April 20, 2023

BOOST-3 Bulletin

Brain Oxygen Optimization in Severe TBI Trial Newsletter

474 participants enrolled! Congratulations and thank you!

There are 43 sites open for enrollment

38 - Sites have enrolled at least one subject

Licox PbtO2 Monitor Production Interruption

This is an important notice for sites that use the Integra Licox PbtO2 monitor. Several sites are completely out of probes, impacting enrollment for the BOOST study. Integra recently moved its manufacturing headquarters and announced an interruption in production of probes as a result. They plan to be up and running very soon and are prioritizing the BOOST sites that use Licox to monitor PbtO2.

Neuro-monitoring devices not allowed

Add-on neuro-monitoring devices that are **not** acceptable include: NIRS, Jugular bulb saturation monitors, cerebral oximetry monitors, cerebral blood flow monitors, continuous transcranial doppler (TCD) monitoring, or quantitative EEG algorithms specific for cerebral hypoxia, as these can provide indirect information regarding brain tissue oxygenation. The occasional use of TCDs to confirm suspected vasospasm or assess autoregulation is allowed. The use of quantitative EEG for detection of seizures is acceptable.

Words of Wisdom from WebDCU

There were a few patients who were ‘running’ at the time of Daylight Saving Time change over. We have been instructing sites to leave the Moberg CNS

running without changing the time whenever there is a Daylight Saving Time change, since changing the time would make it look like a 'missing hour' in the data and would be more confusing in data interpretation. The data managers are working on compensating for and fixing this.

SCREENING Reports----- OOPS!!

Several sites have no screen failures entered into WebDCU for the last several months or years. If you are screening patients, you must enter the failures (or successes) into WebDCU. Otherwise, it appears that your site is no longer screening patients.

Refer to the MOP Section 3.4 "Screening Report"

Screen results (failure or enrollment) should be entered into WebDCU within 5 days of screening.

The rule for Screening a patient is:

Screening should be inclusive of all patients admitted to an ICU with a TBI and placement of an intracranial monitoring device. Inclusion of patients on the screening log is independent of whether the study team was contacted on the day of service or not.

MOBERG Manifests

1. Reminder:

When Discontinuing a Monitoring Session, **DO NOT unplug the Moberg CNS monitor** until the system is properly **shut down**!

2. If you are having problems with the Moberg, be sure to first check your connections and wall plug.

3. New Moberg Tracking Feature Being Added to WebDCU

We are now able to track information about your device in WebDCU. This will make it easier to keep track of your Moberg CNS device and locate the shipping address for your site.

Please anticipate an email asking you to review and confirm this information in the READINESS REPORT section of WebDCU.

Frequently Asked Questions

FiO2 Challenges

Q: How can you do an FiO2 challenge if the ventilator is already set at 100% FiO2?

A: Consider performing a blood gas to determine the safety of lowering the FiO2 temporarily for the FiO2 challenge.

- If lowering FiO2 below 100% results in lowering PbtO2 by >5 mmHg, raise FiO2 to 100% again. If that results in increase in PbtO2 by at least 5 mmHg again, that is considered passing the FiO2 challenge.
- If it is not feasible to lower the FiO2, consider doing a MAP or CO2 challenge **to determine if that raises the PbtO2**. **A MAP or CO2 challenge should not be performed in subjects in the ICP-only group.**

Study Trainers' Site Assignments

BOOST 3 Trainer	**Site Assignments**	**2023**
Ava Puccio puccAM@upmc.edu	**Anita Fetzick** fetzal@upmc.edu	**Carol Moore** carol.moore.ctr@usuhs.edu
Froedtert	OHSU Oregon	Baylor- Ben Taub
University of Utah Healthcare	Strong Memorial	University of Pennsylvania
University of Chicago Medical Center	Regions	Pittsburgh UPMC
UC Davis	Maine	U Washington Harborview
Montreal (Sacre Coeur)	Mass Gen	UT Health Sciences-San Antonio
Yale New Haven Hospital, New Haven	Univ. of Florida Health Shands Hospital	U of New Mexico –
Detroit Receiving/Wayne State	UMass	Cooper (NJ)
Cincinnati	Stanford	Thomas Jefferson
Queen's Medical Center, Honolulu	Univ. of North Carolina	UTSW/Parkland
WVU Ruby Memorial Hospital, Morgantown	Duke	U Michigan Ann Arbor
North Shore Univ. Hospital, Manhasset	NYP Columbia Univ. Medical Center	Cedars Sinai, LA
IU Health Methodist (St Vincent) Hospital, Indianapolis	Beth Israel Deaconess Medical Center	Grady Memorial Hospital, Atlanta GA (Emory)
OSU Wexner Columbus, OH		Univ. of Maryland Medical Center
St. Michaels Hospital, Toronto		Jacobi
Henry Ford		VCU (Richmond)
Foothills		UCLA

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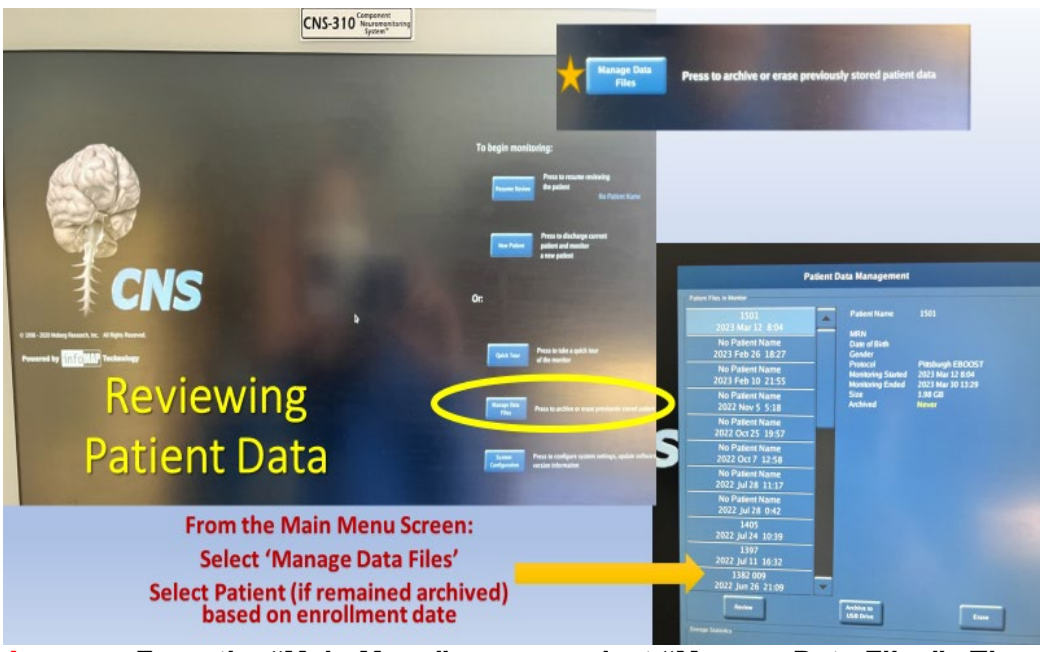
Question: How can I look back and retrieve participant data in Carepath???



Answer: From the "Main Menu" screen, select "Manage Data Files". Then select "Patient" (if the patient's data remained archived) based on the enrollment date of the patient. That will take you to the patient's data.

BOOST Outcomes

Congratulations to all of our sites for the impressive follow-up rate of 96%!
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.

The range for the 180-day outcome evaluation is day 150 through day 210. Often the participant is already in range at the time of the 5-month call. Use that opportunity to schedule the 180-day visit.
If you get the sense that interest in the study is waning or the monthly calls are becoming burdensome, consider asking the participant or family member if an interview with the central examiner could be completed over the phone. Suggest a time early in the window.
If the participant is in range and further participation is questionable, ask the participant or family member if they would mind answering just a few more questions with another team member. Call Kim Boase [206-849-4291] and we will try to get the 6-month interview completed the same day.

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)

120 enrollments with 12 sites enrolling

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

April 20, 2023

Current Approved Sites	Enrolled
Baylor College of Medicine/Ben Taub Hospital	34
Oregon Health and Sciences University	24
University of Pittsburgh Medical Center	17
Strong Memorial Hospital	9
Maine Medical Center	9
University of Chicago	8
Penn Presbyterian Medical Center	6
UC Davis	5
University of Florida, Shands	3
University of Cincinnati	3
Utah	1
Detroit Receiving	1
Total enrollments	120

Electro-BOOST

For ELECTROBOOST the total has risen from 15 to 26 since our last newsletter. Congratulations Electro-BOOST sites!

Total enrolled subjects: 26

Sites with Enrollments: 5

Active Sites: Six new sites since the last newsletter for a total of 10.

- 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.