The RE-ENERGIZE Rag

Volume 12, March 2018

The RE-ENERGIZE protocol has been published

We are excited to announce the publication of this trial protocol in the *Journal of Scars, Burns & Healing*. This will be the first large international multi-centre RCT examining the effects of glutamine in burn patients and the largest study of burn-injured patients ever.

In an accompanying editorial, Dr Dheansa and Dr O'Boyle from Queen Victoria Hospital and Nottingham University Hospitals in the UK have published an article entitled "*Re-energising burns research: insights from the largest randomised trial ever undertaken in burn care*". They endorsed and applauded our efforts and both authors conclude that our burn community must perform international high quality research collaborations similar to that performed daily by you and all our RE-ENERGIZE colleagues around the world.

FREE FULL ARTICLE: http://journals.sagepub.com/doi/full/10.1177/2059513117745241

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What is new?

Activation of Latin American sites. The Hospital Dr. Luis E. Aybar in Santo Domingo, Dominican Republic, lead by Dra Victoria Soñé was our first site in Latin America activated. Dr. Heyland recently visited and trained 2 sites in Mexico; Dr Miguel Ibarra leads the Burn Unit at the Hospital Civil Fray Antonio, while Dr Mario Martinez leads the team at the Hospital Central "Dr. Ignacio Morones Prieto", in Guadalajara and San Luis Potosi-Mexico, respectively.

January 2018: Dr. Heyland conducting training at our sites in Mexico

From left to right: Dr Ibarra, Dr Heyland, Dra Aguirre, Briseño RD & Navarro, RD.

From left to right: Dr Martinez, Dra Mercedes, Dr Heyland, Dra Cantu, Dr Hurtado & Dr Romero.

YOU'RE INVITED!

What: **The RE-ENERGIZE Study Site Investigators' Meeting**

When: **Tuesday, April 10th 2018 / 12:00 PM - 1:30 PM**

Lunch will be provided!

Where: **Continental Ballroom C, Hilton Chicago**

This meeting is being held in in conjunction with the ABA 50th Annual Meeting.

Goal: 1 Patient/Site/Month	ACTIVATED SITES and ENROLLMENTS			
INSTITUTION and Location	**17-Dec**	**18-Jan**	**18-Feb**	**Randomized To Date**
Tampa General Hospital-USF	1		2	5
University of Iowa* (47)			2	66
St Helens & Knowsley Teaching Hospitals		2	1	3
Hotel-Dieu de Montreal - CHUM	1	1	1	7
RWTH Aachen University, Aachen		1	1	6
Queen Elizabeth Hospital Birmingham		1	1	5
Arizona Burn Center - U of Arizona			1	8
MedStar Health Research Institute			1	6
Newcastle upon Tyne Hospitals			1	1
Joseph M Still RF, Doctors Hospital* (37)	1	3		57
Mercy Hospital St. Louis* (31)		2		46
JBSA Fort Sam Houston		2		4
Chelsea and Westminster Hospital		2		3
Uppsala University Hospital		2		3
Hamilton General Hospital	1	1		8
University of Colorado Denver* (26)		1		38
Oregon Burn Center* (21)		1		35
University of Southern California		1		9
Akron Children's Hospital		1		5
Ross Tilley Burn Centre, Sunnybrook* (13)	1			31
AHN West Penn Burn Center	1			14
UT Southwestern Medical Center	1			11
University of California, Davis	1			5
Hospital Universitario La Fe, Valencia	1			5
Ghent University Hospital	1			2
Hopital l'Enfant-Jésus				22
Harborview Medical Center - Seattle				17
Pilot Study additional enrollments*				15
Firefighters' Regional Burn Center TN * (14)				14
Columbia - St. Mary's Hospital				10
Wake Forest University Health Sciences				9
Foothills Hospital				6
Bridgeport Hospital				5
University of Texas Health Science Centre				3
The Ohio State University Medical Center				3
CHI Health St. Elizabeth				2
University of Nebraska				2
University Hospital of Liège				2
UF Health at Shands Hospital				1
Instituto Tecnologico de Santo Domingo				0
Hospital Civil F. Antonio Alcalde, GDL				0
*(pilot + definitive)TOTAL	10	21	11	494

IMPORTANT NOTES

Benchmark Report

Sites with a minimum of 5 patients that have completed the treatment phase of the study (patients must have clean and complete data) will receive a benchmarked report some time before ABA meeting.

What can be found in the benchmark report?

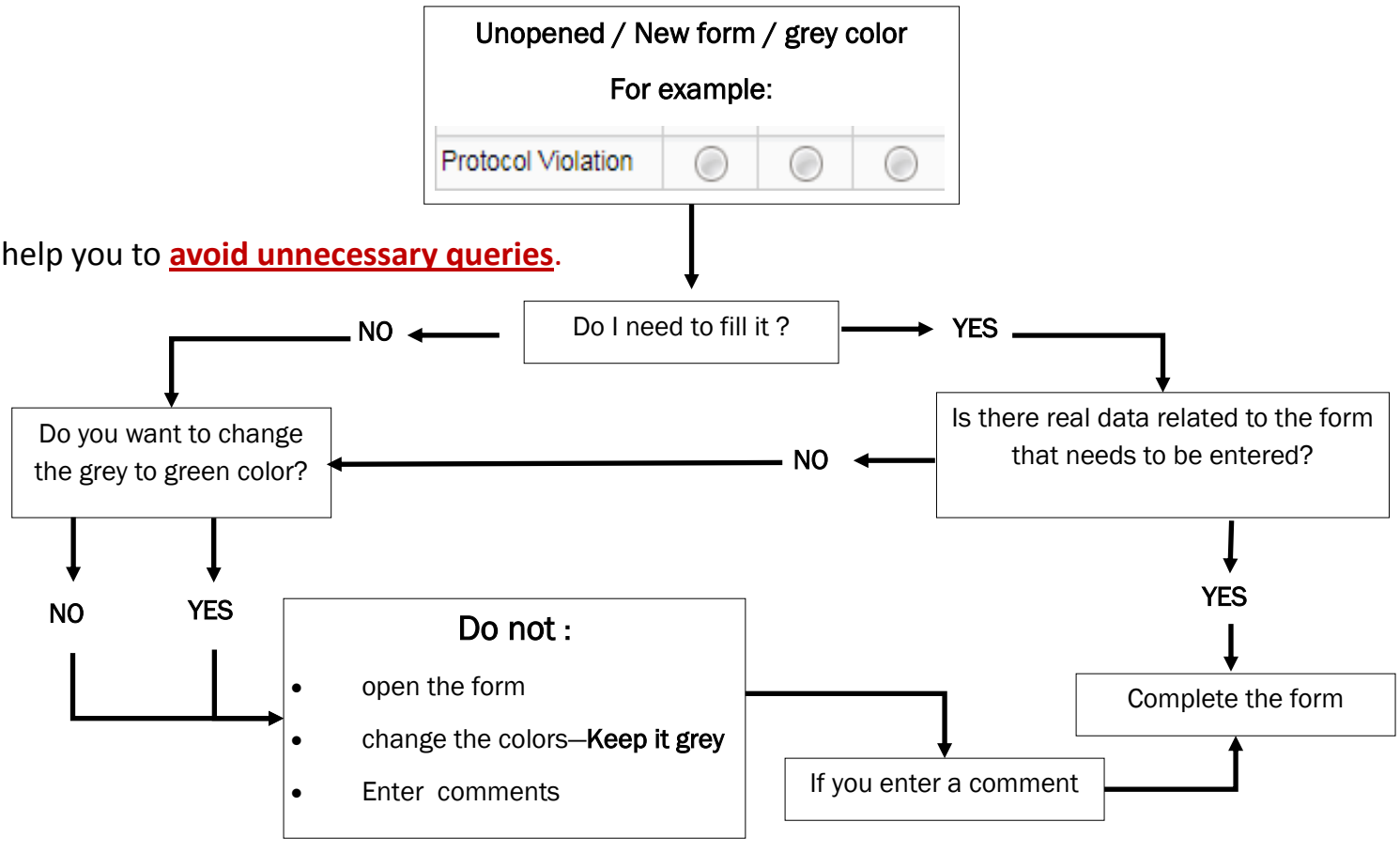
The report will provide answers to questions such as:

- Is data being entered in a timely manner?
- Do we have the right patients?
- Is the intervention being applied optimally?
- Are patients being fed appropriately?
- What is your compliance with the study protocol?

This site report provides a look into how you are doing at the site ('Site') level and will allow you to compare your progress with data from all participating sites ('All'). Please have a look at your strengths and weaknesses and make a plan to improve the quality of your work.

Are you having excessive queries from your enrolled patients?

A query will be automatically generated once you open a form in REDCap, therefore, If you do not open a form without reason, you will not have unnecessary-queries. Below is an algorithm that will help you to **avoid unnecessary queries**.



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

FAQ

Question:
Now that our patient is more than 7 days post last graft, and the study treatment has stopped, may we add glutamine to the patient's normal enteral feeding?

Answer:
No. Once the patient is randomized, do not give glutamine or arginine enriched formulas (>6g/L) until after the 6 month Survival Assessment has been obtained and questionnaires completed. The Primary Outcome of the study is 6 Month Mortality. Giving glutamine or arginine enriched products before the completion of the 6 month follow-up data would contaminate the study results.

Question:
We have a potential patient with ~ 30% TBSA mixed depth burns, including 15% that is 2nd-3rd degree, so patient fits the criteria for the study. We plan to use enzymatic debridement and will not know right away if the patient will need a skin graft. The decision to graft or not may not be made for a couple of weeks. Should we approach for consent anyway or exclude the patient from the study?

Answer:
If you were not using an enzymatic debridement strategy, would you be planning to graft the patient? If the answer is yes, go ahead and enroll the patient. As long as there is an 'intention to graft' the patient is eligible.

CERU contact Info

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RE-ENERGIZE SPECIAL POINTS OF INTEREST:

- **Total patients randomized: 494 / 2700**
- **8 Active Sites in Europe**
- **2 Active sites in Latin America**
- **40 active sites worldwide**
- **10 Latin sites in Start-up**