AUG 11, 2022

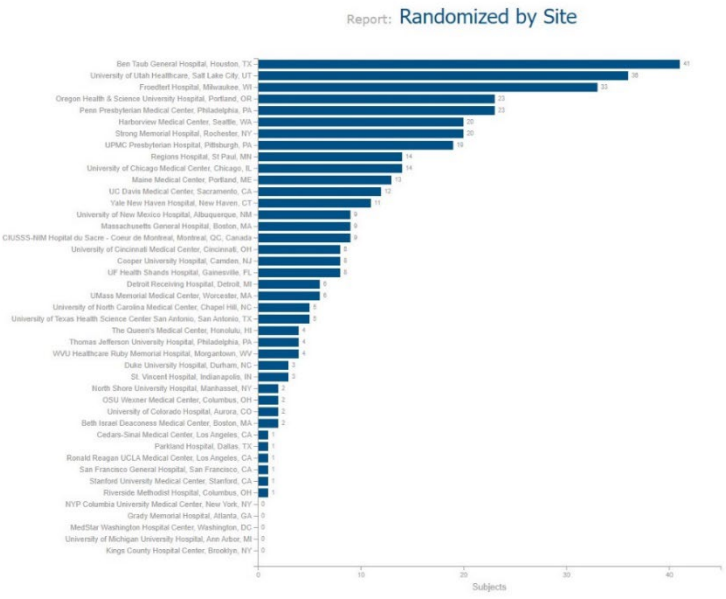
BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

385 participants enrolled! Congratulations and thank you!

There are 43 sites open for enrollment

38 - Sites have enrolled at least one subject

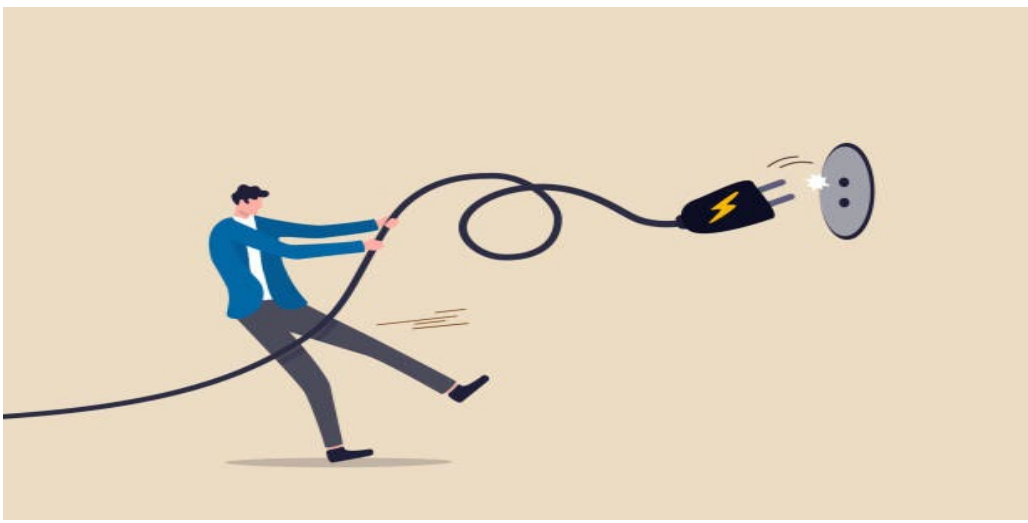


Newsflash from WebDCU!!

BOOST 3 Moberg data upload to the cloud has changed to a new website. The new URL to use for uploading Moberg data is- https://boost3.bedsideinfo.org/. Try to upload within a week of ending monitoring the participant.

Moberg CarePath CNS

Don't do it!!! NO NO NO NO!!!!



Time to end a session? There is a proper way. Don't pull the plug! Shut it down first.

When Discontinuing a Monitoring Session, **DO NOT unplug the Moberg CNS monitor** until the system is properly shut down! See below for detailed instructions:

VII. END A MONITORING SESSION

Stop Monitoring: When ready to end the monitoring session, close CNS Reader/CarePath, then *Switch Desktop* to the CNS Monitor. On the Protocol Step Bar of the CNS Monitor, press *Stop Monitoring*. To end monitoring and discharge the patient, press *Discharge Patient*. A dialog will prompt the user to confirm the intent to discharge the patient. Once confirmed, the monitor will address any changes made to the monitoring protocol (including changes to display screens, etc.). If changes were made, a dialog box will ask how to handle those changes.

Archiving Patient Data: Upon discharging the patient, the CNS Monitor offers options for managing the collected patient data. To create a permanent record of patient data on external media, press *Archive Now*. To keep the session on the monitor until you are ready to archive, press *Archive Later*.

- Archive Now: Pressing *Archive Now* gives the user the option to archive collected data to an external USB drive. The user will be instructed to insert the USB drive. Once the USB drive has been verified, archiving will begin and a moving status bar will indicate the progress of archiving. A dialog box will appear once archiving is complete.
- Archive Later: Pressing *Archive Later* saves the patient file on the CNS Monitor for review or archiving at a later time. Saved files can be found by pressing *Manage Data Files* on the CNS opening/start-up screen. Selecting the desired patient provides information about the file and allows the user to *Review*, *Archive*, or *Erase* data.

Note: It is recommended to password protect the *Erase* option to avoid accidental deletion by non-study personnel. Password protection settings can be changed when in the opening/start-up screen by pressing *System Configuration* and then selecting *System Administration*. Enter the administrator password (default: *moberg*) and press *Password Setup* to select the desired level of protection.

Answers to a Frequently Asked Questions

Question: Do we keep the Moberg connected if we leave the monitors in past the 5-day mark?

Answer: It is not a requirement to keep the Moberg connected, but it is encouraged as long as the monitors are in place in order to continue to collect data. No further CRF entry is required past the first 120 hours. No further FiO2 challenges beyond standard practice are required. NEVER unblind a participant who was in the blinded arm, even after the 120 hours are complete.

Question: Can we use an EVD to collect ICP values?

Answer: Yes with these caveats: An EVD can be used as the ICP monitor. If an EVD is placed, it is to be zeroed at the tragus. The ICP readings may be from the EVD monitor only if continuous readings can be recorded. Interruptions in ICP measurements are allowed for brief intervals (less than or equal to 5 minutes) for intermittent CSF drainage from the EVD. If CSF drainage from the EVD is continuous, ICP readings must come from a parenchymal ICP monitor in order to obtain continuous ICP readings.

Question: How long do we collect AEs and SAEs?

Answer: All adverse events (AEs) occurring within 5 days of treatment or discharge, whichever comes first, and all serious adverse events occurring during study participation will be documented on the AE case report form.

ATTENTION!!!!!!!!!

Reminders from the Study Monitors

Some CRF completion reminders:

1) **ICF log CRF-**First entry to log should capture whether or not an LAR or another family member was identified prior to randomization; e.g.,
   - No LAR present, or
   - LAR present and consent was obtained prior to randomization, or
   - LAR was reached by telephone and told about the study.

   We ask that you initiate this CRF as soon as possible from time of randomization.
2) **The EOS CRF**-Though this CRF does not show up as Missing in the Alerts tab, please remember to submit this CRF once the participant has completed/exited the study.
3) **AE CRF**-When reporting an SAE, please be sure to include in the narrative of Q12, the detail of initial admission in the format, e.g., "Patient is a/an [age/sex] who had [mechanism of injury] on [date of admission]. He/she suffered from [any details on intracranial and bodily injury]." The medical reviewer is unable to see the other CRFs that report this information and will help him to make a determination.

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BOOST Outcomes

Congratulations to all of our sites for the impressive follow-up rate of 96%!
A couple of reminders:

1) Attempt to obtain multiple contacts for each participant.
2) If you have been unable reach your participant or LAR for a couple of months, review the medical record for other potential contacts. Social work notes from the ED or therapy notes are often good places to look.
3) Review the medical record for any upcoming appointments.

For any questions regarding the monthly calls, outcome examiner certification, or the 180-day visit please contact Kim Boase at kboase@uw.edu or call 206-849-4291.

Important Contacts for help

- For immediate emergency assistance (enrollment, clinical, protocol, adverse events, etc.), please use the 24/7 BOOST 3 Principal Investigator Hotline: 855-4-BOOST3 (855-426 -6783).
- For urgent WebDCU randomization questions call: 1-866-450-2016
  WebDCU: Zeke Lowell (lowelle@musc.edu) or Sara Butler (butlers@musc.edu).
- Questions about BOOST 3? Send to boost-contact@umich.edu and/or boost-trainers@umich.edu

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BIO-BOOST

Biomarkers in the Brain Oxygen Optimization in Severe Traumatic Brain Injury Trial

A multicenter, observational study examining the longitudinal changes of brain physiologic parameters in target molecular biomarker levels (serum, plasma, CSF, DNA and RNA)

78 enrollments with 11 sites enrolling

PIs: Frederick Korley, MD, PhD and Ramon Diaz-Arrastia, MD, PhD

AUG 11, 2022

Current Approved Sites	Trained	Enrolled
Oregon Health and Sciences University	Yes	14
Baylor College of Medicine/Ben Taub Hospital	Yes	24
University of Pittsburgh Medical Center	Yes	11
Maine Medical Center	Yes	7
University of Cincinnati	Yes	3
Penn Presbyterian Medical Center	Yes	5
Utah	Yes	1
Strong Memorial Hospital	Yes	2
UC Davis	Yes	4
University of Florida, Shands	Yes	3
University of Chicago	Yes	4

Electro-BOOST

For ELECTROBOOST, there were no new enrollments. The total remains at 15.

Total enrolled subjects: 15

Sites with Enrollments: 4

Active Sites: 4

- As a reminder, if the subject will be participating in Electro-BOOST, please complete F311 on the Baseline visit before posting any other visits to the subject CRF binder.