NOV 28, 2021

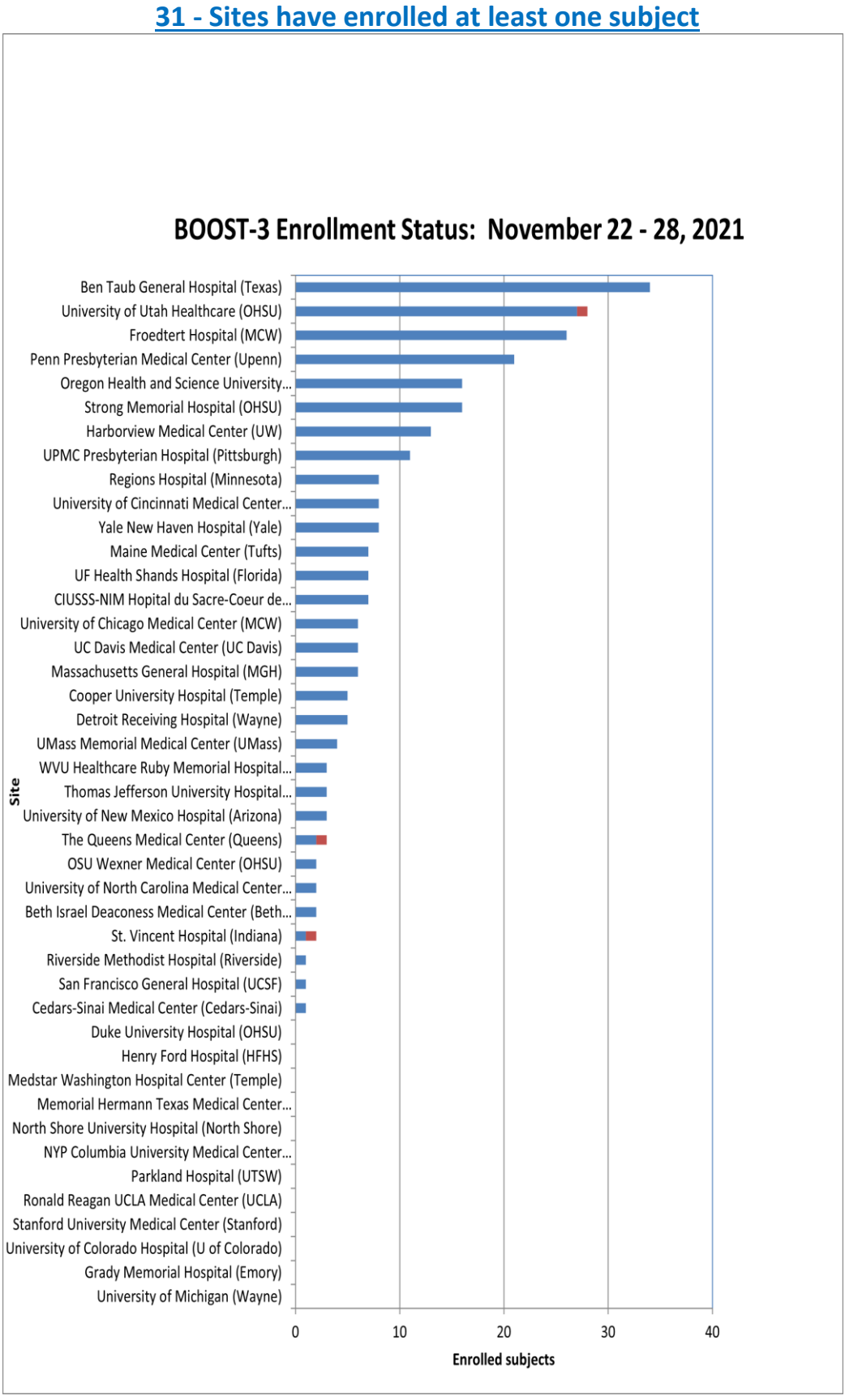
BOOST-3 Bulletin

Brain **O**xygen **O**ptimization in **S**evere **T**BI Trial Newsletter

265 participants enrolled! Congratulations and thank you!

There are 43 sites open for enrollment

31 - Sites have enrolled at least one subject



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ANSWERS TO A FREQUENTLY ASKED QUESTIONS

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

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 FiO2 challenges beyond standard practice are required. NEVER unblind a participant who was in the blinded arm, even after the 120 hours are complete.

Follow-Up payments to participants: $$$$$

BOOST Outcomes: There has been some confusion surrounding BOOST sites' ability to pay participants for the 180-day outcome evaluation. Although it was never the intention that sites could not offer compensation to participants, Advarra has clarified this language for all Siren studies including the BOOST trial.

BOOST sites **can** offer payment as an incentive. Several sites are offering $100 but each can make their own determination as they see fit. Currently BOOST has a 96% retention rate. Amazing work through challenging times. Congratulations!
If you have questions relating to the monthly calls, local examiner certification, or the 180-day visit, please email Kim Boase at kboase@uw.edu or call 206-849-4291.

BOOST senior management proposes the following changes to the protocol: (These are not yet approved by the cIRB.)

1) Section 4.1: Inclusion Criteria. The decision to place monitors is made within 6 hours of arrival at the enrolling hospital and within 12 hours from injury. If unable to actually place the monitors for some reason, the site must call the BOOST PI hotline for approval extending the 6-hour rule, and the site must document in Comment/Issues in WebDCU to avoid violations.
2) Section 4.2: Exclusion Criteria. Bilaterally absent pupillary response in the absence of paralytic medication with GCS = 3.
3) Refractory hypotension (SBP < 90 mmHg for two consecutive readings at least 15 minutes apart any time prior to randomization).
4) PaO2/FiO2 ratio <150 and ICU chart the ABG, if done.)

Reminders: ATTENTION!!!!!!!!!

Instructions for updating the Reader/Carepath license were emailed to all sites Nov. 12. The current license will expire Dec. 31, 2021, and Carepath will stop working if not updated by that date.

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 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)

28 enrollments with 8 sites enrolling

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

Current Approved Sites	Trained	Enrolled
Oregon Health and Sciences University	Yes	7
Baylor College of Medicine/Ben Taub Hospital	Yes	9
University of Pittsburgh Medical Center	Yes	4
Maine Medical Center	Yes	2
Temple University	No	-
University of Cincinnati	Yes	2
Penn Presbyterian Medical Center	Yes	1
Detroit Receiving Hospital	No	-
University of Florida/Shands Hospital	Yes	2
Utah	No	-
Strong Memorial Hospital	Yes	1