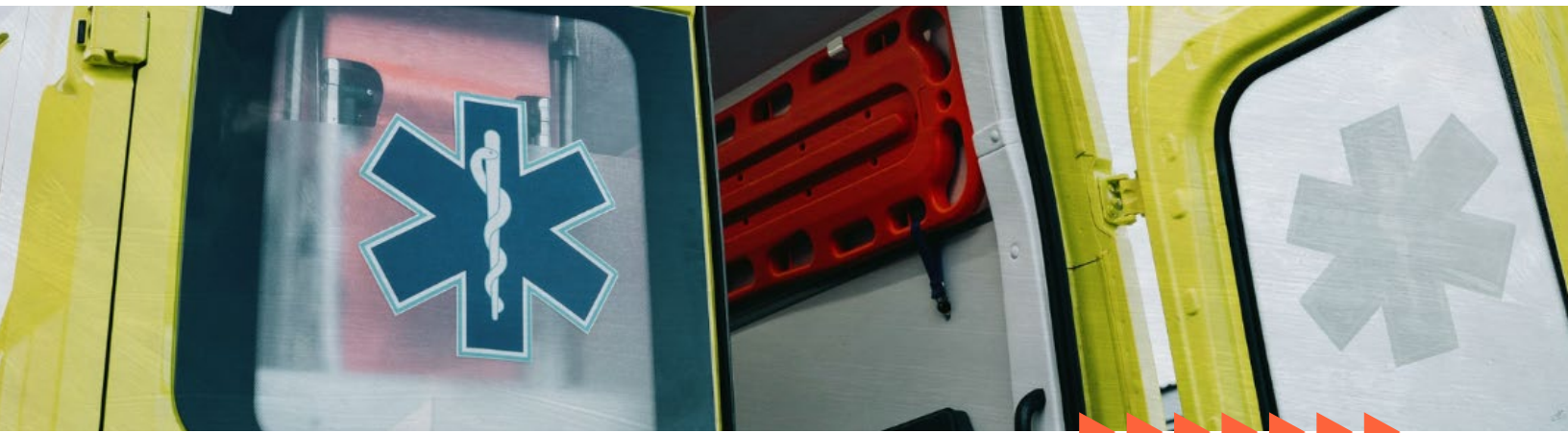


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OPERATIONS MEMOS

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

- ▶ **T05 #36 distributed 7/2/25** notifying sites about the DSMB renewal and an update to MOP v5.0.
- ▶ **T06 #22 distributed, 7/3/25** notifying sites that changes have been made to the INJ form.
- ▶ **T06 #23 distributed 7/28/25** notifying sites of the Utility Forms Upgrade along with changes that have been made to the DEV, EVT and AER forms.
- ▶ **T06 #24 distributed 8/22/25** notifying sites that Protocol v13.0, MOP v10.0, Form Grid Report updates are available and that changes have been made to the PREH and DEV forms.
- ▶ **T010 #24 distributed 7/16/25** notifying sites that changes have been made to the INJ and PREH forms.
- ▶ **T010 #25 distributed 8/21/25** notifying sites that Form Grid Report updates are available and that changes have been made to the EVT, AER, DEV and PDR forms. Changes have also been made to the following Q-by-Q's: EVT and SCRIH.
- ▶ **T010 #26 distributed 9/24/25** notifying sites that changes have been made to the ID_REGISTRY, SCRIH, EDS and CLO forms. Changes have also been made to the following Q-by-Q's: EVT and BLDS.

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.



TASK ORDER 002 / SWAT UPDATE

SWAT (Shock, Whole Blood, and Assessment of TBI) was an observational study conducted at seven U.S. trauma centers with 1,051 patients at risk of hemorrhagic shock (70% of whom received massive transfusion). Study data was recently published in the Journal of Trauma and Acute Care Surgery, "Early achievement of hemostasis defined by transfusion velocity: A possible mechanism for whole blood survival benefit." The SWAT dataset can be used for secondary analyses and was made available to all LITES investigators in February 2025. If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the LITES Data Coordinating Center.

Please remember;

1. Presentations that use SWAT data must include the following:

"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024-0002. Any opinions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Department of Defense. The views, opinions and/or findings contained in this report are those of the author(s) and are not an official Department of the Army position, policy or decision."

2. Publications in peer-reviewed journals must include the following:

"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024-0002."



TASK ORDER 004 / CriSP UPDATE

CriSP-HS

CriSP-HS data remains available for secondary analyses; anyone interested should complete a publication request form here:

<https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>.

CriSP-TBI

Publication of the TBI dataset on the FITBIR database is nearly complete.

As with CriSP-HS, data for CriSP-TBI remains available for secondary analyses. If interested, please complete a publication request form, found here:

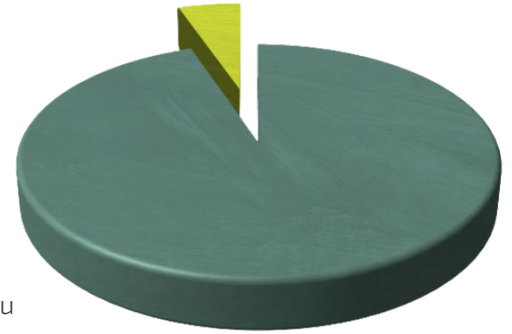
<https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>.



TASK ORDER 005 / PACT UPDATE

*As of 9/30/25, we are at **1904** enrollments which means we only need **105** enrollments to complete enrollment!*

Monitoring Committee/All-Site calls continue the 2nd Friday of each month at 10am (ET). The next calls will be on Oct 10th, Nov 14th, and Dec 12th. This once-a-month call provides all the details of how the study is progressing and distributes the Study Monitoring Committee tables so that all sites can follow our progress. All 24 EMS services are in the SGA-first arm and will stay in that arm as we complete the study. We are scheduling our next DSMB meeting for end of Fall. We will keep you posted when we have a scheduled date.



As a reminder, all consent resolutions for last quarter were due by the end of September. The next consent uploads will be due on October 31st. These will be for all enrollments that occurred July, Aug, and Sep. Also, continue to bill LITES monthly for percent effort and any data payment reports that you receive each month. 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. As we are approaching the end of enrollments, it is imperative that we complete invoicing and billing in a timely manner.

Lastly, we are working on the creation of a 'Last 100 enrollments' encouragement video for all EMS services. We are hoping to complete and distribute this video by the end of October. Please help us in our efforts to support these amazing crews, provide praise for jobs well done, and acknowledge all the work they have done to help us with this study.



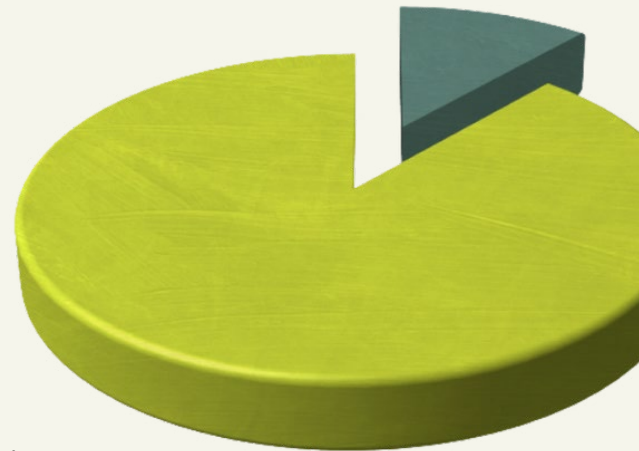
STUDY SPOTLIGHT

TASK ORDER 003 / PAIN UPDATE *previously Task Order 006*

*As of 9/30/25, we are at **128** of our **994** enrollments needed for the PAIN (Prehospital Analgesia Intervention) study.*

We have 14 finalized study sites. The status of each site is as follows:

- ▶ **Nine sites are currently enrolling:** AGH, UPMC, Cooper University Hospital, University of California San Diego, University of Cincinnati, University of Utah, Donald Guthrie Foundation, Atrium Health and University of California San Francisco
- ▶ **Site/EMS enrolling soon:** Utah Salt Lake City Fire (expected start OCT-2025)
- ▶ **Site reviewing CC/PD results:** Vermont
- ▶ **Sites completing CC/PD efforts:** JPS/Fort Worth Fire
- ▶ **Site in start-up reliance process:** Intermountain Medical Center (IMED)
- ▶ **Site working on contract:** Northeast Georgia Medical Center (NGMC)
- ▶ **Site currently not enrolling:** Medical College of Wisconsin (Milwaukee)



TASK ORDER 003 *previously Task Order 006* / **PAIN UPDATE****STUDY SPOTLIGHT**

With many sites/EMS enrolling, we have noticed a higher than anticipated deviation rate due to ineligible enrollments. These deviations are primarily due to miscalculations of shock index; however, additional issues include enrollment of females under 50, administration of study drug to non-trauma subjects, and "Kit Open Not Given" (KONG) occurrences. We are working with individual sites on training strategies, submitting deviations to IRB as they are received, and building thresholds into the Manual of Procedures (MOP) to identify sites quickly and mitigate the issue. However, please help us to emphasize that all inclusion/exclusion criteria must be reviewed by the EMS clinicians prior to opening the study kit and that using the Shock Index Chart can help alleviate calculation errors when determining that key shock index (heart rate divided by systolic blood pressure).

Because this trial has moved to a new funding stream, the task order name has changed from Task Order 006 to Task Order 003. Many documents will be updated during the annual IRB renewal in January. However, this change requires the immediate execution of updated contracts. Please assist in facilitating the execution of the new contracts, which have already been distributed to all sites. Billing will continue to commence once an updated contract has been executed at your site. The next data 'freeze' for payment will occur on Nov 30th. Any subject with complete data entry and without edits on this day is eligible for payout when we send out quarterly invoice requests.

Quarterly consent uploads were due on Aug 31st for all enrollments in May, Jun, Jul. Those consent reports were generated Sept 30th. Please complete any queries from the consent reports by the end of October. The next quarterly consent upload will be due Nov 30th for all enrollments that occur Aug, Sept, and Oct.

Thank you to everyone for their patience during the two-part study drug distribution in August. Pine Pharmaceutical worked diligently to minimize the impact of the raw drug material delay and does not anticipate similar issues moving forward. The current Fall 2025 study drug will expire on November 12th. To ensure timely replacement, the PAIN Study Team will begin requesting DEA-222 forms in mid-October so that new drug shipments arrive with sufficient time before the expiration date.

Updated EMS training slide decks (Full training, Refresher training, and Enrollment Reminder training) are available on the EMS Resource tab on the LITES network website using the passcode **ems2021**. Also, additional hangtags, posters, placards, stickers, and magnets are available if you anticipate any Fall/Winter trainings where you can help to remind the crews of the study inclusion criteria. Please reach out to the PAIN team to request these items.

Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls are November 5th and December 3rd. Talk to you all then!

**TASK ORDER 006****TASK ORDER 003**

TASK ORDER 007 / TOWAR UPDATE

TOWAR reached accrual and closed to enrollment on 06/28/2025. Data entry, query completion, and cleaning was due 8/15/25, with the exception of AIS and a handful of other outstanding queries. Updates to 30-day status were due by 9/30/25. Preliminary analyses are currently underway, with a plan to submit the primary manuscript to a high-impact journal in late Autumn at the earliest.

Close-Out Visits: Halfway Mark Reached!

The monitoring team has successfully completed five close-out visits, with the remaining five scheduled for October. We're making steady progress and are right on track to wrap things up as planned. Stay tuned for the final updates next month!

Final enrollment totals are as below:

Pitt	UW	Vandy	UMMC	UC	UT Hou	Knox	Metro	Lou	UAB	Man	TOTAL
150	140	82	116	63	251	114	39	34	24	7	1020

The DCC and CCC want to extend our thanks and gratitude to the TOWAR site teams, EMS agencies, and everyone else involved in the execution of this trial. We look forward to sharing the results with everyone soon!



TASK ORDER 008 / DEEP UPDATE

DSUVIA Early Evaluation of Pain (DEEP) was an open-label, prospective, randomized, interventional trial comparing standard pain medication to DSUVIA (sublingual sufentanil) for adult trauma patients with moderate to severe pain in the emergency department. The primary manuscript, originally published online, was published in print in the July 2025 issue of Anesthesia & Analgesia, "A Randomized Controlled Trial of Sublingual Sufentanil in Early Management of Pain in Trauma."

The DEEP dataset was made available to all LITES investigators in April 2025. If you would like access to the data, please contact Laurie Silfies (silfies@pitt.edu) at the LITES Data Coordinating Center. Additionally:



1. Presentations that use DEEP data must include the following:
"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-21-F-0448. Any opinions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Department of Defense."
2. Publications in peer-reviewed journals must include the following:
"This research is supported by DoD Contract No. W81XWH-16-D-0024, Task Order W81XWH-21-F-0448."

TASK ORDER 010 / CAVALIER UPDATE

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

Enrollment is now underway at six sites: Allegheny General Hospital, University of Arizona, Denver Health, Hennepin County Medical Center, University of Miami, and University of Pittsburgh - with several other sites gearing up to launch this fall. Kudos to Arizona for enrolling the 100th subject!

A big thank you to everyone who has contributed to the CAVALIER community consultation and public disclosure (CC/PD) efforts. We appreciate all your hard work and dedication that has gone into this important process! Special shout out to the Arkansas, Mississippi, Missouri, Mount Carmel East, and Ohio State teams on receiving sIRB approval of their CC/PD results, as well as University of Colorado on the approval of their plan.

In-hospital CAVALIER enrollment is 64 as of 9/30/25. Prehospital CAVALIER enrollment is 39 as of 9/30/25. No dual phase enrollments have occurred to date.

Monthly CAVALIER All-Site calls are held on the first Friday of each month at 2pm (EST). Our next All-Site call will be held on 10/3/2025. At least one representative from each site and service should attend each call in this monthly series. Please make every effort to attend.

Enrolling sites, please note the following deadlines:

Consent forms uploaded to Florence eTMF	December 31, 2025
Data entry complete in MATRIX to qualify for quarterly payment.	December 31, 2025



LITES 2: TASK ORDER 002 / PREEVEnT

The Plasma Resuscitation Early to Evaluate Volume and Endotheliopathy of Thermal Injury (PREEVEnT) Trial continues to make strong progress. We are pleased to share that the study has now received sIRB approval, a critical step forward in preparing for enrollment. In addition, our Pittsburgh-based Community Consultation and Public Disclosure activities are underway, ensuring that our study is introduced broadly and transparently across participating regions.

In August, members of the study team presented a poster for the PREEVEnT Study Design and Rationale at the Military Health System Research Symposium (MHSRS), further strengthening awareness and engagement across the research and clinical community.

Participating trial sites include:

- ▶ UPMC Mercy – Pittsburgh
- ▶ University of Alberta
- ▶ United States Army Institute of Surgical Research
- ▶ Emory University
- ▶ Hamilton Health Services – Ontario
- ▶ University of Louisville
- ▶ The Ohio State University
- ▶ University of Tennessee – Memphis
- ▶ University of Alabama – Birmingham
- ▶ University of Texas Southwestern
- ▶ University of Washington
- ▶ Valleywise Health
- ▶ Vanderbilt University
- ▶ Georgetown University – MedStar
- ▶ University of Utah Health

Monthly all-site calls will commence on October 13th at 1pm ET and will continue to be held on the second Monday of every month until trial completion. The CCC asks that all participating sites make a genuine effort to have at least one representative on each call.

IMPORTANT DATES

► October 3, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
► October 10, 2025	10:00am ET	PACT Study Monitoring Committee and conference call
► October 13, 2025	1:00 pm ET	PREEVEnt monthly all site call
► October 31, 2025		PACT data due to be eligible for payment
► October 31, 2025		PACT consent uploads due
► November 5, 2025	2:00 pm ET	PAIN monthly Coordinator call
► November 7, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
► November 10, 2025	1:00 pm ET	PREEVEnt monthly all site call
► November 14, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
► November 30, 2025		PACT data due to be eligible for payment
► November 30, 2025		PAIN data due to be eligible for payment
► November 30, 2025		PAIN consent uploads due
► December 3, 2025	2:00 pm ET	PAIN monthly Coordinator call
► December 5, 2025	2:00 pm ET	CAVALIER monthly Coordinator call
► December 8, 2025	1:00 pm ET	PREEVEnt monthly all site call
► December 12, 2025	10:00 am ET	PACT Study Monitoring Committee and conference call
► December 31, 2025		PACT data due to be eligible for payment
► December 31, 2025		CAVALIER data due to be eligible for payment
► December 31, 2025		CAVALIER consent uploads due
► January 2, 2026	2:00 pm ET	CAVALIER monthly Coordinator call
► January 7, 2026	2:00 pm ET	PAIN monthly Coordinator call
► January 9, 2026	10:00 am ET	PACT Study Monitoring Committee and conference call
► January 12, 2026	1:00 pm ET	PREEVEnt monthly all site call
► January 31, 2026		PACT data due to be eligible for payment
► January 31, 2026		PACT consent uploads due

This material is based upon work supported by the U.S. Department of the Army under Contract No. W81XWH-16-D-0024

Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the DoD.