QUARTERLY UPDATE

2022 QUARTER 3

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OPERATIONS MEMOS

One new Operations Memo has been sent since the last Quarterly Update.

- **T05 #18, distributed 4/26/2022, notifying sites about required quarterly uploads, updated notification letters and Step 3 announcement.**

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 Request. **https://www.ctsiredcap.pitt.edu/redcap/surveys/?s=3LANCM7TH8**

Subject enrollment ended on June 30th, 2021. The goal of Task Order 001 was to better characterize the preventable factors of moderate and severe injury as well as the regional variations in management practices and trauma system factors that are associated with preventable mortality.

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

Sites are working on final Cause of Death determinations and PPM consensus calls are being held as COD have been completed. Five sites have completed their PPM reviews: Louisville, Denver, Oregon, Arizona, Baylor.

We would like to thank all of the Task Order 001 Sites for their tremendous efforts over the years!

DATA RECEIVED AS OF JANUARY 18, 2022

Site	TQIP Quarters Submitted	TQIP	Pre-Hospital	In-Hospital
Pittsburgh	18	9343	9245	9333
Denver	18	6513	2834	6512
Oregon	18	6309	3311	6234
Houston	18	17406	7371	15377
Vanderbilt	18	15239	5653	14252
Arizona	18	8029	4817	8011
Louisville	18	10650	4034	10627
Baylor	18	4706	2645	4642

TASK ORDER 002 / SWAT UPDATE

The Shock, Whole Blood, and Assessment of TBI (SWAT) study is an observational, multicenter trial examining morbidity and mortality outcomes associated with whole blood resuscitation practices in trauma patients who have evidence of hemorrhagic shock. Additionally, it seeks to produce knowledge about TBI patients with evidence of hemorrhagic shock.

Enrollment was completed in September 2021. In the last quarter, all data entry has been completed! We are moving on to the close-out portion of the studies – sites are asked to complete the consent query process before their close-out visits. It's been fun, but we're looking forward to closing this chapter with our awesome SWAT sites.

TASK ORDER 004 / CriSP-HS UPDATE

Since the last quarterly update, all five HS sites have completed Site Initiation Visits. Three have obtained HRPO approval, and the remaining two sites have been submitted and are awaiting approval. Congrats to the UCSF site on being the first to initiate enrollment! UCSF was activated on 6/21 and have already enrolled 4 subjects. The four remaining sites are close to being initiated and we hope to have all sites enrolling by August.

All-sites meetings have been scheduled for 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. The Clinical and Data Coordinating Centers want to thank the participating sites for their ongoing efforts in preparation for study start. We are excited to start enrolling soon!

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 15 subjects randomized and enrolled since study activation.

TASK ORDER 005 / PACT UPDATE

OVERALL PROGRESS

Thank you to everyone who has been attending the Study Monitoring Committee/All-Site calls on the 2nd Friday of each month at 10am (EST). The next three calls; July 8, August 12, and September 9th, will have Florence training sessions immediately after. Please make sure your immediate staff and any regulatory personnel are on at least one of those calls to receive the Florence information.

Hopefully everyone was able to see the *One Year Video* we released to thank all of the EMS providers and update them on the study. We also released a Quarterly EMS Newsletter in June to share our success with EMS personnel. The next four EMS agencies who are stepping to the SGA-first arm of the study are Air Evac – Wash U, Chicago Fire, STAT MedEvac, and Susquehanna Regional EMS. The step will occur when our total enrollment reaches 861.

The end of June marked the end of Quarter 2 for the year 2022 which also marks the patient pay out period for completed data. Data lock for payout was on June 30, 2022. In addition to having data completed for payout, we are asking sites to have all data 'verified' and locked by July 15th so we can prepare for the interim analysis. To review your forms that still need to be completed or verified, please run a Data Compliance report in MATRIX.

Sites are required to upload all consents and supporting documentation for those enrolled from Apr - June by July 31, 2022. We are officially 1/3 of the way through our enrollments! Great work to everyone who is working on this dynamic study.

ENROLLMENT SUMMARY REPORT AS OF JULY 5, 2022

Location	Total Registered
University of Pittsburgh	219
Allegheny-Singer	14
Oregon Health and Science University	63
Vanderbilt University	44
University of Louisville	46
East Carolina University	67
Washington University	16
Tulane University	106
Emory University	48
Chicago- Cook County (Stroger)	90
Chicago- Northwestern	28
Chicago- U of Chicago	60
Chicago- Mt. Sinai	30
Chicago Total	208
TOTAL	831

TASK ORDER 006 / PAIN UPDATE

The Prehospital Analgesia INtervention Trial, TO-006 (PAIN) is a prospective, interventional, randomized trial in trauma patients with compensated shock (SI>0.9) who require pain management. It compares patient-centered outcomes following prehospital administration of ketamine hydrochloride versus fentanyl citrate in patients who will be brought to a LITES trauma center. In January 2022, the FDA removed the Clinical Hold and approved the IND. The initial application for the IRB review was approved in May 2022. The Community Consultation and Public Disclosure materials will be submitted to the IRB for this EFIC trial.

The eight preliminary sites have been contacted and continue to have an interest in participating in the study. Regulatory calls have begun with the sites to start the sIRB reliance process and community consultation/public disclosure plans.

The compounding pharmacy, Pine Pharmaceuticals, sent the final 120-day stability test results for the study drugs to the CCC in March 2022. We are finalizing labeling, packaging and distribution processes with Pine.

TASK ORDER 007 / TOWAR UPDATE

The Pitt Site opened to enrollment on April 19, 2022 and is currently on target with 20 subjects enrolled since study activation. Four sites have completed their community consultation and public disclosure efforts and are compiling their results. For sIRB approval, sites are required to submit their results, HRPO EMS Addendum Form, and consent templates with local language. The remaining sites are working to complete their efforts. We anticipate the first sites to commence enrollment in late July/early August. As a reminder, all sites should be compiling their regulatory documents so that we submit your site for HRPO approval without delay.

The Clinical and Data Coordinating Centers want to thank the participating sites for their ongoing efforts in preparation for study start. We are excited to start enrolling soon!

TASK ORDER 008 / DEEP UPDATE / STUDY SPOTLIGHT

The DSUVIA Early Evaluation of Pain (DEEP) study is an open-label, three-year prospective, randomized, interventional trial comparing the standard pain medication used in an emergency department (ED) for moderate to severe pain with DSUVIA (Sublingual Sufentanil) for trauma patients in a hospital setting.

The DEEP study aims to examine the effectiveness, safety, and acceptability of DSUVIA following traumatic injury with moderate to severe pain. DSUVIA is an opioid agonist, is FDA approved, and indicated to treat adults in severe acute pain in a certified medically supervised health care setting (REMS certified) where alternative treatments are inadequate. The primary outcome for the trial will be the Verbally administered Numeric Rating Scale (VNRS) for clinical pain measurement at 30 minutes following randomized medication administration. Secondary outcomes include adverse events, cognitive and sedation assessments, and feedback from health care providers about study medication.

The study is designed to enroll 150 subjects, with a tentative start date in mid-July 2022. We will begin enrolling first at UPMC Presbyterian, followed by UPMC Mercy. The enrolled patients will be electronically randomized to either standard of care-pain medication or DSUVIA. Those in the DSUVIA group will receive 1 dose of 30 mcg DSUVIA sublingually, those in standard care group will receive 1 dose of standard pain medication IV. The subjects will be assessed for pain, sedation, and cognition up to the point of rescue medication, discharge from ED, or 120 minutes, whichever comes first. Health care providers will be asked to complete a survey on how they felt about the method and acceptability of pain control. The study is funded by the U.S. Department of Defense. Clinical and data coordination is being handled by the University of Pittsburgh.

Currently, we are providing Protocol training for the Clinical Research team along with mandatory Risk Evaluation Mitigation Strategy (REMS) training for the ED nurses who will be administering the drug in the hospital. The Data Safety Monitoring Board (DSMB) is set to meet on June 30, 2022, to approve, conduct, and establish monitoring guidelines before study initiation. The University of Pittsburgh's Human Research Protection Office (HRPO) is serving as IRB for DEEP. We thank everyone involved for their ongoing efforts in preparation for the study start. We are excited to start enrolling soon!

IMPORTANT DATES

July 6, 2022	12:00 pm ET	TOWAR monthly call
July 8, 2022	10:00 am ET	Study Monitoring Committee T05 and Conference call with TO5/PACT sites
July 13, 2022	12:00 pm ET	CriSP monthly call
July 14, 2022	1:00 pm ET	Conference call with TO2/SWAT sites
August 3, 2022	12:00 pm ET	TOWAR monthly call
August 10, 2022	12:00 pm ET	CriSP monthly call
August 12, 2022	10:00 am ET	Study Monitoring Committee T05 and Conference call with TO5/PACT sites
September 7, 2022	12:00 pm ET	TOWAR monthly call
September 9, 2022	10:00 am ET	Study Monitoring Committee T05 and Conference call with TO5/PACT sites
September 14, 2022	12:00 pm ET	CriSP monthly call
October 5, 2022	12:00 pm ET	TOWAR monthly call
October 12, 2022	12:00 pm ET	CriSP monthly call
October 14, 2022	10:00 am ET	Study Monitoring Committee T05 and Conference call with TO5/PACT sites