THE RE-*ENERGIZE* STUDY

The RE-ENERGIZE Rag

Volume #3 **October 2016**

On September 9th, Daren and our European Partner team hosted a training seminar in Athens, Greece for some of our European site investigators from Austria, Serbia, and of course Greece.
We took a moment to capture a the moment at the end of the day!

Front row (left to right):
Dr. Michael Chourdakis (CERU European Partner, Thessaloniki, Greece), Dr. George Karapiperis (Athens, Greece), Dr. Eugenia Kyriopoulos (Athens, Greece), Dr. Gabriela Muschitz (Vienna, Austria), Dr. Olivia Salameh (Vienna, Austria), Dr. Militsa Bitzani (Thessaloniki, Greece), Dr. Athina Lavrentieva (Thessaloniki, Greece, Dr. Daren Heyland (Sponsor, CERU Director, Canada).

Back row (left to right):
Dr. Nikolaus Markou (Athens, Greece), Manos Bouras (European Partner Support), Dr. Panagis Georgiou (Athens, Greece), Eirini Kasapidou (European Project Leader), Prof. Sonja Radakovic (Belgrade, Serbia), Dr. Jefta Kozaraski (Belgrade, Serbia).

We optimistically expect to activate our first European site in the coming weeks!
All 30 of our European sites are working hard to get ethics approvals and contracts in place as quickly as possible.

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ENROLLMENTS AS OF SEPTEMBER 30TH 2016:

September enrollments: 7

Monthly GOAL: 1 Patient/Site/Month

Total patients enrolled in the study: 248

Patients needed to reach our goal: 2,452

- **Thank you to all of the sites who continue to enroll and push this study forward!**
- **We need all of you working hard to find those eligible patients and get them in the study.**
- **September was a slow month with only half as many patients as expected enrolled.**
- **We look forward to seeing patients enrolled at our most recently activated sites this month!**

REMINDER

Co-enrollment in the RE-ENERGIZE and Propanolol studies is pre-approved!

ACTIVATED SITES and ENROLLMENTS

Centre	Randomized to date
Hôpital l'Enfant-Jésus,Quebec, QC	7
Mercy Hospital St. Louis, St. Louis, MO	7
Harborview Medical Centre, WA	6
Joseph M. Still RF, Augusta, GA	6
University of Iowa, Iowa City, IA	4
University of Colorado, Denver, CO	4
University of Southern California, Los Angles, CA	4
Wake Forest University Health Sciences, Winston-Salem, NC	3
Ross Tilley Burn Centre, Toronto, ON	2
Columbia, St. Mary's Hospital, Milwaukee, WI	1
Vancouver General Hospital, Vancouver, BC	
UF Health at Shand's Hospital, Gainesville, FL	
CHI Health St. Elizabeth, Lincoln, Nebraska	
University of Calgary-Foothills Medical Centre	
AHN Western Penn Burn Center	
Pilot Study	204
TOTAL	**248**

<u>Activation Challenge</u>:

Dr. Heyland would like ALL sites activated globally by the end of 2016.

Help us accomplish this goal by pushing forward with ethics and contracts at your site.

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Daily Nutrition Data Entry
Enteral Formula vs. Protein Supplement

Enteral Formula vs Protein Supplement has to do with whether or not the formula contains complete nutrition or not.

For example Ensure Plus can be fed on its own and meet all of a patient's nutritional needs (calories, protein, vitamins, minerals, etc.). Ensure Plus should be recorded as an Enteral Formula when given enterally.

By contrast, Beneprotein will not meet a patient's nutritional requirements on its own and must be fed in addition to a complete nutritional formula. As such, Beneprotein should be recorded as a Protein Supplement.

When considering whether or not to record a formula as a protein supplement, consider that protein supplements add to (supplement) the protein a patient is receiving, but cannot stand alone and provide complete nutrition.

REDCap updates to Daily Nutrition Data form:

We have updated EN Formula and Protein Supplement taxonomies in REDCap. You will now find Ensure Plus under the EN formulas. Keep in mind that Ensure Plus and other similar shakes can be fed both enterally and orally. Only record Ensure Plus etc. under EN formulas if the patient received it via the EN route.

If the patient drank the shake, it should then be captured under **oral intake** and be included in your calculation of the adequacy of intake via the oral route.

If you have any doubts about where a formula should be entered asked your dietician.

Nursing Procedures for IP Administration

Many have you have asked if we have instructions for the bedside nursing staff regarding administration of the investigational product. I am happy to report, yes we do!

You will find a one page sheet titled ***Nursing Procedures Investigational Product Administration*** at the back of you Study Procedures Manual attached as Appendix E; posted on the Critical Care Nutrition website at the following link: www.criticalcarenutrition.com/research/reenergize/study-tools ; in the training slides.

Please **place a copy of these instructions at the bedside** of each of your study patients.

REMINDERS and CLARIFICATIONS:

ICF Date and Time - please ensure both date and **time** consent was obtained are recorded on each signed Informed Consent Form.

Mechanical Ventilation start Date and Time

If patient arrives at your facility/unit already mechanically ventilated, record the actual date and time mechanical ventilation was started, even if that occurred at another facility or in the field prior to the patient arriving at your hospital. If the patient arrives mechanically ventilated and the actual start date and time are not available, enter the date and time the patient arrived at/was admitted to your facility as the start date/time.

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FAQ Corner

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

Question: Are screen failure patients that are entered into the CRS considered enrolled?
Answer: No, only patients who are randomized to study treatment are enrolled in the study. The CRS serves as a screening log for eligible and randomized patients, screen failure (not eligible) patients, and eligible but not randomized patients.
Question: Is a patient who is is receiving the study product orally allowed to take all of the daily doses at one time, only once daily?
Answer: No, the patient should not receive more than double the scheduled dose at any one time to maximize absorption of the investigational product (IP). If a patient is receiving the IP orally three times a day (instead of every 4 hours), they are already receiving a double dose at each interval.

PHARMACY Notes from the Central Pharmacy Manager:

The central Pharmacy Depot would like to extend our warm welcome to pharmacists and pharmacy technicians across our network.

- About us: CERU Central Pharmacy Depot Shipment Days: Monday, Tuesday, and Wednesdays
- Availability by email (24/7): securedata@epipharm.com Telephone/Messages: 613.549.6666 e.3339
- Emergency/Urgent SMS: 613.453.0036

Reminder: It is the responsibility of the pharmacists and pharmacy technicians at each site to regularly review your inventory and reorder supplies in a timely manner.

- Please Remember: Urgent reorders and shipments required in less than 5 days can't be guaranteed due to customs / shipment delays.
- Start-Up Supply Shipment: The standard initial shipment of IP contains 4 boxes of 84 packets (336) of Active (l-glutamine) 5gm packets (NutreStore®) and 2 bags of 150 (300) Placebo (maltodextrin). In general terms the footprint of this shipment is similar to 6 shoeboxes.

Important Reminder:

Please ensure that each of your pharmacy staff members involved in RE-ENERGIZE has been properly trained and added to the delegation and training logs.

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