LITES

QUARTERLY UPDATE

2026 QUARTER 3

OPERATIONS MEMOS

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

- **TO5 #38** ..... *distributed 4/16/26*
  notifying sites that IRB continuing review was approved and study enrollment has been completed.

- **TO10 #33** ..... *distributed 5/7/26*
  notifying sites that changes have been made to the EVT and MOF forms.

- **TO10 #34** ..... *distributed 6/22/26*
  notifying sites that the IDSMB approval letter was available and changes have been made to the LAB form and the LAB and MOF QbyQs.

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). 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 was awarded through Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024 -0002 and is funded by the Defense Health Agency (DHA) Research Technology Portfolio Management, Combat Casualty Portfolio. The views and conclusions contained herein are those of the author(s) and should not be interpreted as representing the official policies or endorsements, either expressed or implied, of the U.S. Government."

2. **Publications in peer-reviewed journals must include the following:**
   This research was awarded through Contract No. W81XWH-16-D-0024, Task Order W81XWH-16-D-0024 -0002 and is funded by the Defense Health Agency (DHA) Research Technology Portfolio Management, Combat Casualty Portfolio."

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

The TBI dataset has been uploaded to the FITBIR database.

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

On 3/8/26, we completed enrollment with 2010 subjects!

All sites have completed close out visits. All-site calls have been completed however calls will be held if necessary during data analysis. Appreciation certificates have been mailed to key research staff who were instrumental to completing this study. High enrolling EMS services have received appreciation plaques and special appreciation awards were mailed to EMS champions. These champions are those who met a minimum requirement of attending all-site calls, providing insight, and were pivotal to making this study a success.

STUDY SPOTLIGHT

TASK ORDER 007 / TOWAR UPDATE

TOWAR reached accrual and closed to enrollment on 06/28/2025. Data entry, query completion, and cleaning was completed and official data locking occurred in October 2025. Closeout visits have been completed with all accrual sites.

The primary manuscript was accepted and published in the New England Journal of Medicine! You can read the article here: **https://www.nejm.org/doi/full/10.1056/NEJMoa2602167**

Somewhat surprisingly, the study found that in patients with hemorrhagic shock, the use of whole blood for prehospital transfusion did not result in lower 30-day mortality than the use of blood components. There were no statistically significant differences in observed adverse events, mortality at 3, 6, and 24 hours, or transfusion requirements. The storage age of whole blood also did not appear to be associated with significant differences in 30-day mortality.

An Investigator Meeting to discuss trial results and generate ideas for secondary analyses was held in Chicago on June 16th. The meeting was a success, and we generated over 40 potential analyses! The Steering Committee will review the list and begin to delegate topics to interested investigators.

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.

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 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. Please remember:

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.

CAVALIER continues to enroll at a steady pace, with enrollment underway at 15 sites. We anticipate that Chandler Regional Medical Center, University of Mississippi Medical Center, and University of Colorado Anschutz Medical Center will begin enrollment this summer. As of July 6, 2026, prehospital enrollment is 130, in-hospital enrollment is 183, and dual phase enrollment is 10.

The 2026 CAVALIER Coordinator Convening was held 6/23-6/25/2026 in Pittsburgh, PA. This first-of-its-kind event for LITES brought together nearly 40 CAVALIER site team members from across the country, alongside LITES Coordinating Center staff for educational sessions, workshops, and networking. We were even blessed with beautiful weather, and many attendees got the chance to explore the city! Session recordings, slide decks, and other Convening materials will be shared with sites soon.

The Data and Safety Monitoring Board (DSMB) met in June 2026 and voted for the study to continue as is. The official meeting outcome letter is available in the LITES Document Library.

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 8/7/2026. At least one representative from each site and service should attend each call in this monthly series.

Enrolling sites, please note the following deadlines:

- **Consent forms uploaded to Florence eTMF** ..... **September 30, 2026**
- **Data entry completed in MATRIX to qualify for quarterly payment** ..... **September 30, 2026**

LITES 2:
TASK ORDER 002 / PREEVEnT UPDATE

The Plasma Resuscitation Early to Evaluate Volume and Endotheliopathy of Thermal Injury (PREEVEnT) trial continues to make steady progress as the study transitions from startup activities toward site activation and enrollment. Since the last update, several key regulatory, operational, and infrastructure milestones have been achieved.

The Execution Phase budget has received DoW/OHRO approval, and the study Continuing Review has been submitted, supporting continued regulatory compliance as the trial advances. Additionally, Protocol Versions 1.4 and 1.5 have both been approved, reflecting ongoing refinement of study procedures and documentation. You can find these in the LITES document library. The initial Data and Safety Monitoring Board (DSMB) meeting was successfully completed, with the Board voting to begin study enrollment in May, marking an important milestone for the PREEVEnT trial.

Operational preparations continue across participating sites. Only three site contracts remain to be fully executed, and nine sites are actively conducting Community Consultation and Public Disclosure (CC/PD) activities. UPMC Mercy's Site Initiation Visit was held on June 30th, with the site anticipated to begin enrollment in July 2026.

Study infrastructure continues to reach key milestones. The REDCap Part 11-compliant database has been completed, with the first site training also held on June 30th. The Florence eTMF is now live, while both the Manual of Procedures (MOP) and Laboratory Manual are in their final stages of development.

As the study prepares for activation and enrollment, participating sites are encouraged to continue CC/PD activities, gather required regulatory documentation, and complete any remaining startup requirements to ensure a successful study launch.

LITES 2:
TASK ORDER 003 / PAIN UPDATE

previously Task Order 006

As of 7/6/2026, we are at **201** of our **994** enrollments needed for the PAIN (Prehospital Analgesia INtervention) study. We currently have 15 study sites. The status of each site is as follows:

TEN 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**
- **University of California San Francisco**
- **Vermont**

SITES IN PRE-ENROLLMENT STATUS

- **Penn State Health**
  awaiting Pitt IRB approval for CC/PD plan
- **JPS in Fort Worth**
  completing CC/PD plan
- **THR in Fort Worth**
  completing reliance
- **Intermountain Medical Center (IMED)**
  IRB approved, received OHRO approval
- **Medical College of Wisconsin (Milwaukee)**
  completing CC/PD plan to start Flight for Life

EMS SERVICES IN START-UP PHASE

- **Fort Worth Fire**
  pending CC/PD results
- **Flight for Life**
  pending extra CC/PD at site
- **UC AirCare**
  completed reliance/ onboarding process
- **STAT MedEvac**
  IRB approved, received OHRO approval, Anticipate start JULY 2026
- **Susquehanna Regional EMS**
  IRB approved, received OHRO approval, Anticipate start JULY 2026

continued on next page

LITES 2: TASK ORDER 003 / PAIN UPDATE ..... *previously Task Order 006*

This study has had a steady increase in enrollments but more importantly, eligible enrollments! Paramedics have been doing a great job of identifying subjects who meet inclusion criteria and no exclusion criteria. In an effort to increase our enrollment pace, we have been identifying EMS services at existing sites that might be an easy lift to help increase our enrollment rate. If you would like to review additional EMS services at your site, please reach out to Rachel Molinaro.

To assist with enrollment reminders, Jonathon Jenkins provides a Monthly Qualtrics Case Study for field medics. This can not only help remind them of the inclusion criteria but can keep them engaged and they may even win the monthly raffle! Please reach out to Jonathon Jenkins if you would like to have the link re-forwarded to your crews and good luck to everyone in the raffle!

The next data 'freeze' for payment will occur on Aug 31st. Any subject with complete data and without edits on this day is eligible for payout when we send out quarterly invoice requests. Also, quarterly consent uploads into Florence are also due on Aug 31st for all enrollments in May, Jun, and Jul. Please see table below for reference

Table 1: Quarterly consent upload/data freeze dates for PAIN:

	Months	Upload Deadline
Quarter 1	Feb, Mar, Apr	May 31
Quarter 2	May, Jun, Jul	August 31
Quarter 3	Aug, Sept, Oct	November 30
Quarter 4	Nov, Dec, Jan	February 28

STUDY DRUG STATUS

- **Summer2026A study drug expired on June 25th, 2025**
- **Summer2026B study expires on September 16, 2026**
- **Fall2026 study drug will need to be ordered mid-August for early September delivery**

Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls are July 1st, Aug 5th and Sept 2nd. Talk to you all then!

IMPORTANT DATES

- **Aug 5, 2026** 2:00 pm ET PAIN monthly Coordinator call
- **Aug 7, 2026** 2:00 pm ET CAVALIER monthly Coordinator call
- **Aug 10, 2026** 1:00 pm ET PREEVEnT monthly all site call
- **Aug 31, 2026** PAIN consent uploads due
- **Aug 31, 2026** PAIN data due to be eligible for payment

- **Sept 2, 2026** 2:00 pm ET PAIN monthly Coordinator call
- **Sept 4, 2026** 2:00 pm ET CAVALIER monthly Coordinator call
- **Sept 14, 2026** 1:00 pm ET PREEVEnT monthly all site call
- **Sept 30, 2026** CAVALIER data due to be eligible for payment
- **Sept 30, 2026** CAVALIER consent uploads due

- **Oct 2, 2026** 2:00 pm ET CAVALIER monthly Coordinator call
- **Oct 7, 2026** 2:00 pm ET PAIN monthly Coordinator call
- **Oct 12, 2026** 1:00 pm ET PREEVEnT monthly all site call

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