QUARTERLY UPDATE

2022 QUARTER 4

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OPERATIONS MEMOS

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

- **T04 TBI #1, distributed 7/13/2022, notifying sites about an update to the Screening (TBSCR) and Deviation (TBDEV) forms as well as updated Reports**
- **T05 #19, distributed 7/25/2022, notifying sites about delayed notification of enrollments**
- **T05 #20, distributed 8/5/2022, notifying sites about an update to the Consent Form (CON)**
- **T04 HS #1, distributed 8/5/2022, notifying sites about an update to the Consent Form (CON) and the addition of the Comments Form (COM)**
- **T04 TBI # 2, distributed 8/5/2022, notifying sites about an update to the Consent Form (CON) and the addition of the Comments Form (COM)**
- **T07 #1, distributed 8/5/2022, notifying sites about an update to the Consent Form (CON)**
- **T07 #2, distributed 8/19/2022, notifying sites about an update to the ED Summary Form (EDS)**
- **T04 HS #2, distributed 8/22/2022, notifying sites about an update to the Platelet Form (HSPLT)**
- **T04 TBI #3, distributed 8/22/2022, notifying sites about an update to the Platelet Inhibition (TBINH) form**
- **T04 HS #3, distributed 8/24/2022, notifying sites about an update to the Screening Form (HSSCR)**
- **T04 TBI #4, distributed 8/24/2022, notifying sites about an update to the Screening Form (TBSCR)**
- **T05 # 21, distributed 9/8/2022, notifying sites about Notification of Study-Wide Corrective and Preventative Action (CAPA) Plan and Rapid Escalation Plan for Noncompliance**
- **T07, # 3, distributed 9/19/22, notifying sites about an update to the Screening Form (SCR)**
- **T08 # 1, distributed 9/23/22, notifying sites about an update to the Medications Form (MEDS)**
- **T05 # 22, distributed 9/29/22. Notifying sites about and update to the Non PACT Trauma Center Form (NTR)**

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

The coordinating center is working to prioritize papers that were 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.

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	7871	4817	7853
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. Close-out efforts are complete at all of the SWAT sites! Data analysis has started; we look forward to submitting the first (of many!) manuscripts for publication review. Our extensive laboratory analyses on patient samples (biomarkers, proteomics and metabolomics - oh my!) are ongoing.

TASK ORDER 004 / CriSP-HS UPDATE

Since the last quarterly update, all five HS sites have obtained OHARO approval. Congrats to the UMMC site on being the second to initiate enrollment! UCSF has been steady with 16 enrolled subjects. UMMC knocked it out of the park with their first enrollment within hours of activation! They currently have 5 enrolled subjects. The three remaining sites are close to being activated and we hope to have all sites enrolling by early October.

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 on the study.

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 28 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 calls will be on October 14, November 11th, and Dec 9th. Please make all effort to attend those calls as this study seems to be always evolving 🙂

A review by the IRB determined that our consent and notification process required some refinement; therefore, we are operating under a CAPA plan (performance improvement plan) to ensure our compliance. A few of these items include prompt EMS notification, more robust consent/notification documentation, and requiring signatures on all consent tracking documentation. Details can be found in Op Memo 21 released on 9/8/2022.

The end of September marks the end of Quarter 3 for the year 2022 which also marks the patient pay out period for completed data. Data lock for payout is on Oct 1, 2022. To review your forms that still need complete or verified for payment, please run a Data Compliance report in MATRIX.

Sites are required to upload all consents and supporting documentation for those enrolled from July - Sept by Oct 31, 2022.

We have completed the interim data analysis and the results will be reviewed by the Data Safety Monitoring Board on Oct 7, 2022. Dr. Guyette will present these results at the NAEMSP conference in January 2023. An informal gathering we be scheduled at NAEMSP for those who are attending the conference and the session will be available remotely as well.

ENROLLMENT SUMMARY REPORT AS OF SEPTEMBER 26, 2022

Location	Total Registered
University of Pittsburgh	258
Allegheny-Singer	17
Oregon Health and Science University	76
Vanderbilt University	49
University of Louisville	50
East Carolina University	89
Washington University	16
Tulane University	116
Emory University	51
Chicago - Cook County (Stroger)	93
Chicago - Northwestern	48
Chicago - U of Chicago	77
Chicago - Mt. Sinai	33
Chicago Total	251
TOTAL	973

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 were approved by the IRB in September 2022 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.

We are finalizing labeling, packaging and distribution processes with Pine Pharmaceuticals.

TASK ORDER 007 / TOWAR UPDATE

Since the last quarterly update, three sites have completed a Site Initiation Visit and five sites have received full sIRB approval. All other sites are working through their community consultation and public disclosure efforts. Remaining SIV and MATRIX trainings will be conducted throughout the next quarter.

Congratulations to the University of Washington for being the first external site to commence enrollment! UW opened to enrollment on 9/12/2022 and has enrolled four patients. We hope to have a few more sites enrolling in October.

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

TASK ORDER 008 / DEEP UPDATE

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.

Enrollment commenced in August 2022. Currently there are 35 subjects enrolled at UPMC Presbyterian Hospital. We are planning on opening UPMC Mercy for enrollment in the late fall of 2022.

The study is funded by the U.S. Department of Defense. Clinical and data coordination is being handled by the University of Pittsburgh. We thank everyone involved for their ongoing efforts in this trial.

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

October 5, 2022	12:00 pm ET	TOWAR monthly call
October 12, 2022	12:00 pm ET	CriSP monthly call
October 14, 2022	10:00am ET	Study Monitoring Committee T05 and Conference call with T05/PACT sites
November 2, 2022	12:00 pm ET	TOWAR monthly call
November 9, 2022	12:00 pm ET	CriSP monthly call
November 11, 2022	10:00am ET	Study Monitoring Committee T05 and Conference call with T05/PACT sites
December 7, 2022	12:00 pm ET	TOWAR monthly call
December 9, 2022	10:00 am ET	Study Monitoring Committee T05 and Conference call with T05/PACT sites
December 14, 2022	12:00 pm ET	CriSP monthly call
January 4, 2023	12:00 pm ET	TOWAR monthly call
January 11, 2023	12:00 pm ET	CriSP monthly call
January 13, 2023	10:00 am ET	Study Monitoring Committee T05 and Conference call with T05/PACT sites

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.

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