Enrollment Update:  

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<th>ALIAS</th>
<th>RAMPART</th>
<th>ProTECT</th>
<th>POINT</th>
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Cassidy Conner
POINT and ProTECT Data Manager
Medical University of South Carolina

Cassidy is a Data Manager at the Medical University of South Carolina’s Data Coordination Unit (DCU) where he manages the WebDCU™ POINT and ProTECT trial databases. He handles database design, functionality, and QA, and provides assistance to study team members across all NETT sites that need help using WebDCU™’s POINT and ProTECT databases. Cassidy received an M.S. in applied sociology from Clemson University with a focus in research methods and survey design, and this background has been especially helpful in research database development and case report form design. Outside of work, Cassidy enjoys spending his free time with his girlfriend, Jaime, and golden retriever, Colette.

Catherine Dillon, CCRP
Program Manager
Medical University of South Carolina

Catherine Dillon graduated from the College of Charleston and started her career as a marine biologist at the South Carolina Department of Natural Resources. When she wasn’t shark fishing or scuba diving, she created and maintained databases for the Office of Fisheries Management. After a career change in 2002, Catherine joined the Medical University of South Carolina as a study coordinator within the Institute of Psychiatry. She joined the Data Coordination Unit (DCU) in 2003 and has been there ever since. During her time with DCU, she has been responsible for a broad range of project and data management activities for over 40 protocols including multi-site, international, industry and federally-funded, acute and exception from informed consent trials. She is married to her husband Dan. Together they have a 12-year-old son named Joseph, a 3-year-old daughter named Sophia, and a puppy named Dusty.

Keith Pauls, BS
Senior Applications Analyst
Medical University of South Carolina

Keith Pauls joined the Data Coordination Unit (DCU) over 6 years ago after receiving a BS in Computer Information Systems from Clemson University and a minor in Business Administration. As a Senior Applications Analyst he works on developing and maintaining the web-based clinical trial management system (WebDCU™) created by the DCU. Keith enjoys his job because of the freedom to learn and develop new technologies that can be applied to the WebDCU™ system and the wonderful people he has an opportunity to work with. When not in front of a computer, Keith enjoys the outdoors and likes being at the beach and biking around the Charleston area. He also stays active by working out regularly (when motivated) and playing in competitive basketball and tennis leagues.
High-Dose Albumin Therapy For Neuroprotection In Acute Ischemic Stroke
Principal Investigator: Myron Ginsberg, MD

Mark Your Calendars: For selected sites the next Regional Meeting is scheduled for January 9-10, 2011 in Las Vegas, NV.

Other Reminders: Passed Validation in ALIAS WebDCU is now Ready to Submit. Ready to Submit indicates the CRF is saved and has successfully passed all validation rules which might have resulted in either a Rejection or Warning status, and from the viewpoint of the WebDCU system is ready to be Submitted.

-Sam Mawocha (smawocha@umich.edu)

Platelet-Oriented Inhibition in New TIA Trial
Principal Investigator: Clay Johnston, MD

Thank you for your continued commitment to the POINT study! Here are a few important reminders:

1) A study team member must witness and record the loading dose!
2) Please make sure the patient understands that the 8 tablet loading dose is ONLY for day one, and thereafter he/she should take only 1 tablet of study medication per day!
3) Randomization must take place within 12 hours of the symptom onset.
4) Screen Failure Logs are due the 10th day of the following month.

-Tess Bonham (tbonham@umich.edu)

ProTect

Progestosterone for the Treatment of Traumatic Brain Injury
ProTECT™ III Principal Investigator: David Wright, MD

Mark Your Calendars: The ProTECT Investigator Meeting is scheduled for April 28-29, 2011 in Atlanta, GA.

Other Reminders: 1) Please provide documentation that Protocol Version 6.0 has been submitted to all IRBs. Remember you have 14 days to submit to your IRB from 12/8/10 when the protocol was made available. Documentation must be uploaded for each Spoke in WebDCU under: ProTECT Full Study v6 IRB Application Submittal. Once approval has been granted, please provide clear documentation from the IRB of the protocol version and approval period: ProTECT Protocol v6 IRB Approval.

2) All Hubs/Spokes need to submit a Revocation Form to IRBs for approval. The updated template is posted in the ProTECT Toolbox under Regulatory. If you have already received IRB approval for a Revocation Form please revise that version to include the updated material provided in the template. Prior to submitting to your IRB, please provide a copy of the site-specific Revocation Form to NETT-CCC for review (ProTECT-milestone@umich.edu). After final approval is granted, please upload the form and documentation of IRB approval in WebDCU: ProTECT IRB Approved Revocation Form.

3) If there are updates to Informed Consent Forms, please provide a copy (using tracked changes) for NETT-CCC review as well (ProTECT-milestone@umich.edu). Current IRB-approved ICFs should be uploaded in WebDCU: ProTECT IRB Approved Informed Consent Form.

-Erin Zaleski (ezajaros@umich.edu)
A round of applause is in order... Congratulations to the Medical College of Wisconsin team for setting a new NETT record! Their team enrolled one patient in each of our four trials within 48-hours this month! We appreciate all the hard work and teamwork that it takes to pull this off. This is an incredible accomplishment!

RAMPART End of Enrollment - Important Reminders

* Please submit patient enrollment data as soon as possible. This will help us provide the most up-to-date enrollment figures.
* Check the RAMPART website frequently! You can find the total enrollment there.
* If there are any specific requests for notification that enrollment has reached 1024, please forward to Erin Zaleski (ezajaros@umich.edu) as soon as possible.
* Ensure your local plan is in place for end of enrollment, including:
  * Training of study team about end of enrollment procedures and timelines
  * Ceasing enrollment and retrieval of study box/study drug within 24 hours of notification that enrollment has reached 1024
  * Spreading the word to all medics and study team members that enrollment has ended
  * Retiring all study drug in the RAMPART Database within 5 days of end of enrollment

Thanks to those who have already provided this information to NETT-CCC. If you have not yet provided information for your Hub, including a 24-hour contact list, please send to Erin Zaleski (ezajaros@umich.edu).

* Please respond to all DCRs and SAE requests. This will help make the final monitoring visit go much smoother!

Look For Updates On Enrollment In The Monthly NETT NewsFlash

The following were submitted for the Society for the Academic Emergency Medicine June 2011 meeting:
