Patient demographics

* Gender dmg_sex
  - ○ Male (1)
  - ○ Female (2)

* Ethnicity
  - ○ Hispanic or Latino (1)
  - ○ Not Hispanic or Latino (2)
  - ○ Not reported (3)

* Race (select all that apply)
  - ☐ American Indian or Alaskan Native dmg_native
  - ☐ Asian dmg_asian
  - ☐ Black or African American dmg_afamer
  - ☐ Native Hawaiian or other Pacific Islander dmg_island
  - ☐ White dmg_white
  - ☐ Not reported dmg_norace

Demographics complete dmg__fcomplete
☐

Death date

Death Date: deathdt

_____

Study participation

☐ CLOVERS study_clovers

Enrollment date study_cloversenrolldt

_____

Discontinuation date study_cloversdiscondt

_____

Contact completion

☐ Contact information completed ci__fcomplete

Contact information has been completed.

*
Contact information has not been completed.

- Click "Save and return" to go back to the dashboard.
- Use the project menu to go to the "LTO Data" study.
- Enroll the subject in the "LTO Data" study if not already done.
- Click the "Edit subject" button and fill out the contact data form.
- Click "Save and return" to save changes.
- Use the project menu to return to the current study.

Randomization

RAND complete rand__fcomplete

This form cannot be completed until after the screening form has been completed and the patient has been enrolled in the study.

Date and time of randomization:

* rand_dt * rand_tm

* Location at time of randomization: rand_loc
  - ED (1)
  - Ward (2)
  - ICU (3)
  - OR (4)
  - Other (5)

  * Specify: rand_locspec

* Randomization assignment: rand_trt
  - Liberal Fluid Group (1)
  - Restrictive Fluid Group (2)

* What was the randomization id provided by the randomization system?

rand_randid

Ventilator History

VENTHX complete venthx__fcomplete

* Was the patient on mechanical ventilation (assisted breathing) between randomization and study day 28? venthx_ventyn
  - Yes (1)
  - No (0)

  * First date of mechanical ventilation (assisted breathing):
    venthx_startdt

  * Last date patient was on mechanical ventilation (assisted breathing):
    venthx_lastdt

* Was patient already intubated (orotracheal, nasotracheal, tracheostomy tube) at the time of randomization? venthx_randint
  - Yes (1)
  - No (0)

  * Was patient intubated (orotracheal, nasotracheal, tracheostomy tube) before study day 28? venthx_studyint
    - Yes (1)
    - No (0)

    * Date of intubation:
      venthx_intdt

Arrhythmia history

ARRHX complete arrhx__fcomplete

* Between randomization and study day 28, did the patient experience one or more episodes of 'supraventricular tachycardia' (SVT), **new** atrial fibrillation, **new** atrial flutter, or other atrial arrhythmia sustained for at least one minute? arrhx_atrialarr
  - Yes (1)
  - No (0)

  * Did this occur in the first 24 hours after randomization? arrhx_atrialarr24
    - Yes (1)
    - No (0)

* Between randomization and study day 28, did the patient experience one or more episodes of ventricular tachycardia or ventricular fibrillation sustained for at least 15 seconds? arrhx_ventarr
  - Yes (1)
  - No (0)

  * Did this occur in the first 24 hours after randomization? arrhx_ventarr24
    - Yes (1)
    - No (0)

ICU history

* Was the patient admitted to an ICU between hospital admission and study day 28? icuhx_icuyn
  - Yes (1)
  - No (0)

* Location prior to ICU admission: icuhx_icuyn

- ED (1)
- Ward (2)
- ICU (3)
- OR (4)
- Other (5)

* Specify: icuhx_iculocspec

Please record the initial ICU admission, all study hospital ICU discharges, and all re-admissions between randomization and study day 28.

		icuhx_dischargeyn_r1		icuhx_readmityn_r1
	Admission date	**Discharged?**	**Discharge date**	**Re-admitted?**
Initial	* icuhx_admitdt_r1	* Yes (1) / No (0)	*icuhx_dischargedt_r1	* Yes (1) / No (0)
Second	* icuhx_admitdt_r2	* Yes / No	*icuhx_dischargedt_r2	* Yes / No
Third	* icuhx_admitdt_r3	* Yes / No	*icuhx_dischargedt_r3	* Yes / No
Fourth	* icuhx_admitdt_r4	* Yes / No	*icuhx_dischargedt_r4	* Yes / No
Fifth	* icuhx_admitdt_r5	* Yes / No	*icuhx_dischargedt_r5	* Yes / No

icuhx_dischargeyn_r5 icuhx_readmityn_r5

ICUHX complete icuhx__fcomplete

Vasopressor history

VASOHX complete vasohx__fcomplete

* Was a vasopressor administered between 48 hours post-randomization and study day 28? vasohx_yn

- Yes (1)
- No (0)

* **First** date of vasopressor infusion (lasting more than 1 hour) between 48 hours post-randomization and study day 28:

vasohx_firstdt

* **Last** date of vasopressor infusion (lasting more than 1 hour) between 48 hours post-randomization and study day 28:

vasohx_lastdt

ARDS history

ARDSHX complete ardshx__fcomplete

If the patient had ARDS at baseline, or developed ARDS between day 0 and day 7, an ARDS source document should be completed.

* Did patient have ARDS at the time of randomization (based on the criteria in protocol section 3.6.2)? ardshx_randyn
  - Yes (1)
  - No (0)

* Did patient develop ARDS between randomization and study day 7? ardshx_randd7yn
  - Yes (1)
  - No (0)

  * Date of ARDS diagnosis:
    ardshx_randd7dt

  * Worst severity of ARDS within first 7 days in study (based on P/F or imputed P/F): ardshx_randd7sev
    - Mild (201-300) (1)
    - Moderate (100-200) (2)
    - Severe (< 100) (3)

RRT history

RRTHX complete rrthx__fcomplete

* Did patient receive new renal replacement therapy (RRT) (excluding dialysis for underlying chronic renal failure) between randomization and day 28? rrthx_newyn
  - Yes (1)
  - No (0)

  * First date subject received RRT:
    rrthx_firstdt

  * Last date subject received RRT:
    rrthx_lastdt

Medications history

MEDICHX complete medichx__fcomplete

Were any of the following medications administered between randomization and study day 7?

* Vitamin C: medichx_vitc
  - Yes (1)
  - No (0)

* Vitamin D: medichx_vitd
  - Yes (1)
  - No (0)

* Thiamine: medichx_thiamine
  - Yes (1)
  - No (0)

* Corticosteroids: medichx_corticoster
  - Yes (1)
  - No (0)

Antibiotic use

ANTIBIOHX complete antibiohx__fcomplete

* Was any antimicrobial (antibiotic, antimycobacterial, antiviral) administered by any route (enteral, IV, IM) between presentation to the study hospital and study day 28? antibiohx_antimicrobyn

- Yes (1)
- No (0)

Date and time of first antiobiotic administration after hospital presentation:

* antibiohx_antimicrobdt * antibiohx_antimicrobtm

Microbiology results

MICROBIORES complete microbiores__fcomplete

* Were any positive blood cultures collected between study hospital presentation and 72 hours post randomization? microbiores_pos

- Yes (1)
- No (0)

Final review of presence of infection

INFREV complete infrev__fcomplete

Final infection status should be arbitrated by an investigator. The source document should be signed by the investigator.

* Arbitrated infection status: infrev_status

- Infection present (1)
- Infection likely present (2)
- Infection likely not present (3)
- Non-infectious diagnosis definitively identified (4)

* Please specify definitive non-infectious diagnosis: infrev_noninfecspec

* With all of the data available at the conclusion of hospitalization, what was the likely **primary** source of infection at the time of enrollment? infrev_primsrc

- Pneumonia (1)
- Urinary tract infection (2)
- Intra-abdominal infection (3)
- Skin or soft-tissue infection (4)
- Vascular catheter-related infection (5)
- Central nervous system infection (6)
- Endocarditis or endovascular infection (7)
- Flu or other virus confirmed by testing (8)
- COVID-19 confirmed by testing (11)
- Other source of infection (9)
- Unknown (10)

* Please specify other source of infection: infrev_primsrcspec

Study termination

TERM complete term__fcomplete

* Was the patient permanently withdrawn from the trial prior to study day 28? term_wd
*(Study completion does **not** qualify as withdrawing from the study.)*
- Yes (1)
- No (0)

  * Date withdrawn:
    term_wddt

  * Reason patient withdrew from CLOVERS:
    term_wdspec

* Was the patient discharged alive from the study hospital prior to day 90? term_disch
- Yes (1)
- No (0)

  * Date of first study hospital discharge:
    term_dischdt

  * Was the patient discharged directly to home from the study hospital? term_dischhomeyn
    - Yes (1)
    - No (0)

    * Was the patient ultimately discharged to home prior to day 90? term_ultimatehome
      - Yes (1)
      - No (0)

Complete day 90 status question below

* Date of discharge to home:
  term_ultimatehomedt

* Day 90 patient status: term_d90stat
- Alive at day 90 (1)
- Dead (2)
- Alive but not yet day 90 (3)

  * Date of death:
    term_deathdt

  * Status date:
    term_statusdt

Patient is home, next follow up at day 90

Patient is not home. Update status until day 90, death or "home", whichever comes first.

* Was written consent obtained from the patient during the study hospitalization? term_consn
- Yes (1)
- No (0)

* Why was the patient not consented? term_consn

- ○ Patient died (1)
- ○ Patient never regained decision-making capability (2)
- ○ Patient declined further participation in the study (3)
- ○ Other (9)

* Please specify:

term_consnspec

Study coenrollment

STCO complete stco__fcomplete

- ☐

* Select all PETAL Network studies the patient was coenrolled into:

- ☐ ROSE stco_rose
- ☐ VIOLET stco_violet
- ☐ *not coenrolled in PETAL network studies* stco_none

Inclusion / Exclusion

IE complete ie__fcomplete

☐

* Did patient meet the following inclusion criteria? ie_incl

- Age ≥ 18 years
- A suspected or confirmed infection
- Hypotension, defined as systolic blood pressure < 100 mmHg or mean arterial pressure < 65 mmHg after a minimum of at least 1 liter fluid bolus (fluids inclusive of pre-hospital fluids)

○ Yes (1)
○ No (0)

Patients who do **not** meet the inclusion criteria should not be entered into StudyTRAX. Please contact the CCC to remove the patient from the CLOVERS study.

* Reasons for exclusion *(select all that apply)*:

☐ Not Excluded ie_notexcl
☐ Unable to obtain informed consent ie_consent
☐ Pregnancy ie_pregnancy
☐ Patient already received **more** than 3 liters of fluid (including pre-hospital volumes) ie_fluid
☐ Hypotension suspected to be due to non-sepsis cause (e.g. hemorrhagic shock) ie_nonsepticht
☐ Blood pressure is at known or reported baseline level ie_bpbaseline
☐ More than 4 hours elapsed since inclusion criteria met ie_toolong4
☐ More than 24 hours elapsed since *presentation* to the hospital ie_toolong24
☐ Severe volume depletion from an acute condition other than sepsis ie_voldep
☐ Pulmonary edema or signs of overt fluid overload ie_pulmedem
☐ Decision to withhold or withdraw life-sustaining treatment (except in patients committed to full support except CPR) ie_withdraw
☐ Immediate surgical intervention planned such that study procedures could not be followed ie_surgery
☐ Prior enrollment in this study ie_alreadyenrolled
☐ MD refusal: ie_mdrefuse

- ○ Treating physician unwilling to give additional fluids as directed by liberal protocol
- ○ Treating physician unwilling to use vasopressors as directed by the restrictive protocol

ie_mdrefusetype

☐ Attending did not have time to consider whether both CLOVERS arms are consistent with good medical care options for this patient ie_mdtoobusy
☐ Patient or surrogate declined all study blood samples ie_noblood
☐ Patient or surrogate declined to provide consent ie_declined
☐ Surrogate unavailable ie_nosurrogate
☐ Patient no longer meets the hypotension inclusion criterion (no available SBP < 100 or MAP < 65 within 30 minutes of randomization, or not receiving a vasopressor infusion) ie_nohypotensive
☐ Not excluded but not enrolled ie_nene

* Reason not enrolled: ie_nenespec

Screening

SCR complete scr__fcomplete

Date and time patient met all inclusion criteria:

* scr_critmetdt * scr_critmettm

* Month patient met inclusion criteria:
  - January (1)
  - February (2)
  - March (3)
  - April (4)
  - May (5)
  - June (6)
  - July (7)
  - August (8)
  - September (9)
  - October (10)
  - November (11)
  - December (12)

* Patient age (randomized patients): scr_age

_____ years

* Patient age (screen fails): scr_agescr

_____ years

* Suspected **primary** source of infection at enrollment: scr_infsrc
  - Pneumonia (1)
  - Urinary tract infection (2)
  - Intra-abdominal infection (3)
  - Skin or soft-tissue infection (4)
  - Vascular catheter-related infection (5)
  - Central nervous system infection (6)
  - Endocarditis or endovascular infection (7)
  - Flu/other virus confirmed by testing (8)
  - COVID-19 confirmed by testing (11)
  - Other source of infection (9)
  - Unknown (10)

  * Please specify: scr_infsrcspec

_____

* Were vasopressors infusing when the patient qualified? scr_qualvasop
  - Yes (1)
  - No (0)

* What was the systolic blood pressure (SBP) when the patient qualified? scr_qualsbp

_____ mmHg

* What was the mean arterial pressure (MAP) when the patient qualified? scr_qualmap

_____ mmHg

* The attending physician **agrees** that both CLOVERS arms are consistent with good medical care options for this patient. scr_cloversok
  - Yes (1)
  - No (0)

* Was the CLOVERS consent video used during the informed consent process for this patient? scr_video

- ○ Yes (1)
- ○ No (0)

* Why was the video not used?

- ○ Video not available (1)
- ○ Patient not approached for consent (2)
- ○ Video not used for other reason (3)

Eligibility status: scrstat_scrstatus

- ○ In screening (1)
- ○ Failed screening (2)
- ○ Passed screening (3)

Consent

CONS complete cons__fcomplete

☐

* Has informed consent been obtained for participation in the CLOVERS study? cons_consyn
  - ○ Yes (1)
  - ○ No (0)

  * Was initial consent obtained from the patient or from a surrogate? cons_constype
    - ○ Subject (1)
    - ○ Surrogate (2)

* Was consent obtained for the collection of samples for future genetic research in severe illness? cons_gensevere
  - ○ Yes (1)
  - ○ No (0)

* Was consent obtained for the collection of samples for future genetic research for other medical conditions? cons_genothers
  - ○ Yes (1)
  - ○ No (0)

* Was consent obtained for participation in the SHAMROC study? cons_shamroc
  - ○ Yes (1)
  - ○ No (0)

Medical history

MEDHX complete medhx__fcomplete

☐

* Is the patient on chronic dialysis? medhx_cdialysisyn
  - ○ Yes (1)
  - ○ No (0)

  * Is there a serum creatinine value available in the previous year prior to hospital arrival that is a baseline (e.g. not acutely elevated)? medhx_creatyn
    - ○ Yes (1)
    - ○ No (0)

    * Most recent pre-hospital creatinine within the last year: medhx_prehospcreat

      _____ mg/dL

    * Lowest creatinine within the last year: medhx_creatl

      _____ mg/dL

* Is the patient on chronic home mechanical ventilation (**does not** include home non-invasive ventilation for sleep disordered breathing)? medhx_homemechvent
  - ○ Yes (1)
  - ○ No (0)

* Height: medhx_height

  _____ * ○ in (1) ○ cm (2) medhx_heightunits

* Weight: medhx_weight

  _____ * ○ lbs (1) ○ kg (2) medhx_weightunits

Date and time of hospital arrival:

* medhx_hosparrdt * medhx_hosparrtm

Date and time of hospital admission:

* medhx_hospadmdt * medhx_hospadmtm

☐ Patient discharged from ED without hospital admission medhx_hospadmnone

* Pre-hospital level of care: medhx_prehosp

- ○ Home independently (1)
- ○ Home with help from family/friends (2)
- ○ Home with professional help (3)
- ○ Intermediate care or rehab facility (e.g. goal is to get patient better) (4)
- ○ Nursing facility (e.g. goal is to meet patient's ongoing needs) (5)
- ○ Acute care hospital (6)
- ○ Homeless or living in a temporary shelter (7)
- ○ Adult family home or other non-medical institutional setting (8)
- ○ Other (888)

* Specify:

medhx_prehospspec

* COVID-19 status: medhx_covid19

- ○ Positive test within 3 weeks prior to admission (1)
- ○ Negative (only negative tests with 3 weeks prior to admission) (2)
- ○ Unknown (no test within 3 weeks prior to admission) (3)

* Date of **first** positive COVID-19 test within the three weeks prior to admission:

medhx_covid19dt

☐ Date of COVID-19 test unknown medhx_covid19dtunk

Charlson (and baseline co-morbidities)

CHARL complete ☐ charl__fcomplete

* Is chronic health information available? charl_yn

- ○ Yes (1)
- ○ No (0)

Indicate whether each condition was present at hospital admission and **prior** to randomization.

		Yes	No	
*	AIDS *(do not include HIV-positive without AIDS criteria)*	○	○	charl_aids
*	Leukemia *(AML, CML, ALL, multiple myeloma)*	○	○	charl_leuk
*	Malignant lymphoma	○	○	charl_lymph
*	Hemiplegia	○	○	charl_hemiplegia
*	Cerebrovascular disease	○	○	charl_cerebvasc
*	A prior myocardial infarction	○	○	charl_myoinfarc
*	Congestive heart failure	○	○	charl_congheart
*	Peripheral vascular disease	○	○	charl_perivasc
*	Dementia	○	○	charl_dementia

		Yes	No	
*	COPD	○	○	charl_copd
*	Connective tissue disease	○	○	charl_contis
*	Peptic ulcer disease	○	○	charl_ulcer
*	History of hypertension	○	○	charl_hypertension
*	HIV positive *(without AIDS)*	○	○	charl_hiv
*	Alcoholism *(ever)*	○	○	charl_alcoholism
*	Coronary artery disease	○	○	charl_cad
*	Rapidly fatal disease *(patient likely to die from underlying illness within 30 days e.g. end-stage AIDS, end-stage cancer, in hospice)*	○	○	charl_fatal

* Solid tumor charl_tumor
  - ○ No solid tumor present (0)
  - ○ Solid tumor present (exclude if > 5 years from diagnosis) (1)
  - ○ Solid tumor with metastasis present (ever) (2)

* Liver disease charl_liver
  - ○ No liver disease present (0)
  - ○ Mild liver disease present (without portal hypertension, includes chronic hepatitis) (1)
  - ○ Moderate/severe liver disease present (cirrhosis with portal HTN or variceal bleeding) (2)

* Diabetes mellitus *(DM)* charl_diabetes
  - ○ No DM present (0)
  - ○ Uncomplicated DM present (no end organ damage present) (1)
  - ○ DM with end organ damage present (excludes diet controlled alone) (2)

* Moderate to severe kidney disease charl_kidney
  - ○ No moderate to severe kidney disease present (0)
  - ○ Moderate to severe kidney disease present (Cr > 3, ESRD, chart diagnosis of CKD stage 5 (eGFR < 15 mL/min/1.73m²) not on dialysis) (1)
  - ○ Moderate to severe kidney disease present and patient is dialysis dependent (2)

Pre-randomization fluids

Enter the total volume infused for each of the solutions listed for the pre-randomization period **(2 hours before study hospital presentation to randomization)**.

Fluid type	Volume	
Normal saline (NS):	* _____ mL	blfluid_ns
Lactated Ringers (LR):	* _____ mL	blfluid_lr
Balanced Solutions / Plasmalyte:	* _____ mL	blfluid_bs
Albumin:	* _____ mL	blfluid_alb

Fluid type	Volume	
IV medications: *(include only when volume administered is documented in the medical record; e.g. if no volume, do not estimate or calculate)*	* _____ mL	blfluid_iv
Blood products:	* _____ mL	blfluid_blood
Other: *(includes ¼ NS, ½ NS, sterile water, d5 alone, etc.)*	* _____ mL	blfluid_other

* Total fluid output prior to randomization: blfluid_flout

_____ mL

BLFLUID complete blfluid__fcomplete

☐

Baseline vasopressors

BLVASO complete blvaso__fcomplete

☐

* Did the patient have a pre-existing form of central venous access prior to this hospital presentation? blvaso_cvpre
(such as central venous catheter, port-a-cath, midline, or peripherally inserted central catheter (PICC))

○ Yes (1)
○ No (0)

* Did the patient have a new central venous access line placed between presentation and randomization? blvaso_cvnew
(such as central venous catheter, port-a-cath, midline, or peripherally inserted central catheter (PICC))

○ Yes (1)
○ No (0)

* Were vasopressors administered between hospital presentation and randomization? blvaso_prerand

○ Yes (1)
○ No (0)

* What was the route of pre-randomization vasopressor administration? blvaso_prerandroute

○ Peripheral line administration (1)
○ Central line administration (2)
○ Both (3)

* Was the patient on vasopressors (continuous infusion) at the time of randomization? blvaso_yn

○ Yes (1)
○ No (0)

* Record infusion rate at time of randomization:

☐ Dobutamine: blvaso_dobutyn * _____ µg/kg/min blvaso_dobut
☐ Dopamine: blvaso_dopayn * _____ µg/kg/min blvaso_dopa
☐ Epinephrine: blvaso_epiyn * _____ µg/kg/min blvaso_epi
☐ Norepinephrine: blvaso_norepiyn * _____ µg/kg/min blvaso_norepi
☐ Neosynephrine: blvaso_neosynyn * _____ µg/kg/min blvaso_neosyn
☐ Vasopressin: blvaso_vasopyn * _____ units/min blvaso_vasop

Baseline vital signs

BLVITAL complete blvital__fcomplete

Please enter the most recent vital signs prior to randomization.

* Temperature: blvital_temp

_____ * (1) C (2) F blvital_tempunits

* Heart rate: blvital_hr

_____ beats per min

* Respiratory rate: blvital_rate

_____ breaths per min

Blood pressure

BP complete bp__fcomplete

Please enter the most recent blood pressure prior to randomization.

Please enter the blood pressure closest to 0800.

* Systolic BP: bp_systolic

* Diastolic BP: bp_diastolic

* Was this blood pressure taken while the patient was on vasopressors? blvital_bpvasoyn

- Yes (1)
- No (0)

Labs

LABS complete labs__fcomplete

Enter the most recent values (if available) collected prior to randomization.

For platelets and total bilirubin only: if platelets or total bilirubin are not available prior to randomization, enter the first available value up to 6 hours following randomization.

Enter the values (if available) closest to 0800.

* White blood cell count: _____ /mm³ labs_wbc

* Hematocrit: _____ % labs_hematocrit

* Platelets: _____ ×1000/mm³ labs_platelets

* Sodium: _____ meq/L labs_sodium

* Potassium: _____ meq/L labs_potassium

* Chloride: _____ meq/L labs_chloride

* Bicarbonate: _____ meq/L labs_bicarbonate

* BUN: _____ mg/dL labs_bun

* Creatinine: _____ mg/dL labs_creatinine

* Blood glucose: _____ mg/dL labs_bloodgluc

* Albumin: _____ g/dL labs_albumin

* Total bilirubin: _____ mg/dL labs_totalbili

* Lactate: _____ mmol/L labs_lactate

* PaO2: _____ mmHg labs_pao2

  * FiO2 at time of PaO2: _____ *(decimal)* labs_pao2fio2

* SpO2: _____ % labs_spo2

  * FiO2 at time of SpO2: _____ *(decimal)* labs_spo2fio2

Glasgow Coma Score

GCS complete gcs__fcomplete

☐

Collect last available GCS prior to randomization.

Collect the GCS score recorded closest to 0800.

* Is the patient on a sedative or neuromuscular blocker? gcs_sedative
  - ○ Yes (1)
  - ○ No (0)
  - ○ *Not available* (-99)

* Eye opening score: gcs_eye
  - ○ None (1)
  - ○ To pain (2)
  - ○ To voice (3)
  - ○ Spontaneous (4)
  - ○ *Score not obtained* (-99)

* Motor response score: gcs_motor
  - ○ Flaccid (1)
  - ○ Abnormal extension (2)
  - ○ Abnormal flexion (3)
  - ○ Flexion withdrawal (4)
  - ○ Localizes to pain (5)
  - ○ Obeys commands (6)
  - ○ *Score not obtained* (-99)

* Verbal response score: gcs_verbal
  - None, or generally unresponsive on ventilator (1)
  - Incomprehensible (2)
  - Inappropriate, or questionably oriented if on ventilator (3)
  - Confused (4)
  - Oriented, or appears oriented on ventilator (5)
  - *Score not obtained* (-99)

* Total GCS score: gcs_total

_____

Sample collection

SAMP complete samp__fcomplete
☐

* Was a sample collected at this time period? samp_yn
  - Yes
  - No

Actual date and time blood drawn for sample collection:

* samp_dt * samp_tm

* Accession number: samp_accno

_____

* Specify why sample was not collected: samp_spec

_____

Basic assessment of prior functioning

PFUNC complete pfunc__fcomplete
☐

Recent living status and hospitalization

* Patient location prior to current hospitalization: pfunc_reside
  - Home independently (1)
  - Home with help (2)
  - Home with professional help (3)
  - Intermediate care or rehab facility (e.g., goal is to get patient better) (4)
  - Nursing facility (e.g., goal is to meet patient's ongoing needs) (5)
  - Acute care hospital (6)
  - Homeless or living in a temporary shelter (7)
  - Adult Family Home or other non-medical institutional setting (8)
  - Other (888)
  - *Not answered* (777)

* Specify other prior location:

pfunc_residespec

_____

ADLs and IADLs

Because of a health or memory problem, did the patient have any difficulty with the following?

* Dressing, including putting on shoes and socks? pfunc_dressing
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Walking across a room? pfunc_walking
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Bathing or showering? pfunc_bathing
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Eating, such as cutting up their food? pfunc_eating
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Getting in or out of bed? pfunc_bed
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Using the toilet, including getting up and down? pfunc_toilet
  - Yes (1)
  - No (2)
  - *Don't do* (6)
  - *Can't do* (7)
  - *Don't know* (8)
  - *Not answered* (777)

* Preparing a hot meal? pfunc_cooking

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Shopping for groceries? pfunc_shopping

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Making phone calls? pfunc_phoning

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Taking medications? pfunc_medicating

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Managing their money, such as paying their bills and keeping track of expenses? pfunc_money

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Stooping, kneeling, or crouching? pfunc_stooping

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

* Lifting or carrying weights over 10 lbs, like a heavy bag of groceries? pfunc_lifting

- Yes (1)
- No (2)
- *Don't do* (6)
- *Can't do* (7)
- *Don't know* (8)
- *Not answered* (777)

AD8

* Who provided answers for the ADL/IADL survey above? pfunc_respondent
  - Patient (1)
  - Surrogate (2)

For each of the following, has there been a change in the patient's cognitive ability over the last *several years*?

* Problems with judgment (e.g., problems making decisions, bad financial decisions, problems with thinking)? pfunc_ad8judge
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Less interest in hobbies or activities? pfunc_ad8hobbies
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Repeats the same things over and over (questions, stories, or statements)? pfunc_ad8repeats
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Trouble learning how to use a tool, appliance, or gadget (e.g., VCR, computer, microwave, remote control)? pfunc_ad8learning
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Forgets the correct month or year? pfunc_ad8date
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Trouble handling complicated financial affairs (e.g., balancing checkbook, income taxes, paying bills)? pfunc_ad8finance
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Trouble remembering appointments? pfunc_ad8appointment
  - Yes, a change (1)
  - No, no change (0)
  - Don't know (2)
  - *Not answered* (-99)

* Daily problems with thinking and/or memory? pfunc_ad8memory

- Yes, a change (1)
- No, no change (0)
- Don't know (2)
- *Not answered* (-99)

The AD8 should only be completed by a surrogate, not by the patient.

CLOVERS
Day 1-3

Fluid intake and output

OSFLUID complete

☐

On **day 1** collect totals starting from 24 hours post-randomization to the time of the intake and output 24-hour totals at your hospital. *(see CRF instructions)*

On **days 2–7** collect totals at the most convenient time at your hospital. *(see CRF instructions)*

If the patient is not in the ICU, only include intake volume documented in the medical record (i.e., if not recorded, do not estimate or calculate).

* Total fluid intake on this study day?

_____ mL osfluid_intake

* Is the patient in the ICU this study day? osfluid_icu

- ○ Yes (1)
- ○ No (0)

* Total fluid output on this study day: osfluid_totalout

_____ mL

* Total urine output on this study day: osfluid_urineout

_____ mL

* Were diuretics given on this study day? osfluid_diuretics

- ○ Yes (1)
- ○ No (0)

Vasopressors

OSVASO complete

☐ osvaso__fcomplete

* Did the patient receive vasopressors for more than 1 hour on this study day? osvaso_yn

- ○ Yes
- ○ No

* Record the highest dose of each vasopressor received on this study day:

osvaso_dobutyn
☐ Dobutamine: * _____ µg/kg/min osvaso_dobut

osvaso_dopayn
☐ Dopamine: * _____ µg/kg/min osvaso_dopa

osvaso_epiyn
☐ Epinephrine: * _____ µg/kg/min osvaso_epi

osvaso_norepiyn
☐ Norepinephrine: * _____ µg/kg/min osvaso_norepi

osvaso_neosynyn
☐ Neosynephrine: * _____ µg/kg/min osvaso_neosyn

osvaso_vasopyn
☐ Vasopressin: * _____ units/min osvaso_vasop

Labs

LABS complete ☐ labs__fcomplete

Enter the most recent values (if available) collected prior to randomization.

For platelets and total bilirubin only: if platelets or total bilirubin are not available prior to randomization, enter the first available value up to 6 hours following randomization.

Enter the values (if available) closest to 0800.

* White blood cell count: _____ /mm³ labs_wbc
* Hematocrit: _____ % labs_hematocrit
* Platelets: _____ ×1000/mm³ labs_platelets
* Sodium: _____ meq/L labs_sodium
* Potassium: _____ meq/L labs_potassium
* Chloride: _____ meq/L labs_chloride
* Bicarbonate: _____ meq/L labs_bicarbonate
* BUN: _____ mg/dL labs_bun
* Creatinine: _____ mg/dL labs_creatinine
* Blood glucose: _____ mg/dL labs_bloodgluc
* Albumin: _____ g/dL labs_albumin
* Total bilirubin: _____ mg/dL labs_totalbili
* Lactate: _____ mmol/L labs_lactate
* PaO2: _____ mmHg labs_pao2
  * FiO2 at time of PaO2: _____ *(decimal)* labs_pao2fio2
* SpO2: _____ mmHg labs_spo2
  * FiO2 at time of SpO2: _____ *(decimal)* labs_spo2fio2

Glasgow Coma Score

GCS complete ☐ gcs__fcomplete

Collect last available GCS prior to randomization.

Collect the GCS score recorded closest to 0800.

* Is the patient on a sedative or neuromuscular blocker? gcs_sedative
  - ○ Yes (1)
  - ○ No (0)
  - ○ *Not available* (-99)

* Eye opening score: gcs_eye
  - None (1)
  - To pain (2)
  - To voice (3)
  - Spontaneous (4)
  - *Score not obtained* (-99)

* Motor response score: gcs_motor
  - Flaccid (1)
  - Abnormal extension (2)
  - Abnormal flexion (3)
  - Flexion withdrawal (4)
  - Localizes to pain (5)
  - Obeys commands (6)
  - *Score not obtained* (-99)

* Verbal response score: gcs_verbal
  - None, or generally unresponsive on ventilator (1)
  - Incomprehensible (2)
  - Inappropriate, or questionably oriented if on ventilator (3)
  - Confused (4)
  - Oriented, or appears oriented on ventilator (5)
  - *Score not obtained* (-99)

* Total GCS score:

gcs_total

Sample collection

SAMP complete

☐ samp__fcomplete

* Was a sample collected at this time period? samp_yn
  - Yes (1)
  - No (0)

Actual date and time blood drawn for sample collection:

* samp_dt * samp_tm

* Accession number:

samp_accno

* Specify why sample was not collected:

samp_spec

Fluid intake and output

OSFLUID complete

☐ osfluid__fcomplete

On **day 1** collect totals starting from 24 hours post-randomization to the time of the intake and output 24-hour totals at your hospital. *(see CRF instructions)*

On **days 2–7** collect totals at the most convenient time at your hospital. *(see CRF instructions)*

If the patient is not in the ICU, only include intake volume documented in the medical record (i.e., if not recorded, do not estimate or calculate).

* Total fluid intake on this study day?

_____ mL osfluid_intake

* Is the patient in the ICU this study day? osfluid_icu

- ○ Yes (1)
- ○ No (0)

* Total fluid output on this study day: osfluid_totalout

_____ mL

* Total urine output on this study day: osfluid_urineout

_____ mL

* Were diuretics given on this study day? osfluid_diuretics

- ○ Yes (1)
- ○ No (0)

Intervention fluids

For each time period, enter the total volume (mL) infused for each solution. Hour 0 is the time of randomization.

Fluid type	Volume (Hours 0–6)	Volume (Hours 6–24)	
Normal saline (NS):	* _____ mL ipfluid_ns6	* _____ mL	ipfluid_ns24
Lactated Ringers (LR):	* _____ mL ipfluid_lr6	* _____ mL	ipfluid_lr24
Balanced Solutions / Plasmalyte:	* _____ mL ipfluid_bs6	* _____ mL	ipfluid_bs24
Albumin:	* _____ mL ipfluid_alb6	* _____ mL	ipfluid_alb24
IV medications: *(include only when volume administered is documented in the medical record; e.g. if no volume, do not estimate or calculate)*	* _____ mL ipfluid_iv6	* _____ mL	ipfluid_iv24
Blood products:	* _____ mL ipfluid_blood6	* _____ mL	ipfluid_blood24
Other: *(includes ¼ NS, ½ NS, sterile water, d5 alone, etc.)*	* _____ mL ipfluid_oth6	* _____ mL	ipfluid_oth24
* What was the total volume of intravenous fluid administered between randomization and the time at which the first vasopressor was initiated? _____ mL ipfluid_totvol			
Total *urine* output:	* _____ mL ipfluid_uout6	* _____ mL	ipfluid_uout24
Total *fluid* output:	* _____ mL ipfluid_flout6	* _____ mL	ipfluid_flout24
* Were diuretics given between randomization and 24 hours? ○ Yes (1) ○ No (0) ipfluid_diuretics			

IPFLUID complete

☐ ipfluid__fcomplete

* Was the full 2 liter infusion completed? ipfluid_full2l
  - ○ Yes (1)
  - ○ No (0)

* Total amount of infusion given:

  _____ ml ipfluid_infamt

* Why was the full infusion not completed? ipfluid_infreas
  - ○ Volume overload (1)
  - ○ After 1st liter, HR<90 and SBP≥110 (or MAP≥70) and patient volume replete and team decided not to give 2nd liter (2)
  - ○ Other (9)

* Please specify: ipfluid_infreasspec

CLOVERS
Study Intervention Period

Intervention ventilator and oxygen use

For each time period, indicate whether the patient received the specified treatment.

Treatment	Before randomization	Hours 0–6	Hours 6–24
High flow O2 (HFNC):	* Yes / No ipvent_hfo2b	* Yes / No ipvent_hfo2h6	* Yes / No ipvent_hfo2h24
NIPPV / CPAP:	* Yes / No ipvent_cpapb	* Yes / No ipvent_cpaph6	* Yes / No ipvent_cpaph24
Invasive ventilation:	* Yes / No ipvent_iventb	* Yes / No ipvent_iventh6	* Yes / No ipvent_iventh24

IPVENT complete

☐ ipvent__fcomplete

Intervention vasopressors

* Were any vasopressors infused between randomization and 24 hours after randomization? ipvaso_yn
  - ○ Yes (1)
  - ○ No (0)

Record any vasopressor used between randomization and 24 hours post randomization. (To enable a row, click on the checkbox in the left-most column.)

If a vasopressor was initiated **before** randomization, please include it and record the actual start time.

If a vasopressor is still infusing at 24 hours, leave the stop date/time blank and check the box in the "still infusing at 24 hours" column.

	Vasopressor	Start date	Start time	Stop date	Stop time	Still infusing at 24 hours
☐ ipvaso_adm1	* ipvaso_name1: ○ Dobutamine (1) ○ Dopamine (2) ○ Epinephrine (3) ○ Norepinephrine (4) ○ Neosynephrine / phenylephrine (5) ○ Vasopressin (6)	* ipvaso_startdt1	* ipvaso_starttm1	* ipvaso_stopdt1	* ipvaso_stoptm1	☐ still infusing ipvaso_infuse1
☐ ipvaso_adm2	* ipvaso_name2: ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ipvaso_startdt2	* ipvaso_starttm2	* ipvaso_stopdt2	* ipvaso_stoptm2	☐ still infusing ipvaso_infuse2

Vasopressor	Start date	Start time	Stop date	Stop time	Still infusing at 24 hours
* ipvaso_name3 ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
ipvaso_adm3 ☐	* ipvaso_startdt3	* ipvaso_starttm3	* ipvaso_stopdt3	* ipvaso_stoptm3	☐ still infusing ipvaso_infuse3
* ipvaso_name4 ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
ipvaso_adm4 ☐	* ipvaso_startdt4	* ipvaso_starttm4	* ipvaso_stopdt4	* ipvaso_stoptm4	☐ still infusing ipvaso_infuse4
* ipvaso_name5 ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
ipvaso_adm5 ☐	* ipvaso_startdt5	* ipvaso_starttm5	* ipvaso_stopdt5	* ipvaso_stoptm5	☐ still infusing ipvaso_infuse5
* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
☐	*	*	*	*	☐ still infusing
* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
☐	*	*	*	*	☐ still infusing
* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin					
☐	*	*	*	*	☐ still infusing

	Vasopressor	Start date	Start time	Stop date	Stop time	Still infusing at 24 hours
☐	* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ________	* ____	* ________	* ____	☐ still infusing
ipvaso_adm10 ☐	ipvaso_name10 * ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ipvaso_startdt10	* ____ ipvaso_starttm10	* ipvaso_stopdt10	* ____ ipvaso_stoptm10	☐ still infusing ipvaso_infuse10
☐	* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ________	* ____	* ________	* ____	☐ still infusing
☐	* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ________	* ____	* ________	* ____	☐ still infusing
☐	* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ________	* ____	* ________	* ____	☐ still infusing
☐	* ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ________	* ____	* ________	* ____	☐ still infusing

Vasopressor	Start date	Start time	Stop date	Stop time	Still infusing at 24 hours
* ipvaso_name15 ○ Dobutamine ○ Dopamine ○ Epinephrine ○ Norepinephrine ○ Neosynephrine / phenylephrine ○ Vasopressin	* ipvaso_startdt15	* ipvaso_starttm15	* ipvaso_stopdt15	* ipvaso_stoptm15	☐ still infusing ipvaso_infuse15

ipvaso_adm15 ☐

IPVASO complete

☐ ipvaso__fcomplete

CLOVERS
Study Intervention Period

Intervention central line placement

IPCLP complete

☐ ipclp__fcomplete

* Was a venous central line inserted between randomization and 72 hours after randomization? ipclp_vclyn

○ Yes (1)
○ No (0)

Date and time of first venous central line insertion between randomization and 72 hours after randomization:

* ipclp_insertiondt * ipclp_insertiontm

For each of the following complications, indicate whether the complication occurred between randomization and study day 28 as a result of **any venous central line inserted between randomization and 72 hours**.

* Catheter-related bloodstream infection? ipclp_bloodinf

○ Yes (1)
○ No (0)

* What was the highest grade of complication experienced? ipclp_bloodinfgrade

(1) ○ Grade 1 – NA
(2) ○ Grade 2 – Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, or antiviral)
(3) ○ Grade 3 – IV antibiotic, antifungal, or antiviral intervention indicated; invasive intervention indicated
(4) ○ Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) ○ Grade 5 – Death (as a result of the catheter-related bloodstream infection)

* Catheter-related deep-vein thrombosis? ipclp_dvt

○ Yes (1)
○ No (0)

* What was the highest grade of complication experienced? ipclp_dvtgrade

(1) ○ Grade 1 – TPA administration into line with no intent for systemic therapy indicated
(2) ○ Grade 2 – Device dislodgement, blockage, leak, or malposition; device replacement indicated
(3) ○ Grade 3 – Pulmonary embolism, deep vein or cardiac thrombosis; intervention indicated (e.g., anticoagulation, lysis, filter, invasive procedure)
(4) ○ Grade 4 – Life-threatening consequences with hemodynamic or neurologic instability
(5) ○ Grade 5 – Death (as a result of the deep-vein thrombosis)

* Pneumothorax? ipclp_pneumothorax

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_pneumothoraxgrade

(1) Grade 1 – Asymptomatic; clinical or diagnostic observations only; intervention not indicated
(2) Grade 2 – Symptomatic; intervention indicated
(3) Grade 3 – Sclerosis and/or operative intervention indicated; hospitalization indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the pneumothorax)

* Arterial injury? ipclp_artinj

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_artinjgrade

(1) Grade 1 – NA
(2) Grade 2 – Repair or revision not indicated
(3) Grade 3 – Severe symptoms; limiting self care ADL (e.g., transient cerebral ischemia); repair or revision indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the arterial injury)

* Venous injury? ipclp_veninj

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_veninjgrade

(1) Grade 1 – NA
(2) Grade 2 – Repair or revision not indicated
(3) Grade 3 – Symptomatic limiting self care ADL; repair or revision indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the venous injury)

* Post-procedural hemorrhage (including hemothorax and insertion site bleeding)? ipclp_pphemorr

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_pphemorrgrade

(1) Grade 1 – Mild symptoms; intervention not indicated
(2) Grade 2 – Moderate bleeding requiring transfusion < 2 units of pRBCs
(3) Grade 3 – Transfusion indicated of >=2 units pRBCs; invasive intervention indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the post-procedural hemorrhage)

* Post-procedural hematoma? ipclp_pphemat

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_pphematgrade

(1) Grade 1 – Mild symptoms; intervention not indicated
(2) Grade 2 – Minimally invasive evacuation or aspiration indicated
(3) Grade 3 – Transfusion; invasive intervention indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the post-procedural hematoma)

* Ventricular arrhythmia? ipclp_ventarrhyth

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_ventarrhythgrade

(1) Grade 1 – Asymptomatic, intervention not indicated
(2) Grade 2 – Non-urgent medical intervention indicated
(3) Grade 3 – Urgent intervention indicated
(4) Grade 4 – Life-threatening consequences; hemodynamic compromise
(5) Grade 5 – Death (as a result of the ventricular arrhythmia)

* Atrial arrhythmia? ipclp_atrarrhyth

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_atrarrhythgrade

(1) Grade 1 – Asymptomatic, intervention not indicated
(2) Grade 2 – Non-urgent medical intervention indicated
(3) Grade 3 – Symptomatic, urgent intervention indicated; device (e.g., pacemaker); ablation; new onset
(4) Grade 4 – Life-threatening consequences; requiring urgent intervention
(5) Grade 5 – Death (as a result of the atrial arrhythmia)

* Infusion site extravasation? ipclp_ise

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ipclp_isegrade

(1) Grade 1 – NA
(2) Grade 2 – Erythema with associated symptoms (eg, edema, pain, induration, phlebitis)
(3) Grade 3 – Ulceration or necrosis, severe tissue damage; operative intervention indicated
(4) Grade 4 – Life-threatening consequences; urgent intervention indicated
(5) Grade 5 – Death (as a result of the infusion site extravasation)

* Air embolism? ipclp_embolism

- Yes (1)
- No (0)

Intervention peripheral venous catheter vasopressor infusion

IPPVC complete

☐ ippvc__fcomplete

* Were vasopressors infused through a peripheral venous catheter (ie, peripheral IV or midline) between randomization and 72 hours after randomization? ippvc_vasopressors

- Yes (1)
- No (0)

Date and time of first infusion of vasopressors through a peripheral venous catheter between randomization and 72 hours after randomization:

* ippvc_infdt * ippvc_inftm

* Did infusion site extravasation occur between randomization and study day 28 as a result of any infusion of vasopressors that occurred through a peripheral venous catheter between randomization and 72 hours? ippvc_ise

- Yes (1)
- No (0)

* What was the highest grade of complication experienced? ippvc_isegrade

(1) Grade 1 – NA

(2) Grade 2 – Erythema with associated symptoms (eg, edema, pain, induration, phlebitis)

(3) Grade 3 – Ulceration or necrosis, severe tissue damage; operative intervention indicated

(4) Grade 4 – Life-threatening consequences; urgent intervention indicated

(5) Grade 5 – Death (as a result of the infusion site extravasation)

Intervention date override

Was this instance of the "study intervention period" interval created incorrectly, and thus should be deleted? intdtover_yn

- Yes (1)
- No (0)

* Please enter the date that the CCC told you to enter here:

intdtover_date

CLOVERS
Protocol Deviation

Protocol deviation

PD complete

☐ pd__fcomplete

* Date deviation occurred:

pd_devdt

* Date deviation discovered:

pd_devrepdt

* Type of deviation: pd_devtype

- ○ Eligibility error (1)
- ○ Randomization error (3)
- ○ Sample error (4)
- ○ Consent error (5)
- ○ Other (888)

* Please specify:

pd_other

* Describe deviation:

pd_desc

* Describe steps taken to resolve the deviation and prevent future occurrences:

pd_resolution

* Were study procedures temporarily or permanently discontinued as a result of this deviation? pd_procstop

- ○ Yes (1)
- ○ No (0)

* Was an adverse event reported as a result of this deviation? pd_ae

- ○ Yes (1)
- ○ No (0)

Protocol deviation ID:

pd_id

CLOVERS
Adverse Event

Adverse event

AE complete

☐ ae__fcomplete

Date and time of adverse event:

* ae_dt * ae_tm

* COSTART term:

ae_userterm [lookup tool]

MedDRA code: ae_meddracode

* Description of adverse event:

ae_desc

* Was the adverse event serious? ae_serious

- ○ Yes (1)
- ○ No (0)

* Was the adverse event related to study procedures? ae_relproc

- ○ Definitely related (1)
- ○ Probably or possibly related (2)
- ○ Probably not related (3)
- ○ Definitely not related (4)
- ○ Uncertain relationship (5)

* Was the adverse event unexpected (not listed in the investigator brochure or protocol)? ae_unexpected

- ○ Yes (1)
- ○ No (0)

* What was the status of the adverse event at the time of the initial AE report? ae_status

- ○ Recovered (1)
- ○ AE present, no treatment (2)
- ○ AE present, being treated (3)
- ○ Residual effect / no treatment (4)
- ○ Residual effect / being treated (5)
- ○ Deceased as a result of the AE (6)

* What was the final outcome of the adverse event? ae_outcome

- ○ Recovered (1)
- ○ AE present, no treatment (2)
- ○ AE present, being treated (3)
- ○ Residual effect / no treatment (4)
- ○ Residual effect / being treated (5)
- ○ Deceased as a result of the AE (6)

* Date of recovery

ae_recdt

Adverse event ID:
ae_id