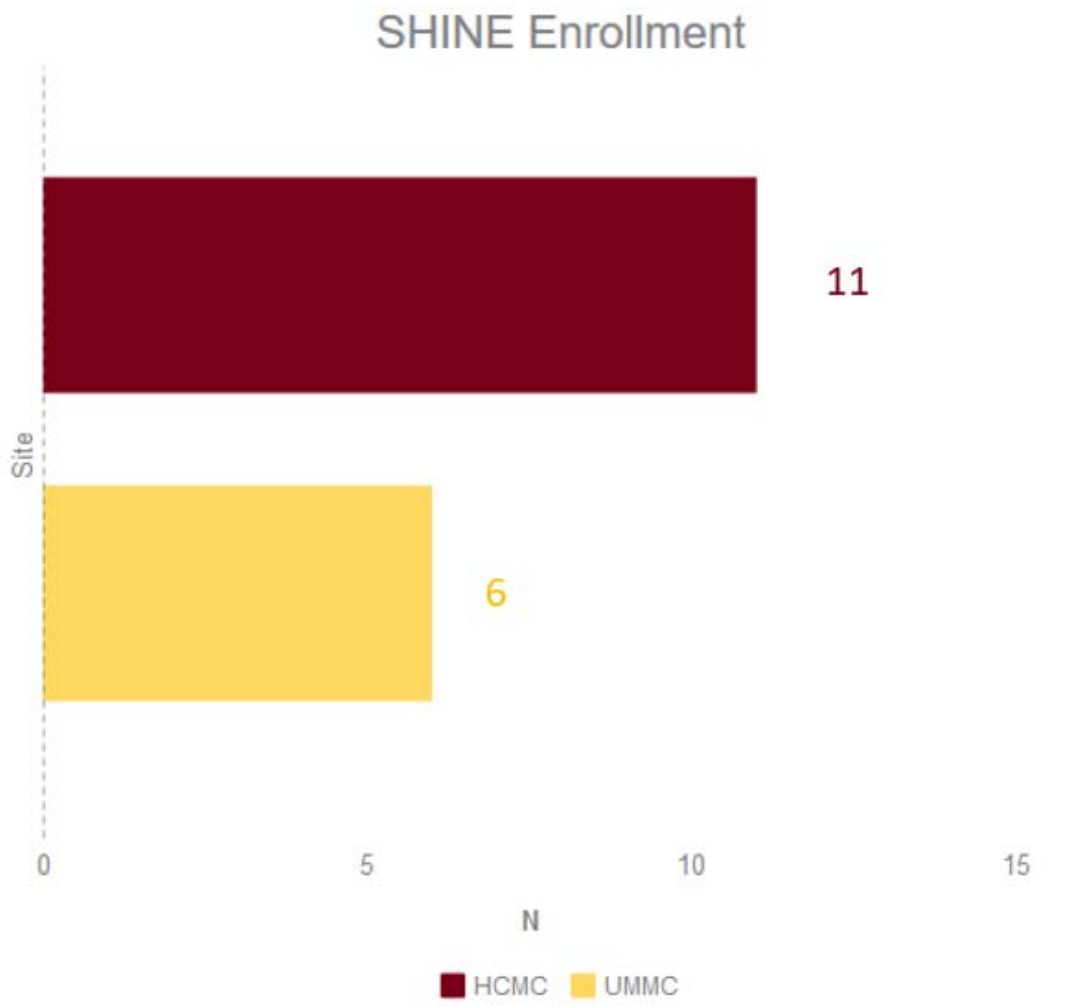


SHINE

Stroke Hyperglycemia Insulin Network Effort

SHINE Study Lead Coordinator: Julie Scherber, RN (sche0245@umn.edu)

This study has just released a new MOP. You can view a tracked changes version and a summary of changes to the MOP on the SHINE website (requires UM Friends login).



Contacts

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