The RE-ENERGIZE Rag

Volume #5 February 2017

RE-ENERGIZE Site Investigators' Meeting - ABA 49th Annual Meeting, Boston, MA

Tuesday, March 21st, 2017 at 2:00 PM

We look forward to seeing many of you there! Let us know if you are attending.

Message from Dr. Daren Heyland

At the outset, thank you for your willingness to support the RE-ENERGIZE trial at your site.

I wanted to let you all know we are in a critical phase of the start-up of the trial. We received the grant for this study over 1.5 years ago and to date, we have only activated about 20 of the intended 80 sites and enrolled 80 patients in 2016. Some of you have been 'in start-up phase' for more than a year.

Unfortunately, this slow progress is having a negative effect on the viability of the trial. The Canadian Gov't, who funded the trial, will demand proof that we can improve performance or they may withdraw their funds. If you remember, the Canadian gov't cut our budget by 27% so we have insufficient funds to finish the trial. So, we are in the middle of applying for additional funds from a US Agency and they are asking key questions about why such a slow start up? Why so few patients enrolled after 1.5 years? We have a hard time answering these questions and reassuring them that additional investment of monies will solve the problem.

I know it can be different. I am the PI on an industry sponsored multicenter ICU trial in North America and Europe and, on average, it takes 2-4 months from engagement to start up. I know industry studies pay more money and this motivates people and institutions to prioritize those trials over these lower paying trials. But here is my problem. I am trying to raise more money, to be able to increase per patient payments, but agencies won't want to fund a trial that can't get off the ground. Over these next few months, both Canadian and US agencies will be looking very carefully at the progress we make.

Can I please ask those of you still in Start-up to prioritize efforts to finalize your start up activities so we can get this trial initiated at your site? If it is the department head, legal counsel, or your ethics boards, that are the rate limiting steps, please speak to them and stress the importance of moving forward quickly with starting up this study.

If the study is initiated at your site, PLEASE do everything you can to enroll the eligible patients who are admitted to your facility.

- Daren

THE RE–*ENERGIZE* STUDY

ENROLLMENTS as of January 31st 2017:

December enrollments: 12

January enrollments: 7

Monthly GOAL: 1 Patient/Site/Month

Total patients enrolled in the study: 288

Patients needed to reach our goal: 2,412

ACTIVATED SITES and ENROLLMENTS

Institution	December	January	Randomized to date
Joseph M. Still RF, Augusta, GA	3		13
Hôpital l'Enfant-Jésus,Quebec, QC	2		10
University of Iowa, Iowa City, IA	1	2	9
Harborview Medical Centre, WA			8
Mercy Hospital St. Louis, St. Louis, MO			8
University of Southern California, Los Angles, CA	1		6
Wake Forest University HS, Winston-Salem, NC		1	5
AHN Western Penn Burn Center	1		4
University of Colorado, Denver, CO - (on hold)			4
Foothills Medical Centre, Calgary, AB		2	3
Ohio State University Med Ctr, Columbus, OH	3		3
Columbia, St. Mary's Hospital, Milwaukee, WI		1	3
Akron Children's Hospital			3
Ross Tilley Burn Centre/Sunnybrook, Toronto, ON			3
Tampa General Hospital, Tampa, FL	1		1
Firefighters' Regional Burn Center, Memphis, TN		1	1
Connecticut Burn Center, Bridgeport, CT			
Legacy Emanuel Hospital, Portland, OR			
UF Health at Shand's Hospital, Gainesville, FL			
Vancouver General Hospital, Vancouver, BC			
CHI Health – St. Elizabeth, Lincoln, NE			
Pilot Study			204
TOTAL	**12**	**7**	**288**

THE RE–*ENERGIZE* STUDY

FAQ Corner

Keep your questions coming so we all continue to learn and grow!

Question: My patient has not received the study product for more than 24 hours due to an ileus. Should I take the patient off of the study?

Answer: No, do not take the patient off of the study. Please restart the study product right away and try to make up the missed doses if possible. Moving forward, please dissociate decisions to hold EN from the decision to hold study IP. Based on clinical findings of enteral feeding intolerance, the clinical team may decide to hold the EN. The only reason to hold the study medication is if the patient is strictly NPO for bowel perforation, obstruction, or upcoming surgery. We discourage stopping the study IP (a bit of powder and water, should be easily absorbed and requires no digestion) for intolerance.

Question: A resident started my patient on open label glutamine and a restricted formula over the weekend. Should I take the patient off the study.

Answer: No, do not take the patient off the study.

1) Stop the open label glutamine
2) Restart the study intervention as soon as possible
3) Stop the restricted EN formula
4) Switch to an EN formula with arginine < 6g/L and with no added glutamine
5) Report a Protocol Violation (PV) by completing the PV form in REDCap for each day the patient received open label glutamine or a restricted formula. PVs should be reported within 24 hours of becoming aware.

Question: Do we enter Tracheotomies as burn related operative procedures?

Answer: No. Although the tracheotomy is likely due to inhalation injury or the burn injury, we do not collect tracheotomy as a burn related operative procedure.

Question: My patient was scheduled to receive the study intervention at 00:30 on study day 10 and it is charted as given at 23:45 on study day 9. This means the patient got more than 100% on study day 9 and less than 100% on study day 10. Do I enter the dose given at 23:45 on study day 9 as the first dose given on study day 10 in REDCap?

Answer: No, please enter all data in REDCap on the date it is charted in the medical chart. Compliance with study intervention is calculated over a 3 day average to account for doses given on the ‘wrong side’ of midnight and allow for missed doses to be made up on the next calendar day.

THE RE–*ENERGIZE* STUDY

Thank you for alerting us to errors or inconsistencies in REDCap. We cannot fix what we are not aware of. ☺

REDCap Notes and Reminders:

- Highest and lowest daily heart rate are recorded on the Concomitant Medication form in REDCap
- Hospital Overview, Survival Status, and 6 Month Follow-up Questionnaires are located on the far right of the grid after you click on the 3rd tab at the top of the grid.
- Use the version of the Employment Questionnaire emailed to you on the 25th of January, 2017. The version in the current CRF worksheets is not correct. This will be updated in the next version.

Central Pharmacy Depot

Shipment Days: Monday, Tuesday, and Wednesdays

Availability by email (24/7): securedata@epipharm.com

Telephone/Messages: 613.549.6666 e.3339

IMPORTANT NOTE: Urgent reorders and shipments required in less than 5 days can not always be guaranteed due to customs / shipment delays. Please remember to plan 10 days ahead and reorder early where possible.

NOTE: Please note that Remote Pharmacy Quality Audits of RE-ENERGIZE sites has commenced. We will contact you in advance of these audits to explain the process and answer any questions.

REMINDER: If your pharmacy staff are involved in RE-ENERGIZE, they need to be trained and added to the delegation and training logs.

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