



# QUARTERLY UPDATE

## 2023 QUARTER 4

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### OPERATIONS MEMOS

Four new Operations Memos have been sent since the last Quarterly Update.

- ▶ **T05 #28, distributed 7/19/23**  
notifying sites that the PACT DSMB issued a directive that study enrollment was to be stopped immediately and to prepare to initiate study close-out procedures
- ▶ **T06 #1, distributed 8/10/23**  
notifying sites that Protocol V7.0 and consent templates were available
- ▶ **T06 #2, distributed 9/13/23**  
notifying sites that Protocol V8.0 and consent templates were available
- ▶ **LITES #3, distributed 9/22/23**  
notifying all LITES users of downtime for LITES website and CriSP MATRIX database
- ▶ **T05 #29, distributed 9/29/23**  
notifying sites of a slight wording update to CLO form

As with all Operations Memos, please ensure that they have been read by anyone who needs the information and that copies are stored with the MOP and/or Regulatory Binder. Operations Memos can be found in the Documents Library area of the LITES website.

## TASK ORDER 001 UPDATE

We truly appreciate all the time and dedication each site has exerted towards this project, and we look forward to collaborating with you on papers and presentations! Please use this link to submit your Publication Requests: <https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>

The coordinating center continues to prioritize manuscript proposals submitted by Co-Investigators.

As the DCC continues to curate and analyze the data, we ask that IRBs remain open at sites until closure memos are issued.

Congratulations to UT Houston for completing their Potentially Preventable Mortality adjudications! All Cause of Death and Potentially Preventable Mortality determinations are complete!

## TASK ORDER 002 / SWAT UPDATE

The Shock, Whole Blood, and Assessment of TBI (SWAT) study's primary publication, previously available online, was printed in the August 2023 issue of the Journal of the American College of Surgeons.

With the primary manuscript behind us, data analysis and manuscript preparation continue for our secondary analyses. The CCC and DCC are working especially hard on two topics at the moment. The first is a manuscript on TBI biomarkers in our patients – for that, we are doing additional analyses of patient samples. The second is a paper discussing the use of whole blood for resuscitation of women of childbearing potential. And there's more to come after those two! Thank you all for your work collecting samples and building a strong dataset that can support these ongoing efforts.

## TASK ORDER 004 / CriSP UPDATE

### CriSP-HS

Total enrollment goal for the study was reached on Sept 7th! The DCC and CCC want to extend our gratitude for the outstanding work of all of our recruiting sites; because of their efforts, recruitment was finished ahead of schedule. Special shout out to the UMMC team for having the highest overall recruitment - honorable mention goes to UCSF. The interim DSMB meeting was held on August 22nd, and the board voted to continue both CriSP studies as planned; the formal continuation letter will be distributed upon receipt. The deadline to finalize all data forms (complete entry and clear all errors/edits) is November 1st. All-site meetings continue to be held on the 2nd Wednesday of every month at 12:00 EST. The CCC would appreciate that each site make an attempt to have at least one member of the team available for each meeting. Final enrollment totals are below:

Site	# Enrolled
UMMC	82
UCSF	52
UT Houston	47
Baylor	19
<b>TOTAL</b>	<b>200</b>

### CriSP-TBI

Cold Stored Platelet Early Intervention – Traumatic Brain Injury (TBI) (CriSP-TBI) trial, is an open label, single center, randomized trial designed to determine the feasibility, efficacy and safety of urgent release cold stored platelets in blunt injured patients with traumatic brain injury requiring platelet transfusion. Over the course of two years, 100 subjects will be enrolled by The University of Pittsburgh. Enrollment is on target with 93 subjects randomized and enrolled since study activation. Completion of enrollment is expected by Q4 of 2023.

## TASK ORDER 005 / PACT UPDATE

### OVERALL PROGRESS

We are at 1301 enrollments out of the 2009 for the study. On July 19th the DSMB asked us to stop all enrollments during a safety review; on 8/17/23 they lifted the suspension to allow study enrollments to resume. At the time of this publication, we are still awaiting final regulatory approvals to resume the study.

Annual OHRO renewal (formerly known as HRPO) occurred on September 14, 2023. All sites can access this annual renewal correspondence in Florence under the PACT files.

Monitoring Committee/All-Site calls continue on the 2nd Friday of each month at 10am (ET). The next calls will be on Oct 13th, Nov 10th, and Dec 8th. This once-a-month call provides all the details of how the study is progressing and distributes the Study Monitoring Committee tables for all sites to follow on our progress. It also provides updates on the re-opening process.

During the enrollment hiatus, we are asking that that all sites continue to bill LITES monthly for percent effort and all completed subjects. Any subject with complete data entry and without edits on the last day of the month is eligible for payout at the beginning of next corresponding month. We are aiming to have all incomplete data completed and locked by the end of October.

Sites are required to upload all consents and supporting documentation for those enrolled up until July 19th by October 31, 2023.

Thank you to all sites who have amended their contracts to extend to 4/30/2025. This is particularly important given our enrollment delay.

Gaumard Airway Mannequins have been delivered to all participating EMS agencies. Please continue to encourage your EMS service to prepare for the study's resumption and reach out to the project manager if you have any issues keeping your services engaged.

## TASK ORDER 006 / PAIN UPDATE / STUDY SPOTLIGHT

The Prehospital Analgesia Intervention (PAIN) trial is a double-blinded, randomized, EFIC study that compares fentanyl to sub-dissociative ketamine for the treatment of pain in the prehospital setting. We aim to enroll 994 adult trauma patients who are in compensated shock (shock index > 0.9).

LITES sites are partnering with their EMS colleagues for this study! The participating EMS agencies will assess patients for eligibility and treat patients who meet all inclusion and no exclusion criteria with up to two doses of blinded study drug.

Pine Pharmaceuticals is currently compounding the drug for initiation of enrollment.

We will begin enrolling first at the University of Pittsburgh Medical Center (UPMC)-Presbyterian and UPMC-Mercy hospitals in Pittsburgh at the end of October. We anticipate that the second study site in Pittsburgh, Allegheny Health Network, will start enrolling shortly after that.

The Community Consultation and Public Disclosure plan has been completed for the Pittsburgh area sites and is currently being conducted at five other sites: University of Cincinnati Medical Center, Cooper University Hospital, University of California San Diego, University of California San Francisco, and the Medical College of Wisconsin.

Future sites participating in the study include: University of Utah, University of Vermont Medical Center, and Washington University in St. Louis.

Currently, all sites are also reaching out to the EMS agencies who will be collaborating on the study to inform them about the study and start the reliance process. Training slide decks and reminder materials are available to all EMS agencies on the EMS Resource tab on the LITES network website.

Monthly all site calls are held on the first Wednesday of each month at 2pm (EST). The next all-site calls will be October 4th, November 1st and December 6th.

## TASK ORDER 007 / TOWAR UPDATE

Since the last quarterly update, the Louisville site has been activated for enrollment (October 2). UAB is working towards submission to OHRO for DoD approval to commence enrollment (target Q4). The first interim target was met on Sept 27, 2023; the CCC is working on scheduling an interim analysis meeting with the DSMB in mid-December, so data will need to be entered and cleaned for the first 340 enrollments in November (exact deadline to be determined). Enrollment totals across sites are as follows:

Pitt	UW	Vandy	UMMC	UC	UT Hou	Knox	Metro	Lou	UAB	TOTAL
81	61	30	36	18	84	27	5	0	N/A	342

The Clinical and Data Coordinating Centers want to thank the participating sites for their ongoing efforts on the study.

## TASK ORDER 008 / DEEP UPDATE

Enrollment continues for the D S U V I A E a r l y E v a l u a t i o n P a i n (DEEP) study! DEEP is an open-label, prospective, randomized, interventional trial comparing standard pain medication to DSUVIA (*sublingual sufentanil*) for trauma patients with moderate to severe pain in the emergency department.

We've enrolled 120 patients – nearly at our goal of 150 enrollments! The rate of enrollment continues to exceed our expectations. Sending a big thank you to our enrolling partners, investigational pharmacies, and ED staff!



## TASK ORDER 010 / CAVALIER UPDATE

The Calcium and VAsopressin following Injury Early Resuscitation trial (CAVALIER), or Task Order 10, is a double blind, multicenter prehospital and in-hospital randomized trial designed to determine if prehospital calcium, early in-hospital vasopressin, or both improve outcomes in injured patients at risk of hemorrhagic shock.

Community consultation and public disclosure efforts are underway at the Pittsburgh site! The CAVALIER Community Consultation and Public Disclosure (CC/PD) toolkit materials are IRB approved and were distributed to all sites. If you have questions as you develop your plan, please contact Ali Merti, Natalie Rogers, and Hannah Hayes ([mertiak@upmc.edu](mailto:mertiak@upmc.edu); [rogersnb@upmc.edu](mailto:rogersnb@upmc.edu); [hayesh@upmc.edu](mailto:hayesh@upmc.edu)). Sites should also be collaborating with their prehospital and in hospital partners to determine study logistics.

All-sites meetings have been scheduled for the 1st Friday of every month at 2:00 PM EST; the CCC would appreciate that each site make an attempt to have at least one member of the team available for each meeting.



## IMPORTANT DATES

October 4, 2023	12:00 pm ET	TOWAR monthly call
October 4, 2023	2:00 pm ET	PAIN monthly Coordinator call
October 6, 2023	2:00 pm ET	CAVALIER monthly Coordinator call
October 11, 2023	12:00 pm ET	CriSP monthly call
October 13, 2023	10:00am ET	PACT Study Monitoring Committee and conference call
November 1, 2023	12:00 pm ET	TOWAR monthly call
November 1, 2023	2:00 pm ET	PAIN monthly Coordinator call
November 3, 2023	2:00 pm ET	CAVALIER monthly Coordinator call
November 8, 2023	12:00 pm ET	CriSP monthly call
November 10, 2023	10:00am ET	PACT monthly Study Monitoring Committee and conference call
December 1, 2023	2:00 pm ET	CAVALIER monthly Coordinator call
December 6, 2023	12:00 pm ET	TOWAR monthly call
December 6, 2023	2:00 pm ET	PAIN monthly Coordinator call
December 8, 2023	10:00am ET	PACT monthly Study Monitoring Committee and conference call
December 13, 2023	12:00 pm ET	CriSP monthly call
January 3, 2024	12:00 pm ET	TOWAR monthly call
January 3, 2024	2:00 pm ET	PAIN monthly Coordinator call
January 5, 2024	2:00 pm ET	CAVALIER monthly Coordinator call
January 10, 2024	12:00 pm ET	CriSP monthly call
January 12, 2024	10:00am ET	PACT Study Monitoring Committee and conference call



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