THE RE-*ENERGIZE* STUDY

THE RE-ENERGIZE RAG

RE-ENERGIZE DOMINICAN REPUBLIC TEAM

Dr. Heyland and our Dominican Republic Partners

at the

RE-ENERGIZE Training in Dominican Republic May-2017

Volume # 7 **July 2017**

First Patient enrolled in Europe

Congratulations to the team at

Hospital Universitario La Fe, Valencia, Spain!

Great work being the 1st activated site in Europe and the 1st European site to enroll a patient.

June 2017 Enrollment

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Goal: 1 Patient/Site/Month

ACTIVATED SITES and ENROLLMENTS

INSTITUTION and Location	June 2017	Randomized to date
UT Southwestern Medical Center, Dallas, TX	4	4
Ross Tilley Burn Centre, Sunnybrook, Toronto, ON*	3	26
Arizona Burn Center - U of Arizona, Phoenix, AZ	2	4
University of Colorado Denver, Denver, CO *	2	33
Hospital Universitario La Fe, Valencia, Spain	2	2
Hôpital l'Enfant-Jésus, Quebec, QC	1	17
University of Iowa, Iowa City, IA *	1	63
Wake Forest University Health Sciences, Winston-Salem, NC	1	9
Harborview Medical Center, Seattle, WA	1	13
AHN West Penn Burn Center, Pittsburgh, PA	1	10
Oregon Burn Center, Portland, OR*	1	25
University of Nebraska Medical Center, Omaha, NE	1	2
Akron Children's Hospital, Akron, OH	1	4
Mercy Hospital St. Louis, St. Louis, MO*		43
Columbia - St. Mary's Hospital, Milwaukee, WI		6
MedStar Health Research Institute, Washington, D.C.		3
University of Southern California, Los Angeles, CA		8
CHI Health St. Elizabeth, Lincoln, NE		2
Bridgeport Hospital, Bridgeport, CT		2
Hotel-Dieu de Montreal – CHUM, Montreal, QC		2
Joseph M Still RF, Doctors Hospital, Augusta, GA *		51
UF Health at Shands Hospital, Gainesville, FL		1
Hamilton General Hospital, Hamilton, ON		1
University of Texas Health Science Centre, Houston, TX		1
JBSA Fort Sam Houston, San Antonio, TX		1
Foothills Medical Centre, Calgary, AB		3
The Ohio State University Medical Center, Columbus, OH		3
Tampa General Hospital/USF, Tampa, FL		1
Firefighters' Regional Burn Center, Memphis, TN*		15
University of California-Davis, Sacramento, CA		
Pilot Study additional enrollments*		11
*(pilot + definitive)TOTAL	21	366

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FAQ Corner

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

Question: Do we record a surgical dressing change, performed without debridement or grafting, as a burn related operative procedure?

Answer: For purposes of this study, we do not consider a dressing change, even if performed under anesthesia, a 'burn related operative procedure'.

Question: At our site, the standard nutritional feed is prescribed and started before the dietician completes the nutritional assessment for the patient. Do we record the standard feed prescription in REDCap as the initial prescription, or wait and enter the prescription made by the dietician as the initial prescription?

Answer: Please enter the standard feed prescription in REDCap as the baseline prescription. After the dietician assesses the patient and determines the nutritional requirements of the patient, enter the new prescription in REDCap as a prescription change.

We are evaluating both the time from admission to start of nutrition and the adequacy of nutrition delivery. Recording the standard prescription as the baseline, will ensure the start of nutrition delivery and the nutritional adequacy is based on the prescription in place at the time the nutrition is being delivered. It is not accurate to look at adequacy based on a prescription that was made after the nutrition delivery occurred.

Question: We are not able to contact a patient or next of kin, but we were able to verify the discharge date from our hospital, should I record this date in REDCap as "Survival Date"?

Answer: If discharge from your facility is the last date the patient was known to be alive, yes that is the date you would enter in that field. Please use every resource possible to obtain the 6 month Follow-up Assessments. Remember to call the patient and/or alternate contact at different times of the day and on different days. Reach out to the family physician to find out if the patient has been into the office, check medical records within your facility/network, search the internet for public records with your patient mentioned.

Question: Is lactulose considered a motility agent for data collection purposes for this study?

Answer: Lactulose is not considered a motility agent for this study.

Question: Is it a protocol violation if the patient receives the study product for more than 7 days after the last grafting procedure?

Answer: No, it is not a protocol violation for the patient to receive the study medication for more than 7 days after the last graft.
Patients should receive the study medication for 7 days or more ($\geq$7 days) post last graft, until the burn surgeon is certain the patient will not require any additional grafting operations. Once the study medication is stopped, continue to collect study data for 3 more days. If the patient is discharged form the ACU/burn unit or is still receiving grafts at 90 days after ACU admission, the study medication should be stopped.

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IMPORTANT NOTES

Overall

- Screening and enrollments are steadily increasing! Thank you each for your hard work to keep this study moving forward.

Reminders

- **<u>Enter ALL patients who meet the Inclusion Criteria into the CRS</u>:**
    - i. **Randomized patients:** meet inclusion criteria, do not meet any exclusion criteria and consent is obtained.
    - ii. **Eligible but not Randomized patients:** meet inclusion criteria, do not meet any exclusion criteria but consent is **not** obtained.
    - iii. **Not Eligible patients:** meet inclusion criteria and also meet at least one exclusion criteria.

Enter your screened patients into the CRS before the end of each month so they show up on the monthly report.

CRS and REDCap

- When using the **password reset function** for the CRS or REDCap, if you do not receive the reset email within 15 minutes of submitting the request, please call the Project Lead or Project Assistant.

Protocol Amendment (27-March-2017)

- Please work to get approval of the amended protocol so you can begin enrolling patients per the revised Inclusion Criteria

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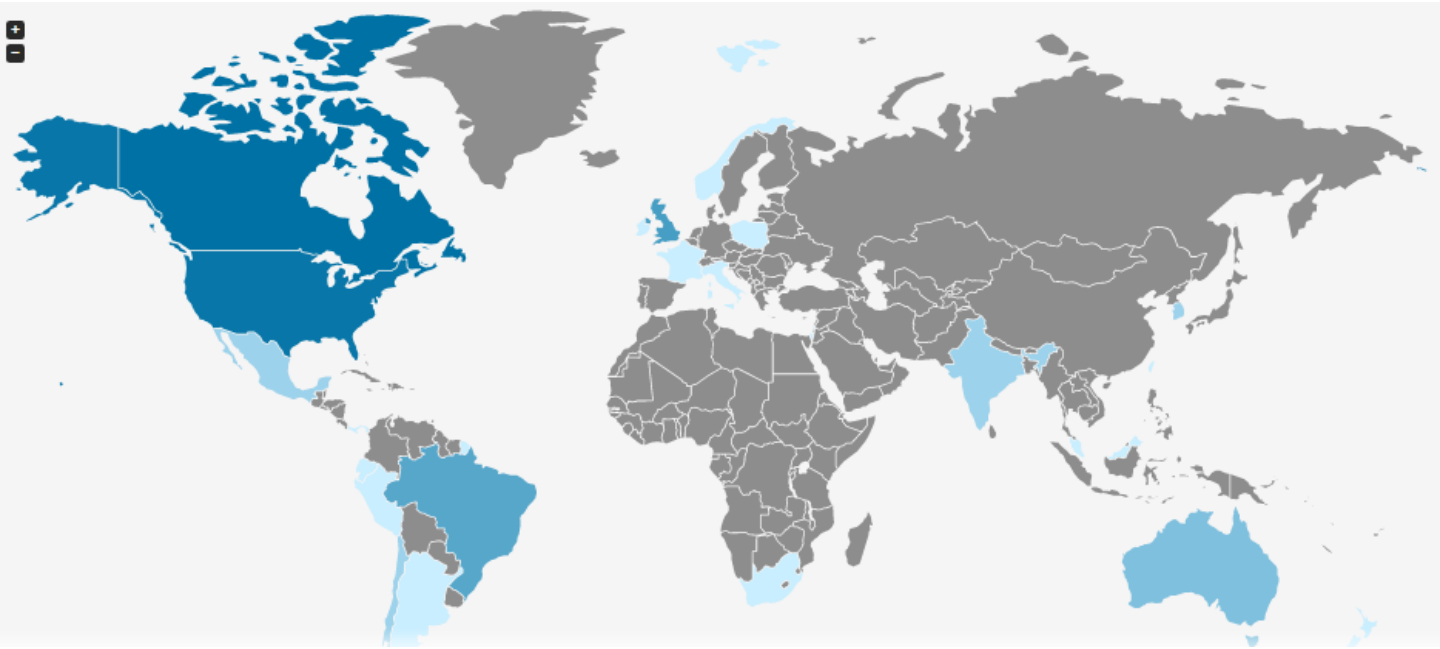
Studies pre-approved for co-enrollment:

- EEX: MRCT, efficacy of early in-patient exercise in improving recovery of children and adults from burns
- EpiFix or EpiBurn: Dehydrated Human Amnion Chorion Membrane (dHACM)
- Porcine Xenograft or Microbial cellulose in the treatment of partial thickness burns
- Antibiotic Concentration in Critical ill ICU patients in Sweden
- Propanolol
- Prospective Evaluation of the ReCell® Autologous Cell Harvesting Device For Specific Compassionate Use Cases
- Tetrodotoxin studies
- Vitamin D Supplementation in Burned Patients

Pharmacy Reminder: Order product well in advance to allow time for delays when the product is in transit! We cannot guarantee short notice orders will be delivered in a timely manner.

Contact Information:	Email	Telephone
Maureen Dansereau, Project Lead	danserem@kgh.kari.net	613-549-6666 ext. 6686 613-888-4320
Eirini Kasapidou, European Project Leader	eirinikasap@auth.gr	+30 2310 999 134
Alfonso Ortiz, Project Assistant	ortizrla@KGH.KARI.NET	613-549-6666 ext. 4146
Chris Gray, Central Pharmacy Manager	chris.gray@epipharm.com	613-453-0036

Real-Time-CCN-Visitor-Map



Dear Colleagues, for more RE-ENERGIZE study tools please visit our website

http://www.criticalcarenutrition.com/

RE-EN Study Tools:

- Manuals and Case Reports Forms
- Tools and Logs
- Training Modules
- Questionnaires