Updates

October flew by before we realized that we had not sent out our monthly newsletter.

Recently, we have had a number of important developments with NETT studies that we want to share with spoke investigators and coordinators. The NETT Investigator meeting was held October 21-22 in Chicago where NETT Hub leaders gathered for updates and heard brief presentations pitching future NETT study ideas and designs. It was a highly interactive meeting that helped future investigators shape their research questions, study design and protocols. Immediate feedback was given to the presenters by NETT CCC and Hub leadership. The format was well received.

2014 Spoke Summit

We will be sending out potential 2014 dates for a teleconference call for all spoke personnel. We would like to take the opportunity to hear from you regarding current and future trials and any other concerns or suggestions you may have.

RAMPART

As you may recall this was a very successful NETT study that wrapped up in record time in 2012. The FDA is requesting more detailed medical records for a number of subjects enrolled: targeting those who died, had prolonged hospitalizations or subsequent hospitalizations. Our staff will be working to collect the data and submit it to the NETT and the FDA. No work is required on your part.
New NETT Study: ATACH2

This study has been active for about 2 years operating out of the University of Minnesota with Dr. Adnan Qureshi and his team. Around November 2013, it will come to the NETT. All Minnesota spokes are encouraged to consider participation in this study. We can provide protocols and help with IRB submissions. We have participated in this study from the start by providing study coordination services. From a spoke point of view, it is a fairly straightforward study with a 24-hour intervention of managing blood pressure in hemorrhagic strokes. As information comes from the NETT, we will pass it along to spokes. Please let us know of your interest, so we can expedite the information. Current spokes participating in the trial are: HCMC and Fairview Southdale.

ProTECT

Progesterone for the Treatment of Traumatic Brain Injury

Dr. Wright informed Hub leaders on 11/1/2013 that the DSMB had put enrollments on hold. This was a stunning announcement for all concerned.

More recently we received word that the study was stopped for futility. We will continue to follow all enrolled patients until their end of study visit (6 months). All spokes will need to submit information to their IRB’s regarding the study’s status. Detailed information related to study closeout has been released including letters for contacting patients, etc. (See the NETT website ProTECT Toolbox.) If you have any questions regarding closeout, please let us know. We anticipate that our last Hub enrollment’s 6-month visit will take place in April 2014. Please email us copies of your IRB correspondence to enter into WebDCU for your site. On behalf of the NETT leadership and Dr. Wright’s team, thank you for the efforts you have put into this trial.

ProTECT Minnesota Spokes Enrollment Summary

<table>
<thead>
<tr>
<th>Spoke</th>
<th>Active</th>
<th>Enrollments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hennepin County Medical Center</td>
<td>09/03/2010</td>
<td>19</td>
</tr>
<tr>
<td>Regions Hospital</td>
<td>11/04/2010</td>
<td>58</td>
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<tr>
<td>North Memorial Medical Center</td>
<td>09/02/2011</td>
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ProTECT National Hub Enrollment Ranking

<table>
<thead>
<tr>
<th>Rank</th>
<th>Hub</th>
<th>Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arizona</td>
<td>96</td>
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<tr>
<td>2</td>
<td>Emory</td>
<td>92</td>
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<tr>
<td>3</td>
<td>Stanford</td>
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<tr>
<td>4</td>
<td>Cincinnati</td>
<td>85</td>
</tr>
<tr>
<td>5</td>
<td>Minnesota</td>
<td>84</td>
</tr>
</tbody>
</table>

Total Enrollment Nationwide: 882
Enrollment Goal: 1140
POINT

Platelet-Oriented Inhibition in New TIA and minor ischemic stroke Trial

The latest version of the protocol was released (version 5) and other supporting documents to include with the IRB submission. Note that many of the changes to the protocol were made to align with practices outside of the U.S. (for instance aspirin dosage). The new version also officially increases the sample size for the study and number of sites.

Please send us your consent revisions to review and forward to Michigan for their review. Changes are very simple and turnaround has been quick. The NETT standard is: IRB submissions must be completed within 14 days of release. (The timeline for this study is IRB submission prior to 11/24/2013.) All supporting documents can be found on the NETT Website (POINT Study Toolbox).

We are looking forward to activating Abbott Northwestern in late November and KUMC in early December.

If you are not currently participating in the DNA - Biomarker portion of the study, you are welcome to add it at any time. It involves collecting one blood sample close to randomization (or up to 24 hours from enrollment). Patients may participate in POINT and decline the ancillary study.

POINT Minnesota Spoke Enrollment Summary

<table>
<thead>
<tr>
<th>Spoke</th>
<th>Active</th>
<th>Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hennepin County Medical Center</td>
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<tr>
<td>UMMC - Fairview</td>
<td>November 2010</td>
<td>11</td>
</tr>
<tr>
<td>Fairview Southdale Hospital</td>
<td>July 2010</td>
<td>8</td>
</tr>
<tr>
<td>Regions Hospital</td>
<td>January 2012</td>
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</tr>
<tr>
<td>Ridgeview Medical Center</td>
<td>February 2012</td>
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<tr>
<td>Essentia Health – St. Mary’s</td>
<td>August 2012</td>
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</tr>
<tr>
<td>United Hospital</td>
<td>August 2012</td>
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POINT National Hub Enrollment Ranking

<table>
<thead>
<tr>
<th>Rank</th>
<th>Hub</th>
<th>Enrollment</th>
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<tbody>
<tr>
<td>1</td>
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<td>2</td>
<td>Wayne State</td>
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<td>3</td>
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<td>Minnesota</td>
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<td>5</td>
<td>Houston</td>
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</table>

Total Enrollment Nationwide: 1809
Total Enrollment Goal: 5841
The study is getting closer to meeting its monthly enrollment goal of one subject per day. We look forward to activating more sites within our Hub. KUMC has IRB approval and is likely to get started very soon. Locally, we have enrolled 4 patients.

Anyone who reads through the protocol for the first time will likely surmise that the study is complicated. However, we have found that the study has built in supports for nursing staff and is not nearly as difficult as we anticipated. It does require vigilance on the part of investigators and research staff during the 72-hour intervention phase. Nursing has responded very favorably to the study once they have been trained and know that research staff is readily available for questions. We are happy to discuss this study with you – please let us know if you are considering participation in this trial.

ISPOT is the ancillary study for SHINE looking at hypercoagulability in acute ischemic stroke patients with hyperglycemia. Only SHINE subjects who did not receive tPA are eligible for this ancillary study. Enrollment has been very low (around 14 subjects) thus far due to the high proportion of subjects receiving IV tPA.

**SHINE Minnesota Spokes Enrollment Summary**

<table>
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<th>Spoke</th>
<th>Active</th>
<th>Enrollments</th>
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<tr>
<td>UMMC - Fairview</td>
<td>11/04/2010</td>
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**SHINE National Hub Enrollment Ranking**

<table>
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<th>Rank</th>
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<td>1</td>
<td>New York Presbyterian</td>
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<td>2</td>
<td>Emory</td>
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<td>3</td>
<td>Kentucky</td>
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<tr>
<td>4</td>
<td>Temple</td>
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<tr>
<td>5</td>
<td>Houston</td>
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<tr>
<td>6</td>
<td>Cincinnati</td>
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<tr>
<td>7</td>
<td>Maryland</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>UPenn, Minnesota, Stanford</td>
<td>4</td>
</tr>
</tbody>
</table>
NETT Contacts

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Shannon Gifford, MA

Spoke
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Hennepin County Medical Center
Regions Hospital
Fairview Southdale Hospital
Ridgeview Medical Center
Two Twelve Medical Center
United Hospital
Essentia Health – St. Mary’s
Abbott Northwestern Hospital
University of Kansas Medical Center

SHINE

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Spoke
University of Minnesota Medical Center
Hennepin County Medical Center
University of Kansas Medical Center

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