

LITES

QUARTERLY UPDATE

2026 QUARTER 4

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OPERATIONS MEMOS

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

- ▶ **PAIN #32**..... distributed 7/17/26
notifying sites that the subject pay-out increased for subjects who opt into the follow-up surveys during consent.
- ▶ **PAIN #33**..... distributed 8/13/26
notifying sites that changes have been made to the SCR form and 'green wraps' were made available to all EMS services to wrap around the study drug in the narcotic containers.
- ▶ **CAVALIER #35**..... distributed 7/7/26
notifying sites that changes have been made to the SCRIH form.
- ▶ **CAVALIER #36**..... distributed 8/21/26
notifying sites that updates have been made to the protocol, Informed Consent forms and SCRIH 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.



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;

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."

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 and final subject data has been locked and verified. We do ask that all study IRBs remain open to accommodate any additional data requests during the final analysis and to address any potential queries that may occur. As we near the final curation/analysis of the data, we may reach out for additional all-site calls as needed.



TASK ORDER 007 / TOWAR UPDATE

The Steering Committee has begun to delegate manuscript topics to investigators that indicated interest.

If you are interested in a particular topic discussed at the Investigator Meeting last June, or if you've thought of a new topic, please complete a publication request form, found here: <https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8>

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."



LITES 2: TASK ORDER 002 / PREEVEnt UPDATE

The PREEVEnt Trial has officially entered the enrollment phase! We are thrilled to share that UPMC Mercy is now open for enrollment, and the trial has enrolled its first participant, an exciting milestone for the study and the culmination of tremendous effort across the LITES Network. Congratulations and thank you to everyone who helped get us here!

And the momentum continues! Valleywise Health has completed their Site Initiation Visit (SIV), while the University of Washington–Seattle and United States Army Institute of Surgical Research (USAISR) have upcoming SIVs scheduled. These sites are anticipated to open for enrollment during Q4, expanding PREEVEnt enrollment across the network.

Community Consultation and Public Disclosure (CC/PD) efforts have also reached a major milestone. Except for two recently added sites, every PREEVEnt site has progressed through sIRB review and received approval of its CC/PD plan. This represents an incredible amount of work by our site teams to prepare to implement this EFIC trial across diverse communities.

Speaking of new sites, we are excited to welcome the University of Michigan and the University of Florida–Gainesville to PREEVEnt! Both sites are beginning startup activities and working toward the regulatory and CC/PD milestones already achieved across the broader network.

Additional regulatory and operational progress continues as the trial moves further into execution. The University of Alberta has received REB approval—YAY, Alberta! Execution Phase contract amendments are rolling out to participating sites, supporting the transition from startup activities into active study conduct.

Study infrastructure has also reached important milestones. Both the Manual of Procedures (MOP) and Data Management Manual are complete and available in the LITES document library, providing sites with key resources as enrollment expands.

With our first participant enrolled, additional sites preparing to open, CC/PD approvals nearing completion across the network, and two new institutions joining the study, PREEVEnt is closing out the year with exciting momentum. Thank you to all of our site teams and collaborators for the tremendous work that has brought the trial to this point. We look forward to seeing enrollment continue to grow across the network!



LITES 2: TASK ORDER 003 / PAIN UPDATE

previously Task Order 006

As of 9/30/2026, we have enrolled **234** of the **994** enrollments needed for the PAIN (Prehospital Analgesia Intervention) study. We currently have 15 study sites. The status of each site is as follows:

ELEVEN 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
- ▶ Intermountain Medical Center in Utah

SITES CURRENTLY COMPLETING CC/PD

- ▶ JPS in Fort Worth
- ▶ THR in Fort Worth
- ▶ Penn State Health

SITES NOT ENROLLING

- ▶ Milwaukee (Medical College of Wisconsin)

EMS SERVICES IN START-UP PHASE

- ▶ Fort Worth Fire
pending CC/PD results
- ▶ Flight for Life
pending extra CC/PD at site
- ▶ Cabarrus County, NC
anticipated start date November 02, 2026
- ▶ Susquehanna Regional EMS
anticipate start November 14, 2026



EMS crews have done an amazing job of decreasing the ineligible enrollment rate by choosing appropriate patients and taking the time to review the inclusion/exclusion criteria before entering subjects into the study. As this is a slower enrolling prehospital study, providing reminder materials, giving a pat-on-the back, and working with your EMS crews to keep up the engagement is crucial to the success of this study. Monthly Qualtrics Case Study links for field medics are being distributed monthly to all EMS. 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 and consent upload will occur on Nov 30th. 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

- ▶ Summer2026B study expired on September 16, 2026.
- ▶ Fall2026 study drug was delivered the week of Sept 14th, 2026 and expires December 16th.
- ▶ Winter drug will need to be ordered via DEA-222 before the Thanksgiving holiday.

Monthly all site calls are held on the first Wednesday of each month at 2pm (ET). The next all-site calls are November 4th and December 2nd. Talk to you all then!

LITES 2: TASK ORDER 004 / CAVALIER UPDATE

previously Task Order 010

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

A new Task Order (LITES-2 Task Order 4) has been established with the DoW to complete CAVALIER. New subcontracts are being issued to each participating site to ensure uninterrupted support for trial activities.

As of September 2026, all 18 participating sites have commenced enrollment! The most recent sites to open include Chandler Regional Medical Center, University of Colorado Anschutz Medical Campus, and University of Mississippi Medical Center. This is a huge achievement, and it wouldn't have happened without the dedication of every coordinator, investigator, and site/EMS teams involved. Thank you for making this possible!

Enrollment continues at a steady pace. As of 9/30/26:

- ▶ Prehospital enrollment = 198
- ▶ In-hospital enrollment = 246
- ▶ 17 were dually enrolled in both phases

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 11/6/2026. 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 December 31, 2026
- ▶ Data entry completed in MATRIX to qualify for quarterly payment December 31, 2026

STUDY SPOTLIGHT

TOWAR-SWIFT COLLABORATION

Following completion of the TOWAR trial, LITES is excited to partner with investigators from the United Kingdom who conducted the SWiFT trial (Study of Whole Blood in Frontline Trauma) to explore what we can learn by bringing the two datasets together.

TOWAR and SWiFT were independently conducted randomized clinical trials evaluating prehospital resuscitation with whole blood compared with component blood products in adults with serious bleeding. Both studies found no statistically significant difference in their primary outcomes between treatment groups. However, neither trial was large enough to adequately evaluate important patient subgroups and other clinical outcomes. Combining the datasets provides an opportunity to answer questions that could not be addressed by either study alone.

On August 10–11, 2026, TOWAR and SWiFT investigators, along with administrators, data managers, and statisticians from both teams, met in person to begin planning this collaborative effort. The group discussed similarities and differences between the studies, developed a plan for data harmonization, and identified five high-priority topics for initial analyses and manuscripts:

- ▶ Study design and patient population
- ▶ Ethical considerations for emergency research in the U.S. and U.K.
- ▶ Treatment effects of whole blood versus component therapy in key patient subgroups
- ▶ Age of whole blood
- ▶ Time to first blood transfusion, including in patients with TBI

Next steps include completing data-sharing agreements, beginning the data harmonization process, and starting work on the first manuscripts. The teams will meet again in October to review progress and continue developing the collaborative analyses. This partnership provides an exciting opportunity to extend the impact of TOWAR and generate new insights into prehospital blood resuscitation that neither trial could provide on its own.

IMPORTANT DATES

- ▶ Oct 12, 2026 1:00 pm ETPREEVEnt monthly all site call
- ▶ Nov 4, 2026..... 2:00 pm ETPAIN monthly Coordinator call
- ▶ Nov 6, 2026..... 2:00 pm ETCAVALIER monthly Coordinator call
- ▶ Nov 9, 2026..... 1:00 pm ETPREEVEnt monthly all site call
- ▶ Nov 30, 2026PAIN consent uploads due
- ▶ Nov 30, 2026PAIN data due to be eligible for payment
- ▶ Dec 2, 2026 2:00 pm ETPAIN monthly Coordinator call
- ▶ Dec 4, 2026 2:00 pm ETCAVALIER monthly Coordinator call
- ▶ Dec 14, 2026 1:00 pm ETPREEVEnt monthly all site call
- ▶ Dec 31, 2026.....CAVALIER data due to be eligible for payment
- ▶ Dec 31, 2026.....CAVALIER consent uploads due
- ▶ Jan 6, 2027..... 2:00 pm ETPAIN monthly Coordinator call
- ▶ Jan 11, 2027 1:00 pm ETPREEVEnt monthly all site call

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