

Public Use Dataset  
Annotated eCRF

**Bleeding and Thrombosis During ECMO  
(BATE)**

**CPCCRN Protocol Number 048**

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Collaborative Pediatric Critical Care Research Network  
*Eunice Kennedy Shriver* National Institute for Child  
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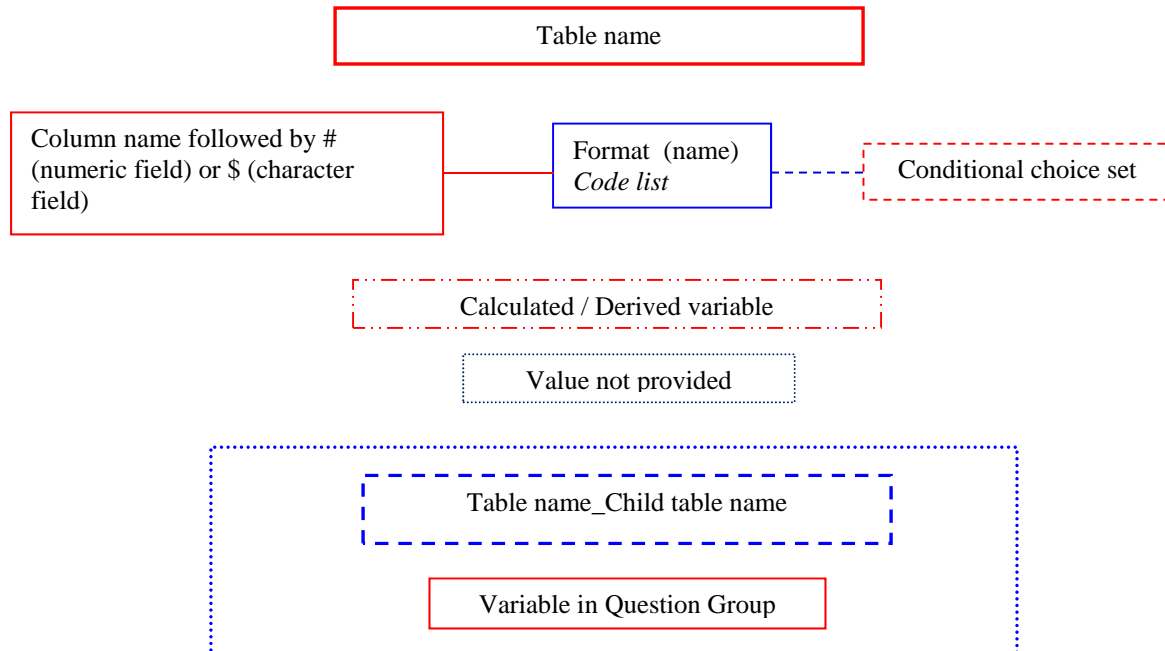
Annotated eCRF Version 1.0

Version Date: February 16, 2016

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## Annotations key



## Notes

StudySubjectID was replaced by PudID, sequential integers, that uniquely identifies a patient across datasets, it does not contain information about original site or medical record number. Occurrence and ItemGroupRepatKey are also unique subject identifiers.

All out of range and other questionable data have been included in the public use datasets.

Sensitive and/or identifying information entered in free text fields have been removed from the public use datasets.

'Date' variables are replaced with 'day' variables. Day variables are populated with the number of days since the reference date, ICU admission date. ICU admission date is coded as 0 (Day 0) and all other dates will be recoded as number of days after Day 0 (if any dates occur before the ICU admission day, these dates will have a negative value).

Eligibility (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Eligibility:**

◀ Inclusion... (0/4) Exclusion... (0/2) ▶ -- Select to Jump -- ▼

**Title: Inclusion Criteria**

Screening Date:  \* (DD-MMM-YYYY)

**Inclusion Criteria**

1. Is the patient between 0 (zero) days and < 19 years of age?

☐ Yes ☐ No \*

2. Has the patient been admitted to a Pediatric, Cardiac, or Neonatal ICU?

☐ Yes ☐ No \*

3. Did the patient receive ECMO during the ICU stay?

☐ Yes ☐ No \*

If the patient does not meet inclusion criteria, do not save this information to the database.

◀ Inclusion... (0/4) Exclusion... (0/2) ▶ -- Select to Jump -- ▼

**Title: Exclusion Criteria**

**Exclusion Criteria**

1. Has the patient been previously enrolled in this study?

☐ Yes ☐ No \*

**Is patient eligible?**

Eligible patients have all inclusion criteria as Yes, and all exclusion criteria as No.

☐ Yes ☐ No \*

If "No", save this page and do not continue. You have completed data entry for this patient.

Demog (1 of 1)

## ECMO Demographics:

PudID #

Occurrence #

ItemGroupRepeatKey #

Demog (0/5) -- Select to Jump --

**Title: Demographics**

Date of birth: BirthDay, # (DD-MMM-YYYY)

Sex: ☐ Male ☐ Female Sex, #

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown or Not Reported Ethnicity, #

Race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown or Not Reported (select all that apply)

Gestational age at birth: GestationAge, # (weeks)

Ethnic  
1 = Hispanic or Latino  
2 = Not Hispanic or Latino  
92 = Unknown or Not Reported

Sex  
1 = Male  
2 = Female

## Additional / derived variables included in the DEMOG dataset:

Variable	Type	Label	Algorithm / Notes
RACE1	#	American Indian or Alaska Native	1 = Yes, 0 = No
RACE2	#	Asian	1 = Yes, 0 = No
RACE3	#	Black or African American	1 = Yes, 0 = No
RACE4	#	Native Hawaiian or Other Pacific Islander	1 = Yes, 0 = No
RACE5	#	White	1 = Yes, 0 = No
RACE92	#	Unknown or Not Reported	1 = Yes, 0 = No

# BATE Annotated eCRF

Diagnoses (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Diagnoses:

Diagnoses... (0/8) -- Select to Jump --

Title: Diagnoses

Primary Diagnosis: PrimaryDx, # Other (specify): PrimaryDxOther, \$

Does the patient have any secondary diagnoses?

SecondDxYN, # If yes, provide diagnoses below.

Secondary Diagnoses	Other (specify)	Diagnoses_Second
SecondDx, #	SecondDxOther, \$	
ADD		

Does the patient have any chronic diagnoses?

ChronicDxYN, # If yes, provide diagnoses below.

Chronic Diagnoses	Other (specify)	Diagnoses_Chronic
ChronicDx, #	ChronicDxOther, \$	
ADD		

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

- PrimDX
- 1=Airway/tracheal abnormality, obstruction, surgery
  - 2=Asthma
  - 3=Cancer
  - 4=Cardiac arrest
  - 5=Cardiovascular disease – acquired
  - 6=Cardiovascular disease – arrhythmia
  - 7=Cardiovascular disease – congenital
  - 8=Central nervous system infection
  - 9=Congenital anomaly or chromosomal defect
  - 10=Diabetes (non-DKA)
  - 11=Diabetic ketoacidosis (DKA)
  - 12=Drowning / asphyxia / hanging
  - 13=Gastrointestinal disorder
  - 14=Hematologic disorder
  - 15=HIV infection
  - 16=Hypoxic ischemic encephalopathy
  - 17=Ingestion (drug or toxin)
  - 18=Medical device malfunction
  - 19=Musculoskeletal condition
  - 20=Neurological miscellaneous
  - 21=Neurological - cords, bones
  - 22=Neurological - vascular malformations
  - 23=Neurological CSF related (hydrocephalus / Chiari / fenestrations / arachnoid cysts)
  - 24=Pertussis
  - 25=Pneumonia / bronchiolitis
  - 26=Renal failure
  - 27=Respiratory distress / failure
  - 28=Scoliosis / spine surgery
  - 29=Seizures
  - 30=Sepsis / SIRS / septic shock
  - 31=Shock (non-septic)
  - 32=Stroke / cerebral ischemia / cerebral infarction
  - 33=Suicide attempt
  - 34=Transplant
  - 35=Trauma
  - 90=Other

- ChronDX
- 1=Asthma
  - 2=Cancer
  - 3=Cardiovascular disease – acquired
  - 4=Cardiovascular disease – arrhythmia
  - 5=Cardiovascular disease – congenital
  - 6=Chronic renal failure
  - 7=Chronic lung disease (BPD, CF)
  - 8=Congenital anomaly or chromosomal defect
  - 9=Diabetes
  - 10=Musculoskeletal
  - 11=Neurologic - static encephalopathy
  - 12=Neurologic - Other chronic condition
  - 13=Neurologic - chronic seizures
  - 14=Transplant
  - 90=Other

\* excluded values: Diagnoses\_Second with SecondDx = 15 (HIV), DIAGNOSES\_CHRONIC with ChronicDxOther = 'HIV infection'

TechDepend (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Technology Dependence:**

◀ TechDep...(0/8) ▶ -- Select to Jump -- ▼

Title: Technology Dependence	
Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.	
Gastrostomy tube: (select one) ▼	Gastrostomy, #
Other feeding tube: (select one) ▼	OtherFeedTube, #
Oxygen: (select one) ▼	Oxygen, #
Tracheostomy: (select one) ▼	Tracheostomy, #
Home ventilator: (select one) ▼	HomeVent, #
Ventricular shunt (CSF): (select one) ▼	VentricularShunt, #
Chronic dialysis: (select one) ▼	Dialysis, #
Chronic vascular access: (select one) ▼	VascularAccess, #

YesNo  
1=Yes  
0=No

Dates (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Hospitalization Dates and Death Information:**

◀ **Dates (0/12)** ▶ -- Select to Jump -- ▼

Title: Study Dates			
<b>Hospital Admission Date and Time</b>			
Hospital Admission Date:	HOSPADMITDAY, #	(DD-MMM-YYYY)	Hospital Admission Time: HospAdmitTime, \$ (HHMM)
<b>ICU Admission Date and Time</b>			
ICU Admission Date:	ICUADMITDAY, #	(DD-MMM-YYYY)	ICU Admission Time: ICUAdmitTime, \$ (HHMM)
<b>ICU Discharge Date and Time</b>			
ICU Discharge Date:	ICUDISDAY, #	(DD-MMM-YYYY)	ICU Discharge Time: ICUDisTime, \$ (HHMM)
<b>Hospital Discharge Information</b>			
Hospital Discharge Date:	HOSPDISDAY, #	(DD-MMM-YYYY)	Hospital Discharge Time: HospDisTime, \$ (HHMM)
Vital Status at Hospital Discharge:	(select one) ▼	HospVitalStatus, #	VitStat 1=Alive 0=Dead
<b>Death Information</b>			
Date of Death:	DEATHDAY, #	(DD-MMM-YYYY)	Time of Death: DeathTime, \$ (HHMM)
Did the patient die following withdrawal of support?			
(select one) ▼	WithdrawOfSupport, #		
YesNo 1=Yes 0=No			



PM (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Physical Measurements:**

◀ **Measure...**(0/4) ▶ -- Select to Jump -- ▼

Title: Measurements			
Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.			
Length / Height:	Height, #	(cm)	Weight: Weight, # (kg)
Head Circumference:	HeadCirc, #	(cm)	HeadCircND, # <input type="checkbox"/> Head circumference not documented

NotDoc  
94=Head circumference not documented

VM (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Vital Measurements:

◀ **Vitals (0/10)** **PR (0/3)** ▶ -- Select to Jump -- ▼

**Title: Vital Signs**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Cardiorespiratory vitals

Date: **CARDIODAY, #** (DD-MMM-YYYY) Time: **CardioTime, \$** (HHMM)

Heart rate: **HeartRate, #** (beats/min) Respiratory rate: **RespRate, #** (breaths/min)

Systolic blood pressure (SBP): **SBP, #** (mmHg) Diastolic blood pressure (DBP): **DBP, #** (mmHg)

Mean arterial blood pressure: **MeanBP, #** (mmHg)

Temperature

Date: **TEMPDAY, #** (DD-MMM-YYYY) Time: **TempTime, \$** (HHMM)

Temperature: **Temperature, #** (°C)

◀ **Vitals (0/10)** **PR (0/3)** ▶ -- Select to Jump -- ▼

**Title: Pupillary Reflexes**

Date: **PUPILDAY, #** (DD-MMM-YYYY) Time: **PupilTime, \$** (HHMM)

Pupillary reflexes: **PupilReflex, #** ▼

Pupil  
 1=Both reactive  
 2=One non-reactive (> 3mm)  
 3=Both non-reactive (> 3mm)  
 4=Both pupils < 3mm, cannot be scored

BaseVent (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Ventilator Settings:

Vent (0/15) -- Select to Jump --

**Title: Ventilator Settings**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Was the patient receiving respiratory support in the 12 hours prior to ECMO initiation?

VentSupportYN, #  If yes, provide details below
 

YesNo  
 1=Yes  
 0=No

Date: VENTDAY, #  (DD-MMM-YYYY)
 Time: VentTime, \$ (HHMM)

Ventilator Mode: VentMode, # 
 Other (specify): VentModeOther, \$

Ventilator Rate: VentilatorRate, # (bpm)

Tidal Volume Exhaled: VTEinhaled, # (mL)

Set Tidal Volume: VTSet, # (mL)

PIP: PIP, # (cmH2O)

Pressure Support: PS, # (cmH2O)

Mean Airway Pressure: MAP, # (cmH2O)

PEEP: PEEP, # (cmH2O)

FIO2: FiO2, # (#.##) \*MUST be a decimal\*

HFOV Frequency: HFOVFrequency, #

HFOV Amplitude: HFOVAmplitude, #

VentMode  
 1=Pressure Control  
 2=PRVC  
 3=HFOV  
 4=Volume Control  
 5=Non-invasive Ventilation  
 6=Pressure Support and CPAP  
 90=Other

# BATE Annotated eCRF

BaseCBC (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Complete Blood Count w/o diff:

CBC (0/6)
-- Select to Jump --

**Title: Complete Blood Count without differential**  
Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date (DD-MMM-YYYY)	Time (HHMM)	Hemoglobin (g/dL)	Hematocrit (%)	Platelets (10 <sup>3</sup> /μL)	WBC (10 <sup>3</sup> /μL)
<div>CBCNODIFFDAY, #</div>	<div>CBCNoDiffTime, \$</div>	<div>HgbMass, #</div>	<div>HCTPct, #</div>	<div>Platelet, #</div>	<div>WBC, #</div>

# BATE Annotated eCRF

BaseABG (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Arterial Blood Gases:

ABG (0/10) -- Select to Jump --

Title: Arterial Blood Gases

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date (DD-MMM-YYYY)	Time (HHMM)	pH (#.#)	paCO2 (mmHg)	paO2 (mmHg)	HCO3 (mmol/L)	SaO2 (%)	FI02 (#.#) Must be a decimal	Ionized Calcium	Ionized Calcium Unit
ABGDAY, #	ABGTime, \$	pHArtBld, #		PaO2ArtBld, #		SaO2, #		CalonArtBld, #	select one) X
			PCO2ArtBld, #		HCO3, #		ABGFI02, #		CalonArtBldUnit, #

ADD

Ion  
1=mg/dL,  
2=mmol/L

BATE Annotated eCRF

BaseBMP (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

ECMO Baseline Chemistries:

BMP (0/9)
Chem (0/14)
-- Select to Jump --

**Title: Basic Metabolic Panel**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date (DD-MMM-YYYY)	Time (HHMM)	Sodium (mmol/L)	Potassium (mmol/L)	Chloride (mmol/L)	HCO3 (mmol/L)	BUN (mg/dL)	Creatinine (mg/dL)	Glucose (mg/dL)
BMPDAY, #	BMPTIME, \$	Sodium, #	Potassium, #	Chloride, #	Bicarbonate, #	BUNmg, #	Creatinine, #	Glucose, #

ADD

Note: Although the case report form reflects HCO3 as being collected, the lab value being provided in this data field represents total CO2.

BaseChemOne (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Chemistries:

◀ BMP (0/9) Chem (0/14) ▶ -- Select to Jump -- ▼

Title: Chemistries

Date (DD-MMM-YYYY)	Time (HHMM)	Total Bilirubin (mg/dL)	Alkaline phosphatase (ALP) (IU/L)	Aspartate aminotransferase (AST) (IU/L)	Alanine aminotransferase (ALT) (IU/L)	Lactate dehydrogenase (LDH) (IU/L)	
CHEMDAYONE, #	ChemTimeOne, \$	TotalBilirubin, #	ALP, #	AST, #	ALT, #	LDH, #	X
ADD							

BaseChemTwo (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Chemistries:

Date (DD-MMM-YYYY)	Time (HHMM)	Albumin (g/dL)	Total Protein (g/dL)	Calcium (mg/dL)	Lactate	Lactate Unit	
CHEMDAYTWO, #	ChemTimeTwo, \$	Albumin, #	TotalProtein, #	Calciummg, #	Lactate, #	(select one) ▼	X
						LactateUnit, #	
<div>ADD</div>							

Lactate  
1=mg/dL  
2=mmol/L



BATE Annotated eCRF

BaseCoag (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

ECMO Baseline Coagulation Labs:

Coag (0/5)

OtherCo...(0/7)

-- Select to Jump --

Title: Coagulation Labs

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date (DD-MMM-YYYY)	Time (HHMM)	PT (seconds)	PTT (seconds)	INR
<div>COAGDAY, #</div>	<div>CoagTime, \$</div>	<div>PT, #</div>	<div>PTT, #</div>	<div>INR, #</div>

ADD

BaseOtherCoag (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Baseline Coagulation Labs:

◀ Coag (0/5) OtherCo... (0/7) ▶ -- Select to Jump -- ▼

Title: Other Coagulation Labs

Date (DD-MMM-YYYY)	Time (HHMM)	Fibrinogen	Fibrinogen unit	Activated clotting time (ACT) (seconds)	ATIII (%)	Anti Xa (IU/mL)	
OTHERCOAGDAY, #	OtherCoagTime, \$	Fibrinogen, #	(select one) ▼	ACT, #	ATIIICoag, #	AntiXa, #	X
FibrinogenUnit, #							
ADD							

fib  
1=mg/dL  
2=ng/mL

## Infection (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Infection Information:

Infecti...(0/10)

-- Select to Jump --

## Title: Infection Information

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Was a culture- or PCR-proven bacterial or fungal infection diagnosed prior to ECMO initiation?

BaseFungalInfect, #

If yes, provide details below

YesNo  
1=Yes  
0=No

## Fungal and Bacterial Infections

Specimen Collection Date  
(DD-MMM-YYYY)Specimen Collection Time  
(HHMM)

Upload Report

Infection\_BaseFungal

BASEFUNGALINFECTDAY, #

BaseFungalInfectTime, \$

Value not provided

Click to upload file

X

ADD

Was a culture- or PCR-proven viral infection diagnosed prior to ECMO initiation?

BaseViralInfect, #

If yes, provide details below

YesNo  
1=Yes  
0=No

## Viral Infections

Specimen Collection Date  
(DD-MMM-YYYY)Specimen Collection Time  
(HHMM)

Upload Report

Infection\_BaseViral

BASEVIRALINFECTDAY, #

BaseViralInfectTime, \$

Value not provided

Click to upload file

X

ADD

Was an unproven, suspected infection diagnosed and treated with antibiotics, antifungals, or antivirals prior to ECMO initiation?

BaseUnprovenInfect, #

If yes, specify type

YesNo  
1=Yes  
0=NoType of suspected  
infection:  
(check all that apply)  
☐ Bacterial  
☐ Fungal  
☐ Viral

## Additional / derived variables included in the INFECTION dataset:

Variable	Type	Label	Algorithm / Notes
BaseUnprovenInfectType1	#	Bacterial	1 = Yes, 0 = No
BaseUnprovenInfectType2	#	Fungal	1 = Yes, 0 = No
BaseUnprovenInfectType3	#	Viral	1 = Yes, 0 = No

VIS (1 of 1)

## ECMO Vasoactive-Inotropic Score v1.0:

PudID #


Occurrence #

ItemGroupRepeatKey #

◀ **VIS (0/12)** ▶ -- Select to Jump -- ▼

**Title: Vasoactive-Inotropic Score**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date:	<input type="text" value="VISDAY, #"/>	 (DD-MMM-YYYY)	Time:	<input type="text" value="VISTime, \$"/>	(HHMM)
Dopamine:	<input type="text" value="VISDopamine, #"/>	(µg/kg/min)			
Dobutamine:	<input type="text" value="VISDobutamine, #"/>	(µg/kg/min)			
Nitroprusside:	<input type="text" value="VISNitroprusside, #"/>	(µg/kg/min)			
Milrinone:	<input type="text" value="VISMilrinone, #"/>	(µg/kg/min)			
Epinephrine:	<input type="text" value="VISEpinephrine, #"/>	(µg/kg/min)			
Norepinephrine:	<input type="text" value="VISNorepinephrine, #"/>	(µg/kg/min)			
Phenylephrine:	<input type="text" value="VISPhenylephrine, #"/>	(µg/kg/min)			
Vasopressin:	<input type="text" value="VISVasopressin, #"/>	(munits/kg/hr)			
Isoproterenol:	<input type="text" value="VISIsoproterenol, #"/>	(µg/kg/min)			

Were any bolus vasoactive medications given in the hour prior to ECMO initiation?

<input type="text" value="VISBolusGiven, #"/>	▼	YesNo 1=Yes 0=No
---	---	------------------------

NOTE: Two versions of the Vasoactive-Inotropic Score exist; however, the raw dataset has stacked versions, VIS\_ALLVERSIONS.

VIS\_v2 (1 of 1)

## ECMO Vasoactive-Inotropic Score v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

VIS (0/13) -- Select to Jump --

**Title: Vasoactive-Inotropic Score**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date: VISDAY, # (DD-MMM-YYYY) Time: VISTime, \$ (HHMM)

Dopamine: VISDopamine, # (µg/kg/min)

Dobutamine: VISDobutamine, # (µg/kg/min)

Nitroprusside: VISNitroprusside, # (µg/kg/min)

Milrinone: VISMilrinone, # (µg/kg/min)

Epinephrine: VISEpinephrine, # (µg/kg/min)

Norepinephrine: VISNorepinephrine, # (µg/kg/min)

Phenylephrine: VISPhenylephrine, # (µg/kg/min)

Vasopressin: VISVasopressin, # Unit: (select one) VISVasopressinUnit, #

Isoproterenol: VISIsoproterenol, # (µg/kg/min)

Were any bolus vasoactive medications given in the hour prior to ECMO initiation?

VISBolusGiven, #

YesNo  
1=Yes  
0=No

VasoUnit  
1 = munits/kg/hr  
2 = units/kg/hr  
3 = units/hr  
4 = munits/kg/min  
5 = units/kg/min

NOTE: Two versions of the Vasoactive-Inotropic Score exist; however, the raw dataset has stacked versions, VIS\_ALLVERSIONS.

Severity (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Functional Status Assessments:

StudyEvent, \$

POP/PC...(0/3) FSS (0/7) -- Select to Jump --

**Title: PCPC and POPC**

Date: PCPCDAY, # (DD-MMM-YYYY)

**Pediatric Cerebral Performance Category (PCPC)**

PCPC: PCPCScore, INT

**Pediatric Overall Performance Category (POPC)**

POPC: POPCScore, INT

PCPC

1=1 – Normal

2=2 – Mild disability

3=3 – Moderate disability

4=4 – Severe disability

5=5 – Coma/vegetative state

6=6 – Brain Death

POPC

1=1 – Good

2=2 – Mild disability

3=3 – Moderate disability

4=4 – Severe disability

5=5 – Coma/vegetative state

6=6 – Brain Death

POP/PC...(0/3) FSS (0/7) -- Select to Jump --

**Title: Functional Status Scale**

Date: FSSDAY, # (DD-MMM-YYYY)

Mental Status Classification: FSSMental, INT

Sensory Classification: FSSSensory, INT

Communication Classification: FSSCommun, INT

Motor Function Classification: FSSMotor, INT

Feeding Classification: FSSFeeding, INT

Respiratory Classification: FSSResp, INT

FSS

1=Normal

2=Mild dysfunction

3=Moderate dysfunction

4=Severe dysfunction

5=Very severe dysfunction

NOTE: The SEVERITY dataset has an additional unique identifier that indicates a baseline or discharge measurement.

## ECMO Initiation of ECMO:

PudID #

Occurrence #

ItemGroupRepeatKey #

ECMO (0/18)

-- Select to Jump --

## Title: ECMO Information

Initiation date of ECMO: **ECMOSTARTDAY, #** (DD-MMM-YYYY)  
(start of flow)Initiation time of ECMO: **ECMStartTime, \$** (HHMM)

Mode of ECMO:

**ModeECMO, #**

Other (specify):

**ModeECMOOther, \$**

Mode

1=VA

2=VA + V

3=VA-VV

4=VV

5=VV-VA

6=VVA

7=VVDL

8=VVDL + V

90=Other

Location of ECMO Care:

**LocationsECMO, #**

(select one)

ECMOCare

1=ICU

2=NICU

3=CICU

Primary ECMO Indication:

**IndicationECMO, #**

(select one)

ECMOInd

1=Respiratory

2=Cardiac

3=ECPR

Does the patient have meconium aspiration syndrome?

**MAS, #**

(select one)

Does the patient have congenital diaphragmatic hernia?

**CDH, #**

(select one)

Does the patient have congenital cystic adenomatoid malformation?

**CCAM, #**

(select one)

Does the patient have persistent pulmonary hypertension of the newborn?

**PPHTN, #**

(select one)

Did the patient have any operative procedures in the 24 hours prior to ECMO initiation?

**OpProcedure, #**

(select one)

If yes, record the date and start time of the most recent procedure

Stop date:

**OPPROCEDUREDAY, #** (DD-MMM-YYYY)

Stop time:

**OpProcedureTime, \$** (HHMM)

Was the patient on cardiopulmonary bypass in the 24 hours prior to ECMO initiation?

**CBP, #**

(select one)

If yes, record the most recent occurrence

Stop date:

**CPBDAY, #** (DD-MMM-YYYY)

Stop time:

**CPBTime, \$** (HHMM)

Was the patient placed on ECMO directly from cardiopulmonary bypass?

**CPBToECMO, #**

(select one)

Was the patient placed on ECMO by way of an EXIT procedure?

**ExitToECMO, #**

(select one)

YesNo

1=Yes

0=No

## ECMO Equipment and Setup:

PudID #

Occurrence #

ItemGroupRepeatKey #

Setup (0/31) -- Select to Jump --

**Title: ECMO Equipment and Setup**

**Pump**

Is the pump type centrifugal?

CentrifugePump, # (select one) If yes, specify pump ID

Pump ID: (from ELSO registry) CentrifugePumpID, #

Is the pump type roller head?

RollerPump, # (select one) If yes, specify pump ID

Pump ID: (from ELSO registry) RollerPumpID, #

**Oxygenator**

Is the oxygenator a silicone lung?

SiliconeLung, # (select one) If yes, provide size Size of oxygenator: OxygenatorSize, # (m2)

Is the oxygenator hollow fiber?

HollowFiber, # (select one) If yes, specify model

Vendor: (select one) Other (specify): HollowFiberVendorOther, \$

HollowFiberVendor, #

Is the oxygenator coated?

OxygenCoating, # (select one) If yes, specify type

Type: (select one) Other (specify): OxygenCoatingTypeOther, \$

OxygenCoatingType, #

**Tubing**

Provide the name of the circuit tubing vendor:

TubingVendor, \$

Is the circuit tubing coated?

TubingCoating, # (select one) If yes, specify type

Type: (select one) Other (specify): TubingCoatingTypeOther, \$

TubingCoatingType, #

YesNo  
1=Yes  
0=No

HiFiber  
1=Infinity  
2=Lilliput  
3=Medos  
4=Medtronic  
5=Medtronic minimax  
6=Quadrox  
7=Quadrox-D  
8=Quadrox-iD  
9=Terumo  
90=Other

Coat  
1=Bioline  
2=Carmeda  
3=Safeline  
90=Other



## Equipment\_v2 (2 of 2)

## ECMO Equipment and Setup:

PudID #

Occurrence #

ItemGroupRepeatKey #

## Priming

How was the circuit primed?

Prime  
1=Non-blood (clear)  
2=Blood product

MethodPrimeCircuit, #

Note: if circuit was primed with blood product, record the amount on the blood product information form

If the circuit was primed with non-blood, was there a hemodilution correction strategy?

NonBloodPrimeCorrect, #

If yes, provide details

YesNo  
1=Yes  
0=No

What was the

(select one)

Other (specify):

NonBloodPrimeOther, \$

strategy for

NonBloodPrimeMethod, #

Non-blood (clear)  
priming volume

NonBloodPrimeVolume, #

(mL)

Strategy  
1=Exchange transfusion  
2=Hemofiltration  
90=Other

## Other Setup Information

What is the configuration of the circuit bridge?

CircuitBridgeConfig, #

Circuit  
1=In-line with stopcock  
2= In-line but clamped  
3=Not in-line

Does the equipment setup include a bladder / venous reservoir?

BladderReservoir, #

Does the equipment setup include negative pressure monitoring?

NegativePressure, #

## Heparin

Was a heparin bolus used for cannulation?

HeparinBolus, #

If yes, provide dose

Dose

HeparinBolusDose, #

(IU/kg)

At what time was the initial heparin infusion given after the initiation of ECMO?

Date:

HEPARINAFTERECMODAY, # (YYYY)

Time:

(HHMM)

HepAfterECMOTime, \$

## Activated Clotting Time

Date of first ACT after  
ECMO initiation  
(if measured):

FIRSTACTDAY, #



(DD-MMM-YYYY)

Time of first ACT after  
ECMO initiation  
(if measured):

FirstACTTime, \$

(HHMM)

First ACT Results  
(if measured)

FirstACTResult, #

☐ Too high to read

FirstACTTooHigh, #

YesNo  
1=Yes  
0=No

TooHigh  
1=Too high to read

HeparinPrime (1 of 1)


PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Heparin Units for Circuit Priming:**

◀ **Heparin...**(0/2) ▶ -- Select to Jump -- ▼

Title: Heparin Units for Circuit Priming	
Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.	
Study date:	HEPARINUNITDAY, #  (DD-MMM-YYYY)
How many units of heparin were used to prime the circuit prior to ECMO initiation?	
HeparinPrimingUnits, #	(units)

## Cannulation\_v2 (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Cannulation Characteristics:

Cannula...(0/8) VenArtC...(0/21) OtherCa...(0/14) -- Select to Jump --

**Title: Basic Cannula Information**

Date initial cannulation achieved: CANNULASTARTDAY, # (D-MMM-YYYY)
 Time initial cannulation achieved: CannulaStartTime, \$ (HHMM)

The questions below only need to be answered on the day of patient's final separation from ECMO.

Date of final separation: CANNULASTOPDAY, # (D-MMM-YYYY)
 Time of final separation: CanRemoveStopTime, \$ (HHMM)

Status at time of final separation: StatusAtCanRemove, #

On the day of final separation, what was the flow rate one hour prior to removal?
 FlowAtCanRemove, #

Flow Rate Unit (select one)
 FRUnit  
 1=mL/min  
 2=L/min

FlowAtCanRemoveUnit, #

After final separation, was the patient recannulated within 24 hours?

(select one)

Recannulated, #

YesNo  
 1=Yes  
 0=No

Dstat  
 1=Alive  
 0=Dead  
 2=Transition to VAD

Cannulation\_Venous\_v2 (1 of 1)

## ECMO Cannulation Characteristics :

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ Cannula...(0/7) VenArtC...(0/21) OtherCa...(0/14) ▶ -- Select to Jump -- ▼

**Title: Venous and Arterial Cannulae**

Instructions: Document each inserted cannula for this patient while enrolled in this study.

**Venous Cannulae**

Date of Cannula Placement (DD-MMM-YYYY)	Time of Cannula Placement (HHMM)	Cannula Site	Other (specify)	Cannula ID (from ELSO registry)	Date of Cannula Removal (DD-MMM-YYYY)	Time of Cannula Removal (HHMM)
<input type="text"/>	VenousCanPlaceTime, \$	VenousCannulaSite, #	<input type="text"/>	VenousCannulaID, #	<input type="text"/>	<input type="text"/>
		VenousCannulaSiteOther, \$				

VENOUSCANPLACEDAY, #

VENOUSCANREMOVEDAY, #

VenousCanRemoveTime, \$

VeinSite  
1=Right Internal Jugular Vein (RIJV)  
2=Left Internal Jugular Vein (LIJV)  
3=Right Femoral Vein (RFV)  
4=Left Femoral Vein (LFV)  
5=Right Atrium (RA)  
90=Other

## Cannulation\_Arterial\_v2 (1 of 1)

## ECMO Cannulation Characteristics:

PudID #

Occurrence #

ItemGroupRepeatKey #

## Arterial Cannulae

Date of Cannula Placement (DD-MMM-YYYY)	Time of Cannula Placement (HHMM)	Cannula Site	Other (specify)	Cannula ID (from ELSO registry)	Date of Cannula Removal (DD-MMM-YYYY)	Time of Cannula Removal (HHMM)
<input type="text"/>	ArterialCanPlaceTime, \$	(select one) ▼	<input type="text"/>	ArterialCannulaID, #	ARTERIALCANREMOVEDAY, #	<input type="text"/>
ARTERIALCANPLACEDAY, #		ArterialCannulaSite, #	ArterialCannulaSiteOther, \$			ArterialCanRemoveTime, \$

ArtSite  
1=Right Common Carotid Artery (RCCA)  
2=Left Common Carotid Artery (LCCA)  
3=Right Femoral Artery (RFA)  
4=Left Femoral Artery (LFA)  
5=Left Atrium (LA)  
6=Pulmonary Artery (PA)  
7=Aorta  
90=Other

Cannulation\_DLC\_v2 (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Cannulation Characteristics:

## Double Lumen Catheters

Date of Catheter Placement (DD-MMM-YYYY)	Time of Catheter Placement (HHMM)	Catheter Site	Other (specify)	Cannula ID (from ELSO registry)	Date of Catheter Removal (DD-MMM-YYYY)	Time of Catheter Removal (HHMM)
DLCCANPLACEDAY, #	DLCCanPlaceTime, \$	DLCCannulaSite, #		DLCCannulaID, #		DLCCanRemoveTime, \$
ADD			DLCCannulaSiteOther, \$	DLCCANREMOVEDAY, #		

DLCSite  
1=Right Internal Jugular Vein (RIJV)  
2=Left Internal Jugular Vein (LIJV)  
3=Right Femoral Vein (RFV)  
4=Left Femoral Vein (LFV)  
90=Other

Cannulation\_Cephalad\_v2 (1 of 1)

## ECMO Cannulation Characteristics:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ Cannula...(0/7) VenArtC...(0/21) **OtherCa...(0/14)** ▶ -- Select to Jump -- ▼

## Title: Other Cannulae

Instructions: Document each inserted cannula for this patient while enrolled in this study.

## Cephalad Cannulae

Date of Cannula Placement (DD-MMM-YYYY)	Time of Cannula Placement (HHMM)	Date of Cannula Removal (DD-MMM-YYYY)	Time of Cannula Removal (HHMM)	
CEPHALADCANPLACEDAY, #	CephaladCanPlaceTime, \$	<input type="checkbox"/> CEPHALADCANREMOVEDAY, #	CephaladCanRemoveTime, \$	X

ADD

Cannulation\_LAD\_v2 (1 of 1)

## ECMO Cannulation Characteristics:

PudID #

Occurrence #

ItemGroupRepeatKey #

## Left Atrial Drainage Cannulae

Date of Cannula Placement (DD-MMM-YYYY)	Time of Cannula Placement (HHMM)	Date of Cannula Removal (DD-MMM-YYYY)	Time of Cannula Removal (HHMM)	
LADCANPLACEDAY, #	LADCanPlaceTime, \$	LADCANREMOVEDAY, #	LADCanRemoveTime, \$	X
ADD				



Cannulation\_DPC\_v2 (1 of 1)

## ECMO Cannulation Characteristics:

Distal Perfusion / Drainage Cannulae						PudID #	Occurrence #	ItemGroupRepeatKey #
Date of Cannula Placement (DD-MMM-YYYY)	Time of Cannula Placement (HHMM)	Cannula Site	Other (specify)	Date of Cannula Removal (DD-MMM-YYYY)	Time of Cannula Removal (HHMM)			
DPCCANPLACEDAY, #	DPCCanPlaceTime, \$	(select one) ▼	DPCCannulaSiteOther, \$		DPCCanRemoveTime, \$	X		
ADD		DPCCannulaSite, #	DPCCANREMOVEEDAY, #					

DPCCannulaSite, #

DPCCannulaSite, #

1=Right arm  
2=Left arm  
3=Right leg  
4=Left leg  
90=Other

ECMODaily (1 of 8)

PudID #

Occurrence #

ItemGroupRepeatKey #

**ECMO Related Daily Data v1.0:**

Infecti...(0/6) BloodLo...(0/13) ThromEv...(0/15) -- Select to Jump --

**Title: Daily Infection Information**

Study date:  (DD-MMM-YYYY)

Was the patient separated from ECMO on this study day?

RemovedFromECMO, #  If yes, provide information on the cannulation characteristics form

Was a new culture- or PCR-proven infection diagnosed on this study day?

NewInfect, #  If yes, provide details below

Specimen collection date (DD-MMM-YYYY)	Specimen collection time (HHMM)	Upload report	ECMODaily_Infect
<input type="text" value="NEWINFECTDAY, #"/>	<input type="text" value="NewInfectTime, \$"/>	Value not provided	<input type="button" value="Click to upload file"/>
<input type="button" value="ADD"/>			

YesNo  
1=Yes  
0=No

NOTE: Three versions of the ECMO Related Daily Data exist, including the tables embedded within the CRF; however, the raw dataset has stacked versions, ECMODAILY\_ALLVERSIONS, ECMODAILY\_INFECT\_ALLVERSIONS.

ECMODaily (2 of 8)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v1.0:

Infecti...(0/6)    BloodLo...(0/13)    ThromEv...(0/15)    -- Select to Jump --

**Title: Daily Blood Loss Hx**

On this study day, what is the:

Total blood loss from lab sampling?  (mL)  ☐ Not tabulated

Total chest tube output?  (mL) ☐ No chest tube

ChestTubeOutputND, #

On this study day, did blood loss from any of the following contribute to a need for transfusion?

Lab sampling? (select one)

Sanguineous chest tube output? (select one)

Surgical site bleeding? (select one)

Cannula site bleeding? (select one)

Gastrointestinal bleeding? (select one)

Pulmonary hemorrhage? (select one)

Intracranial bleeding? (select one)

Genitourinary bleeding? (select one)

On this study day, was there new or increased intracranial bleeding? (select one)

NotTab  
98=Not tabulated

NoCT  
1=No chest tube

YesNo  
1=Yes  
0=No

ECMODaily (3 of 8)

PudID #

Occurrence #

Item GroupRepeatKey #

## ECMO Related Daily Data v1.0:

BloodLo...(0/13) ThromEv...(0/15) Thrombo...(0/36) -- Select to Jump --

**Title: DailyThrombotic Events**

**Did any of the following thrombotic events occur or persist on this study day?**

Intracranial infarction:	(select one) ▼	If yes, what is the status of the intracranial infarction?	IntraInfarctStatus, #	(select one) ▼
ThromIntraInfarct, #				
Limb ischemia:	(select one) ▼	If yes, what is the status of the limb ischemia?	IschemiaStatus, #	(select one) ▼
ThromIschemia, #				
Pulmonary embolus:	(select one) ▼	If yes, what is the status of the pulmonary embolus?	EmbolusStatus, #	(select one) ▼
ThromEmbolus, #				
Intracardiac clot:	(select one) ▼	If yes, what is the status of the intracardiac clot?	IntracardiacStatus, #	(select one) ▼
ThromIntracardiac, #				
Aortopulmonary shunt clot:	(select one) ▼	If yes, what is the status of the aortopulmonary shunt clot?	AortopulmStatus, #	(select one) ▼
ThromAortopulm, #				
Hemolysis (plasma hemoglobin >50 mg/dL)	(select one) ▼	If yes, what is the status of the hemolysis?	HemolysisStatus, #	(select one) ▼
ThromHemolysis, #				
Did any other thrombotic event occur on this study day?	(select one) ▼	If yes, what was the thrombotic event?	ThromOtherEvent, \$	If yes, what is the status of the other thrombotic event? (select one) ▼
ThromOtherOccur, #				
			ThromOtherStatus, #	

NBSW  
 1=New  
 2=Better  
 3=Same  
 4=Worse

YesNo  
 1=Yes  
 0=No

ECMODaily (4 of 8)

## ECMO Related Daily Data v1.0:

ThromEv... (0/15) Thrombo... (0/36) Thrombo... (0/24) -- Select to Jump -- PudID # Occurrence # ItemGroupRepeatKey #

**Title: Daily Thrombotic Events (con't)**

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenOne, #

If yes, which circuit components had clots?

Oxygenator: (select one) ThromClotOxygenOne, #

Bladder: (select one) ThromClotBladderOne, #

CVVH circuit: (select one) ThromClotCVVHOne, #

Circuit tubing: (select one) ThromClotTubeOne, #

Arterial cannula: (select one) ThromClotArterialCanOne, #

Bridge: (select one) ThromClotBridgeOne, #

In-line hemofilter: (select one) ThromClotHemofilterOne, #

Pump head: (select one) ThromClotPumpOne, #

Venous cannula: (select one) ThromClotVenousCanOne, #

Clotting of other circuit component: (select one) ThromClotOthCircuitOne, #

If yes, was the entire circuit replaced?

ChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) CircuitChgOxygenOne, #

Bladder: (select one) CircuitChgBladderOne, #

CVVH circuit: (select one) CircuitChgCVVHOne, #

Circuit tubing: (select one) CircuitChgTubeOne, #

Arterial cannula: (select one) CircuitChgArterialCanOne, #

Bridge: (select one) CircuitChgBridgeOne, #

In-line hemofilter: (select one) CircuitChgHemofilterOne, #

Pump head: (select one) CircuitChgPumpOne, #

Venous cannula: (select one) CircuitChgVenousCanOne, #

Clotting of other circuit component: (select one) CircuitChgOthCircuitOne, #

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v1.0:

Did any of the circuit components require change-out for a non-thrombotic event on this study day?

(select one) ▼

CircuitChgNonThrombOne, #

If yes, was the entire circuit replaced?

(select one) ▼

NonThromChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼

Bridge: (select one) ▼

NonThromChgBridgeOne, #

NonThromChgOxygenOne, #

Bladder: (select one) ▼

In-line hemofilter: (select one) ▼

NonThromChgHemofilterOne, #

NonThromChgBladderOne, #

CVVH circuit: (select one) ▼

Pump head: (select one) ▼

NonThromChgPumpOne, #

NonThromChgCVVHOne, #

Circuit tubing: (select one) ▼

Venous cannula: (select one) ▼

NonThromChgVenousCanOne, #

NonThromChgTubeOne, #

Arterial cannula: (select one) ▼

Clotting of other circuit component: (select one) ▼

NonThromChgOthCircuitOne, #

NonThromChgArterialCanOne, #

YesNo  
1=Yes  
0=No

Were there any complications during circuit component change-out?

CircuitChgCompOne, # (select one) ▼

If yes, specify:

CircuitChgCompSpecifyOne, #

If selected 'thrombosis requiring further intervention,' provide circuit component details on the next tab

Comp

- 1=Cardiac arrest
- 2=Hypoxemia requiring hand ventilation or increasing ventilator settings
- 3=Increase in vasoactive agents or bolus vasoactive administration
- 4=Thrombosis requiring further intervention
- 5=Bleeding requiring transfusion

YesNo  
1=Yes  
0=No

ECMO Related Daily Data v1.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Thrombotic Events (complete only if needed)**

Instructions: If the question 'Were there any complications during circuit component change-out?' was answered 'thrombosis requiring further intervention,' provide the circuit componet change-out details on this tab.

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenTwo. # (e) ▼

If yes, which circuit components had dots?

Oxygenator: (select one) ▼	Bridge: (select one) ▼	ThromClotBridgeTwo, #
ThromClotOxygenTwo. #	In-line hemofilter: (select one) ▼	ThromClotHemofilterTwo. #
Bladder: (select one) ▼	Pump head: (select one) ▼	ThromClotPumpTwo, #
ThromClotBladderTwo, #	Venous cannula: (select one) ▼	ThromClotVenousCanTwo, #
CVVH circuit: (select one) ▼	Clotting of other circuit component: (select one) ▼	ThromClotOthCircuitTwo, #
ThromClotCVVHTwo, #		
Circuit tubing: (select one) ▼		
ThromClotTubeTwo, #		
Arterial cannula: (select one) ▼		
ThromClotArterialCanTwo, #		

If yes, was the entire circuit replaced?

(select one) ▼

ChgEntireCiruitTwo. #

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

## ECMO Related Daily Data v1.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼

Bridge: (select one) ▼

CircuitChgOxygenTwo, #

CircuitChgBridgeTwo, #

Bladder: (select one) ▼

In-line hemofilter: (select one) ▼

CircuitChgBladderTwo, #

CircuitChgHemofilterTwo, #

CVVH circuit: (select one) ▼

Pump head: (select one) ▼

CircuitChgCVVHTwo, #

CircuitChgPumpTwo, #

Circuit tubing: (select one) ▼

Venous cannula: (select one) ▼

CircuitChgTubeTwo, #

CircuitChgVenousCanTwo, #

Arterial cannula: (select one) ▼

Clotting of other circuit component: (select one) ▼

CircuitChgArterialCanTwo, #

CircuitChgOthCircuitTwo, #

YesNo  
1=Yes  
0=No

Were there any complications during circuit component change-out?

CircuitChgCompTwo, #

If yes, specify: CircuitChgCompSpecifyTwo, #

YesNo  
1=Yes  
0=No

Comp  
 1=Cardiac arrest  
 2=Hypoxemia requiring hand ventilation or increasing ventilator settings  
 3=Increase in vasoactive agents or bolus vasoactive administration  
 4=Thrombosis requiring further intervention  
 5=Bleeding requiring transfusion



## ECMODaily (8 of 8)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v1.0:

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Additional Daily ECMO Related Data**

**Plasma Free Hemoglobin**

Date: PFHDAY, # (DD-MMM-YYYY) Time: PFHTime, \$ (HHMM)

Plasma Free Hemoglobin (PFH): PlasmaFreeHgb, # (mg/dL) SvO2Site 1=Patient 2=Circuit ☐ Not done PlasmaFreeHgbND, # NotDone 95=Not done

**Central Venous Saturation (SvO2)**

Date: SVO2DAY, # (DD-MMM-YYYY) Time: SvO2Time, ST (HHMM)

SvO2: SvO2, # (%) Site: (select one) ☐ Not done SvO2Site, # SvO2ND, #

**Flow Rate**

Flow Rate: FlowRate, # Flow Rate Unit: (select one) FRUnit 1=mL/min 2=L/min FlowRateUnit, #

**Tubing**

Was the circuit tubing (not including the bridge) clamped off for more than one hour on this study day?

ClampedTube, # (select one)

**Other Treatments**

Did the patient require CVVH on this study day?

RequireCVVH, #

Did the patient require plasmapheresis on this study day?

RequirePlasma, #

Did the patient require in-line hemofiltration on this study day?

RequireHemofiltration, #

YesNo  
1=Yes  
0=No

ECMODaily\_v2 (1 of 8)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v2.0:

◀ Infecti...(0/6) BloodLo...(0/13) ThromEv...(0/15) ▶ -- Select to Jump -- ▼

**Title: Daily Infection Information**

Study date:   (DD-MMM-YYYY)

Was the patient separated from ECMO on this study day?

If yes, provide information on the cannulation characteristics form

Was a new culture- or PCR-proven infection diagnosed on this study day?

If yes, provide details below

Specimen collection date (DD-MMM-YYYY)	Specimen collection time (HHMM)	Upload report	ECMODaily_Infect
<input type="text" value="NEWINFECTDAY, #"/> <input type="button" value="Calendar"/>	<input type="text" value="NewInfectTime, \$"/>	<input type="text" value="Value not provided"/> <input type="button" value="Click to upload file"/>	<input type="button" value="X"/>
<input type="button" value="ADD"/>			

YesNo  
1=Yes  
0=No

ECMODaily\_v2 (2 of 8)

## ECMO Related Daily Data v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Infecti...(0/6)    **BloodLo...(0/13)**    ThromEv...(0/15)    -- Select to Jump --

**Title: Daily Blood Loss Hx**

On this study day, what is the:

Total blood loss from lab sampling?  (mL)  ☐ Not tabulated

Total chest tube output?  (mL) ☐ No chest tube

On this study day, did blood loss from any of the following contribute to a need for transfusion?

Lab sampling? (select one)

Sanguineous chest tube output? (select one)

Surgical site bleeding? (select one)

Cannula site bleeding? (select one)

Gastrointestinal bleeding? (select one)

Pulmonary hemorrhage? (select one)

Intracranial bleeding? (select one)

Genitourinary bleeding? (select one)

On this study day, was there new or increased intracranial bleeding?

(select one)

NotTab  
98=Not tabulated

NoCT  
1=No chest tube

YesNo  
1=Yes  
0=No

ECMODaily\_v2 (3 of 8)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v2.0:

BloodLo...(0/13) ThromEv...(0/15) Thrombo...(0/36) -- Select to Jump --

**Title: DailyThrombotic Events**

**Did any of the following thrombotic events occur or persist on this study day?**

Intracranial infarction:	(select one) ▼	If yes, what is the status of the intracranial infarction?	(select one) ▼	IntraInfarctStatus, #
ThromIntraInfarct, #				
Limb ischemia:	(select one) ▼	If yes, what is the status of the limb ischemia?	(select one) ▼	IschemiaStatus, #
ThromIschemia, #				
Pulmonary embolus:	(select one) ▼	If yes, what is the status of the pulmonary embolus?	(select one) ▼	EmbolusStatus, #
ThromEmbolus, #				
Intracardiac dot:	(select one) ▼	If yes, what is the status of the intracardiac dot?	(select one) ▼	IntracardiacStatus, #
ThromIntracardiac, #				
Aortopulmonary shunt dot:	(select one) ▼	If yes, what is the status of the aortopulmonary shunt dot?	(select one) ▼	AortopulmStatus, #
ThromAortopulm, #				
Hemolysis (plasma hemoglobin >50 mg/dL)	(select one) ▼	If yes, what is the status of the hemolysis?	(select one) ▼	HemolysisStatus, #
ThromHemolysis, #				
Did any other thrombotic event occur on this study day?	(select one) ▼	If yes, what was the thrombotic event?	(select one) ▼	ThromOtherEvent, \$
ThromOtherOccur, #				
			If yes, what is the status of the other thrombotic event?	(select one) ▼
				ThromOtherStatus, #

YesNo  
 1=Yes  
 0=No

NBSW  
 1=New  
 2=Better  
 3=Same  
 4=Worse

ECMODaily\_v2 (4 of 8)

## ECMO Related Daily Data v2.0:

ThromEv... (0/15) Thrombo... (0/36) Thrombo... (0/24) -- Select to Jump -- PudID # Occurrence # ItemGroupRepeatKey #

**Title: Daily Thrombotic Events (con't)**

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenOne, #

If yes, which circuit components had clots?

Oxygenator: (select one) ThromClotOxygenOne, #

Bladder: (select one) ThromClotBladderOne, #

CVVH circuit: (select one) ThromClotCVVHOne, #

Circuit tubing: (select one) ThromClotTubeOne, #

Arterial cannula: (select one) ThromClotArterialCanOne, #

Bridge: (select one) ThromClotBridgeOne, #

In-line hemofilter: (select one) ThromClotHemofilterOne, #

Pump head: (select one) ThromClotPumpOne, #

Venous cannula: (select one) ThromClotVenousCanOne, #

Clotting of other circuit component: (select one) ThromClotOthCircuitOne, #

If yes, was the entire circuit replaced?

ChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) CircuitChgOxygenOne, #

Bladder: (select one) CircuitChgBladderOne, #

CVVH circuit: (select one) CircuitChgCVVHOne, #

Circuit tubing: (select one) CircuitChgTubeOne, #

Arterial cannula: (select one) CircuitChgArterialCanOne, #

Bridge: (select one) CircuitChgBridgeOne, #

In-line hemofilter: (select one) CircuitChgHemofilterOne, #

Pump head: (select one) CircuitChgPumpOne, #

Venous cannula: (select one) CircuitChgVenousCanOne, #

Clotting of other circuit component: (select one) CircuitChgOthCircuitOne, #

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

ECMODaily\_v2 (5 of 8)

## ECMO Related Daily Data v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Did any of the circuit components require change-out for a non-thrombotic event on this study day?

(select one) ▼

CircuitChgNonThrombOne, #

If yes, was the entire circuit replaced?

(select one) ▼

NonThromChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼

NonThromChgOxygenOne, #

Bridge: (select one) ▼

NonThromChgBridgeOne, #

Bladder: (select one) ▼

NonThromChgBladderOne, #

In-line hemofilter: (select one) ▼

NonThromChgHemofilterOne, #

CVVH circuit: (select one) ▼

NonThromChgCVVHOne, #

Pump head: (select one) ▼

NonThromChgPumpOne, #

Circuit tubing: (select one) ▼

NonThromChgTubeOne, #

Venous cannula: (select one) ▼

NonThromChgVenousCanOne, #

Arterial cannula: (select one) ▼

NonThromChgArterialCanOne, #

Clotting of other circuit component: (select one) ▼

NonThromChgOthCircuitOne, #

YesNo  
1=Yes  
0=No

Were there any complications during circuit component change-out?

CircuitChgCompOne, # (select one) ▼

If yes, specify:

CircuitChgCompSpecifyOne, #

If selected 'thrombosis requiring further intervention,' provide circuit component details on the next tab

YesNo  
1=Yes  
0=No

Comp

- 1=Cardiac arrest
- 2=Hypoxemia requiring hand ventilation or increasing ventilator settings
- 3=Increase in vasoactive agents or bolus vasoactive administration
- 4=Thrombosis requiring further intervention
- 5=Bleeding requiring transfusion

ECMODaily\_v2 (6 of 8)

## ECMO Related Daily Data v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Thrombotic Events (complete only if needed)**

Instructions: If the question 'Were there any complications during circuit component change-out?' was answered 'thrombosis requiring further intervention,' provide the circuit componet change-out details on this tab.

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenTwo, #

If yes, which circuit components had dots?

Oxygenator: <input type="text" value="(select one)"/>	Bridge: <input type="text" value="(select one)"/>	ThromClotBridgeTwo, #	<div>YesNo 1=Yes 0=No</div>
ThromClotOxygenTwo, #	In-line hemofilter: <input type="text" value="(select one)"/>	ThromClotHemofilterTwo, #	
Bladder: <input type="text" value="(select one)"/>	Pump head: <input type="text" value="(select one)"/>	ThromClotPumpTwo, #	
ThromClotBladderTwo, #	CVVH circuit: <input type="text" value="(select one)"/>	ThromClotVenousCanTwo, #	
ThromClotCVVHTwo, #	Circuit tubing: <input type="text" value="(select one)"/>	ThromClotOthCircuitTwo, #	
ThromClotTubeTwo, #	Arterial cannula: <input type="text" value="(select one)"/>		
ThromClotArterialCanTwo, #	Venous cannula: <input type="text" value="(select one)"/>		
	Clotting of other circuit component: <input type="text" value="(select one)"/>		

If yes, was the entire circuit replaced?

ChgEntireCiruitTwo, #

YesNo  
1=Yes  
0=No

## ECMO Related Daily Data v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼	Bridge: (select one) ▼	CircuitChgBridgeTwo, #	YesNo 1=Yes 0=No	
CircuitChgOxygenTwo, #	Bladder: (select one) ▼	In-line hemofilter: (select one) ▼		CircuitChgHemofilterTwo, #
CircuitChgBladderTwo, #	CVVH circuit: (select one) ▼	Pump head: (select one) ▼		CircuitChgPumpTwo, #
CircuitChgCVVHTwo, #	Circuit tubing: (select one) ▼	Venous cannula: (select one) ▼		CircuitChgVenousCanTwo, #
CircuitChgTubeTwo, #	Arterial cannula: (select one) ▼	Clotting of other circuit component: (select one) ▼		CircuitChgOthCircuitTwo, #
CircuitChgArterialCanTwo, #				

Were there any complications during circuit component change-out?

CircuitChgCompTwo, # (select one) ▼

If yes, specify: CircuitChgCompSpecifyTwo, # (select one) ▼

YesNo  
1=Yes  
0=No

Comp  
 1=Cardiac arrest  
 2=Hypoxemia requiring hand ventilation or increasing ventilator settings  
 3=Increase in vasoactive agents or bolus vasoactive administration  
 4=Thrombosis requiring further intervention  
 5=Bleeding requiring transfusion



ECMODaily\_v2 (8 of 8)

## ECMO Related Daily Data v2.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Additional Daily ECMO Related Data**

**Plasma Free Hemoglobin**

Date: PFHDAY, # (DD-MMM-YYYY) Time: PFHTime, \$ (HHMM)

Plasma Free Hemoglobin (PFH): PlasmaFreeHgb, # (mg/dL) SvO2Site 1=Patient 2=Circuit

☐ Not done PlasmaFreeHgbND, # NotDone 95=Not done

**Central Venous Saturation (SvO2)**

Date: SVO2DAY, # (DD-MMM-YYYY) Time: SvO2Time, \$ (HHMM)

SvO2: SvO2, # (%) Site: (select one) ☐ Not done

SvO2Site, # SvO2ND, #

**Flow Rate**

Flow Rate: FlowRate, # Flow Rate Unit: (select one) FRUnit 1=mL/min 2=L/min

FlowRateUnit, #

**Tubing**

Was the circuit tubing (not including the bridge) clamped off for more than one hour on this study day?

ClampedTube, # (one)

**Other Treatments**

Did the patient require CVVH on this study day?

RequireCVVH, #

Did the patient require plasmapheresis on this study day?

RequirePlasma, #

Did the patient require in-line hemofiltration on this study day?

RequireHemofiltration, #

YesNo 1=Yes 0=No

ECMODaily\_v3 (1 of 8)

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ Infecti... (0/6) BloodLo... (0/13) ThromEv... (0/15) ▶ -- Select to Jump -- ▼

**Title: Daily Infection Information**

Study date:   YesNo  
1=Yes  
0=No

Was the patient separated from ECMO on this study day?

If yes, provide information on the cannulation characteristics form

Was a new culture- or PCR-proven infection diagnosed on this study day?

If yes, provide details below

Specimen collection date (DD-MMM-YYYY)	Specimen collection time (HHMM)	Upload report	ECMODaily_Infect
<input type="text" value="NEWINFECTDAY, #"/> <input type="text" value=""/>	<input type="text" value="NewInfectTime, \$"/>	<input type="text" value="Value not provided"/> <input type="button" value="Click to upload file"/>	<input type="button" value="X"/>
<input type="button" value="ADD"/>			

ECMODaily\_v3 (2 of 8)

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Infecti...(0/6)    **BloodLo...(0/13)**    ThromEv...(0/15)    -- Select to Jump --

**Title: Daily Blood Loss Hx**

On this study day, what is the:

Total blood loss from lab sampling?  (mL)  ☐ Not tabulated

Total chest tube output?  (mL) ☐ No chest tube

On this study day, did blood loss from any of the following contribute to a need for transfusion?

Lab sampling? (select one)

Sanguineous chest tube output? (select one)

Surgical site bleeding? (select one)

Cannula site bleeding? (select one)

Gastrointestinal bleeding? (select one)

Pulmonary hemorrhage? (select one)

Intracranial bleeding? (select one)

Genitourinary bleeding? (select one)

On this study day, was there new or increased intracranial bleeding?

(select one)

NotTab  
98=Not tabulated

NoCT  
1=No chest tube

YesNo  
1=Yes  
0=No

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

BloodLo...(0/13)   ThromEv...(0/21)   Thrombo...(0/36)   -- Select to Jump --

**Title: DailyThrombotic Events**

**Did any of the following events occur or persist on this study day?**

**Intracranial infarction:**

IntraInfarct, # ☐ If yes, answer the following questions:

Thrombotic? (select one)  What is the status of the thrombotic intracranial infarction? IntraInfarctThromStatus, #  
 IntraInfarctThromType, #

Non-thrombotic? (select one)  What is the status of the non-thrombotic intracranial infarction? IntraInfarctNonThromStatus, #  
 IntraInfarctNonThromType, #

**Limb ischemia:**

Ischemia, # ☐ If yes, answer the following questions:

Thrombotic? (select one)  What is the status of the thrombotic limb ischemia? IschemiaThromStatus, #  
 IschemiaThromType, #

Non-thrombotic? (select one)  What is the status of the non-thrombotic limb ischemia? IschemiaNonThromStatus, #  
 IschemiaNonThromType, #

**Pulmonary embolus:**

ThromEmbolus, # (select one)  If yes, what is the status of the pulmonary embolus? EmbolusStatus, #

**Intracardiac clot:**

ThromIntracardiac, # (select one)  If yes, what is the status of the intracardiac clot? IntracardiacStatus, #

**Aortopulmonary shunt clot:**

ThromAortopulm, # (select one)  If yes, what is the status of the aortopulmonary shunt clot? AortopulmStatus, #

**Hemolysis (plasma hemoglobin >50 mg/dL)**

ThromHemolysis, # (select one)  If yes, what is the status of the hemolysis? HemolysisStatus, #

**Did any other thrombotic event occur on this study day?**

ThromOtherOccur, # ☐ If yes, what was the thrombotic event? ThromOtherEvent, #

If yes, what is the status of the other thrombotic event? (select one)  ThromOtherStatus, #

YesNo  
 1=Yes  
 0=No

NBSW  
 1=New  
 2=Better  
 3=Same  
 4=Worse

ECMODaily\_v3 (4 of 8)

## ECMO Related Daily Data v3.0:

ThromEv...(0/15) Thrombo...(0/36) Thrombo...(0/24) -- Select to Jump --

PudID # Occurrence # ItemGroupRepeatKey #

**Title: Daily Thrombotic Events (con't)**

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenOne, #

If yes, which circuit components had clots?

Oxygenator: (select one) ThromClotOxygenOne, #

Bladder: (select one) ThromClotBladderOne, #

CVVH circuit: (select one) ThromClotCVVHOne, #

Circuit tubing: (select one) ThromClotTubeOne, #

Arterial cannula: (select one) ThromClotArterialCanOne, #

Bridge: (select one) ThromClotBridgeOne, #

In-line hemofilter: (select one) ThromClotHemofilterOne, #

Pump head: (select one) ThromClotPumpOne, #

Venous cannula: (select one) ThromClotVenousCanOne, #

Clotting of other circuit component: (select one) ThromClotOthCircuitOne, #

If yes, was the entire circuit replaced?

ChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) CircuitChgOxygenOne, #

Bladder: (select one) CircuitChgBladderOne, #

CVVH circuit: (select one) CircuitChgCVVHOne, #

Circuit tubing: (select one) CircuitChgTubeOne, #

Arterial cannula: (select one) CircuitChgArterialCanOne, #

Bridge: (select one) CircuitChgBridgeOne, #

In-line hemofilter: (select one) CircuitChgHemofilterOne, #

Pump head: (select one) CircuitChgPumpOne, #

Venous cannula: (select one) CircuitChgVenousCanOne, #

Clotting of other circuit component: (select one) CircuitChgOthCircuitOne, #

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Related Daily Data v3.0:

Did any of the circuit components require change-out for a non-thrombotic event on this study day?

(select one) ▼

CircuitChgNonThrombOne, #

If yes, was the entire circuit replaced?

(select one) ▼

NonThromChgEntireCircuitOne, #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼

NonThromChgOxygenOne, #

Bridge: (select one) ▼

NonThromChgBridgeOne, #

Bladder: (select one) ▼

NonThromChgBladderOne, #

In-line hemofilter: (select one) ▼

NonThromChgHemofilterOne, #

CVVH circuit: (select one) ▼

NonThromChgCVVHOne, #

Pump head: (select one) ▼

NonThromChgPumpOne, #

Circuit tubing: (select one) ▼

NonThromChgTubeOne, #

Venous cannula: (select one) ▼

NonThromChgVenousCanOne, #

Arterial cannula: (select one) ▼

NonThromChgArterialCanOne, #

Clotting of other circuit component: (select one) ▼

NonThromChgOthCircuitOne, #

YesNo  
1=Yes  
0=No

Were there any complications during circuit component change-out?

CircuitChgCompOne, # (select one) ▼

If yes, specify:

CircuitChgCompSpecifyOne, #

If selected 'thrombosis requiring further intervention,' provide circuit component details on the next tab

YesNo  
1=Yes  
0=No

Comp

- 1=Cardiac arrest
- 2=Hypoxemia requiring hand ventilation or increasing ventilator settings
- 3=Increase in vasoactive agents or bolus vasoactive administration
- 4=Thrombosis requiring further intervention
- 5=Bleeding requiring transfusion

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Thrombotic Events (complete only if needed)**

Instructions: If the question 'Were there any complications during circuit component change-out?' was answered 'thrombosis requiring further intervention,' provide the circuit component change-out details on this tab.

**Did circuit components require change-out due to clotting on this study day?**

ThromClotHappenTwo, #

If yes, which circuit components had clots?

Oxygenator: <input type="text"/>	Bridge: <input type="text"/>	ThromClotBridgeTwo, # <input type="text"/>	<div>YesNo 1=Yes 0=No</div>
ThromClotOxygenTwo, # <input type="text"/>	In-line hemofilter: <input type="text"/>	ThromClotHemofilterTwo, # <input type="text"/>	
Bladder: <input type="text"/>	Pump head: <input type="text"/>	ThromClotPumpTwo, # <input type="text"/>	
ThromClotBladderTwo, # <input type="text"/>	Venous cannula: <input type="text"/>	ThromClotVenousCanTwo, # <input type="text"/>	
CVVH circuit: <input type="text"/>	Clotting of other circuit component: <input type="text"/>	ThromClotOthCircuitTwo, # <input type="text"/>	
ThromClotCVVHTwo, # <input type="text"/>			
Circuit tubing: <input type="text"/>			
ThromClotTubeTwo, # <input type="text"/>			
Arterial cannula: <input type="text"/>			
ThromClotArterialCanTwo, # <input type="text"/>			
If yes, was the entire circuit replaced?			
<input type="text"/>			
ChgEntireCircuitTwo, # <input type="text"/>			

YesNo  
1=Yes  
0=No

ECMODaily\_v3 (7 of 8)

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

If no, specify which circuit components were changed-out?

Oxygenator: (select one) ▼	Bridge: (select one) ▼	CircuitChgBridgeTwo, #	YesNo 1=Yes 0=No
CircuitChgOxygenTwo, #			
Bladder: (select one) ▼	In-line hemofilter: (select one) ▼	CircuitChgHemofilterTwo, #	
CircuitChgBladderTwo, #			
CVVH circuit: (select one) ▼	Pump head: (select one) ▼	CircuitChgPumpTwo, #	
CircuitChgCVVHTwo, #			
Circuit tubing: (select one) ▼	Venous cannula: (select one) ▼	CircuitChgVenousCanTwo, #	
CircuitChgTubeTwo, #			
Arterial cannula: (select one) ▼	Clotting of other circuit component: (select one) ▼	CircuitChgOthCircuitTwo, #	
CircuitChgArterialCanTwo, #			

Were there any complications during circuit component change-out?

CircuitChgCompTwo, # (select one) ▼

If yes, specify: CircuitChgCompSpecifyTwo, #

YesNo  
1=Yes  
0=No

Comp  
1=Cardiac arrest  
2=Hypoxemia requiring hand ventilation or increasing ventilator settings  
3=Increase in vasoactive agents or bolus vasoactive administration  
4=Thrombosis requiring further intervention  
5=Bleeding requiring transfusion



ECMODaily\_v3 (8 of 8)

## ECMO Related Daily Data v3.0:

PudID #

Occurrence #

ItemGroupRepeatKey #

Thrombo...(0/24) Thrombo...(0/24) OtherEC...(0/15) -- Select to Jump --

**Title: Additional Daily ECMO Related Data**

**Plasma Free Hemoglobin**

Date: PFHDAY, # (DD-MMM-YYYY) Time: PFHTime, \$ (HHMM)

Plasma Free Hemoglobin (PFH): PlasmaFreeHgb, # (mg/dL) SvO2Site 1=Patient 2=Circuit

☐ Not done PlasmaFreeHgbND, # NotDone 95=Not done

**Central Venous Saturation (SvO2)**

Date: SVO2DAY, # (DD-MMM-YYYY) Time: SvO2Time, \$ (HHMM)

SvO2: SvO2, # (%) Site: (select one) ☐ Not done

SvO2Site, # SvO2ND, #

**Flow Rate**

Flow Rate: FlowRate, # Flow Rate Unit: (select one) FRUnit 1=mL/min 2=L/min

FlowRateUnit, #

**Tubing**

Was the circuit tubing (not including the bridge) clamped off for more than one hour on this study day?

ClampedTube, # (select one)

**Other Treatments**

Did the patient require CVVH on this study day?

RequireCVVH, #

Did the patient require plasmapheresis on this study day?

RequirePlasma, #

Did the patient require in-line hemofiltration on this study day?

RequireHemofiltration, #

YesNo 1=Yes 0=No

HeparinTotal (1 of 1)

**ECMO Total Heparin Dose per Day:**

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ TotalHe...(0/2) ▶ -- Select to Jump -- ▼

Title: Total Heparin Dose Per Day	
Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.	
Study date:	TOTALHEPARINDAY, # (DD-MMM-YYYY)
What was the patient's <b>total</b> heparin dose on this study day?	
	TotalHeparinDose, # (units)

Vent (1 of 1)

## ECMO Ventilator Settings:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ **Vent (0/15)** ▶ -- Select to Jump -- ▼

**Title: Ventilator Settings**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Was the patient receiving respiratory support on this study day?

YesNo  
1=Yes  
0=No

VentSupportYN, # ▼ If yes, provide details below

Date: VENTDAY, # (DD-MMM-YYYY) Time: VentTime, \$ (HHMM)

Ventilator Mode: VentMode, # Other (specify): VentModeOther, \$

Ventilator Rate: VentilatorRate, # (bpm)

Tidal Volume Exhaled: VTEhaled, # (mL)

Set Tidal Volume: VTSet, # (mL)

PIP: PIP, # (cmH20)

Pressure Support: PS, # (cmH20)

Mean Airway Pressure: MAP, # (cmH20)

PEEP: PEEP, # (cmH20)

FiO2: FiO2, # (#.##)  
\*MUST be a decimal\*

HFOV Frequency: HFOVFrequency, #

HFOV Amplitude: HFOVAmplitude, #

VentMode  
1=Pressure control  
2=PRVC  
3=HFOV  
4=Volume control  
5=Non-invasive ventilation  
6=Pressure support and CPAP  
90=Other

CBC (1 of 1)

## ECMO Complete Blood Count w/o diff:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ CBC (0/6) ▶ -- Select to Jump -- ▼

**Title: Complete Blood Count without differential**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date: CBCNODIFFDAY, # (DD-MMM-YYYY)

Time (HHMM)	Hemoglobin (g/dL)	Hematocrit (%)	Platelets (10 <sup>3</sup> /μL)	WBC (10 <sup>3</sup> /μL)	
CBCNoDiffTime, \$	HgbMass, #	HCTPct, #	Platelet, #	WBC, #	X

ADD

CBC\_CBC

# BATE Annotated eCRF

ABG (1 of 1)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Arterial Blood Gases:

ABG (0/10) -- Select to Jump --

**Title: Arterial Blood Gases**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date:  (DD-MMM-YYYY)

Time (HHMM)	pH (###)	paCO2 (mmHg)	paO2 (mmHg)	HCO3 (mmol/L)	SaO2 (%)	FiO2 (###) Must be a decimal	Ionized Calcium	Ionized Calcium Unit
ABGTime, \$	pHArtBld, #		PaO2ArtBld, #	HCO3, #	SaO2, #		CalonArtBld, #	<input type="text" value="select one)"/> X
		PCO2ArtBld, #				ABGFiO2, #		CalonArtBldUnit, #

ABG\_ABG

Ion  
1=mg/dL  
2=mmol/L

## Chemistries (1 of 2)

## ECMO Chemistries:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ **BMP (0/9)** **Chem (0/13)** ▶ -- Select to Jump -- ▼

**Title: Basic Metabolic Panel**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date:  (DD-MMM-YYYY)

Time: (HHMM)	Sodium: (mmol/L)	Potassium: (mmol/L)	Chloride: (mmol/L)	HCO3: (mmol/L)	BUN: (mg/dL)	Creatinine: (mg/dL)	Glucose: (mg/dL)
<input type="text" value="BMPTIME, \$"/>	<input type="text" value="Sodium, #"/>	<input type="text" value="Potassium, #"/>	<input type="text" value="Chloride, #"/>	<input type="text" value="Bicarbonate, #"/>	<input type="text" value="BUNmg, #"/>	<input type="text" value="Creatinine, #"/>	<input type="text" value="Glucose, #"/>

Chemistries\_Chem

Note: Although the case report form reflects HCO3 as being collected, the lab value being provided in this data field represents total CO2.

# BATE Annotated eCRF

## Chemistries (2 of 2)

PudID #

Occurrence #

ItemGroupRepeatKey #

### ECMO Chemistries:

BMP (0/9) Chem (0/13) -- Select to Jump --

Title: Chemistries

Study date: CHEMDAY, # (DD-MMM-YYYY)

Time (HHMM)	Total Bilirubin (mg/dL)	Alkaline phosphatase (ALP) (IU/L)	Aspartate aminotransferase (AST) (IU/L)	Alanine aminotransferase (ALT) (IU/L)	Lactate dehydrogenase (LDH) (IU/L)	
ChemTimeOne, \$	TotalBilirubin, #	ALP, #	AST, #	ALT, #	LDH, #	X
ADD						Chemistries_ChemOne

Time (HHMM)	Albumin (g/dL)	Total Protein (g/dL)	Calcium (mg/dL)	Lactate	Lactate Unit	
ChemTimeTwo, \$	Albumin, #	TotalProtein, #	Calciummg, #	Lactate, #	(select one) ▼	X
ADD						LactateUnit, #

Chemistries\_ChemTwo

Lactate  
 1=mg/dL  
 2=mmol/L





Coag (1 of 2)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Coagulation Labs:

◀ Coag (0/5) OtherCo... (0/7) ▶ -- Select to Jump -- ▼

**Title: Coagulation Labs**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Date: COAGDAY, #  (DD-MMM-YYYY)

Time: (HHMM)	PT: (seconds)	PTT: (seconds)	INR:	
CoagTime, \$ <input type="text"/>	PT, # <input type="text"/>	PTT, # <input type="text"/>	INR, # <input type="text"/>	<input type="button" value="X"/>
<input type="button" value="ADD"/>				

Coag\_Coag

Coag (2 of 2)

PudID #

Occurrence #

ItemGroupRepeatKey #

## ECMO Coagulation Labs:

◀ Coag (0/5) OtherCo...(0/7) ▶ -- Select to Jump -- ▼

Title: Other Coagulation Labs

Date: OTHERCOAGDAY, # (DD-MMM-YYYY)

Time (HHMM)	Fibrinogen	Fibrinogen unit	Activated clotting time (ACT) (seconds)	ATIII (%)	Anti Xa (IU/mL)	
OtherCoagTime, \$	Fibrinogen, #	(select one) ▼	ACT, #	ATIIICoag, #	AntiXa, #	X
ADD		FibrinogenUnit, #				

Coag\_OtherCoag

fib  
1=mg/dL  
2=ng/mL

Parameter\_v2 (1 of 3)

## ECMO Daily Parameter Goals:

PudID #

Occurrence #

ItemGroupRepeatKey #

Goals (0/63) -- Select to Jump --

**Title: Daily Parameter Goals**

Date: GOALSDAY, # (DD-MMM-YYYY)

**Were any daily parameter goals changed on this study day during morning rounds?**  
Note: Study day 1 must always be answered yes.

GoalsChanged, #   
 YesNo  
 1=Yes  
 0=No

**Hematocrit**

Low Hematocrit: HCTGoalLow, # (%) High Hematocrit: HCTGoalHigh, # (%)

HCTNotChg, # ☐ Not changed from previous study day ☐ Not set HCTNotDone, #

**Hemoglobin**

Low Hemoglobin: HgbGoalLow, # (g/dL) High Hemoglobin: HgbGoalHigh, # (g/dL)

HgbNotChg, # ☐ Not changed from previous study day ☐ Not set HgbNotDone, #

**Platelets**

Low Platelets: PlateletGoalLow, # ( $10^3/\mu\text{L}$ ) High Platelets: PlateletGoalHigh, # ( $10^3/\mu\text{L}$ )

PlateletNotChg, # ☐ Not changed from previous study day ☐ Not set PlateletNotDone, #

**PT**

Low PT: PTGoalLow, # (seconds) High PT: PTGoalHigh, # (seconds)

PTNotChg, # ☐ Not changed from previous study day ☐ Not set PTNotDone, #

**PTT**

Low PTT: LowPTTGoal, # (seconds) High PTT: HighPTTGoal, # (seconds)

PTTNotChg, # ☐ Not changed from previous study day ☐ Not set PTTNotDone, #

NotChg  
 2=Not changed from  
 previous study day

NotSet  
 99=Not Set

Parameter\_v2 (2 of 3)

## ECMO Daily Parameter Goals:

PudID #

Occurrence #

ItemGroupRepeatKey #

Fibrinogen			
Low Fibrinogen:	FibrinogenGoalLow, #	High Fibrinogen:	FibrinogenGoalHigh, #
Fibrinogen Unit:	(select one) ▼	FibrinogenGoalUnit, #	
FibrinogenNotChg, #	<input type="checkbox"/> Not changed from previous study day		FibrinogenNotDone, # <input type="checkbox"/> Not set
Anti Xa			
Low Anti Xa:	LowAntiXaGoal, # (IU/mL)	High Anti Xa:	HighAntiXaGoal, # (IU/mL)
AntiXaNotChg, #	<input type="checkbox"/> Not changed from previous study day		AntiXaNotDone, # <input type="checkbox"/> Not set
ATIII			
Low ATIII:	ATIIIGoalLow, # (%)	High ATIII:	ATIIIGoalHigh, # (%)
ATIIINotChg, #	<input type="checkbox"/> Not changed from previous study day		ATIIINotDone, # <input type="checkbox"/> Not set
ACT			
Low ACT:	LowACTGoal, # (seconds)	High ACT:	HighACTGoal, # (seconds)
ACTNotChg, #	<input type="checkbox"/> Not changed from previous study day		ACTNotDone, # <input type="checkbox"/> Not set
PaO2			
Low PaO2:	PaO2GoalLow, # (mmHg)	High PaO2:	PaO2GoalHigh, # (mmHg)
PaO2NotChg, #	<input type="checkbox"/> Not changed from previous study day		PaO2NotDone, # <input type="checkbox"/> Not set

NotChg  
2=Not changed from previous study day

fib  
1=mg/dL  
2=ng/mL

NotSet  
99=Not Set

## ECMO Daily Parameter Goals:

PudID #

Occurrence #

ItemGroupRepeatKey #

## PaCO2

Low PaCO2: LowPaCO2Goal, # (mmHg)

High PaCO2: HighPaCO2Goal, # (mmHg)

PaCO2NotChg, # ☐ Not changed from previous study day☐ Not set PaCO2NotDone, #

## pH

Low pH: LowpHGoal, # (#.##)

High pH: HighpHGoal, # (#.##)

pHNotChg, # ☐ Not changed from previous study day☐ Not set pHNotDone, #

## Temperature

Low Temperature: LowTempGoal, # (°C)

High Temperature: HighTempGoal, # (°C)

TempNotChg, # ☐ Not changed from previous study day☐ Not set TempNotDone, #

## SvO2

Low SvO2: SvO2GoalLow, # (%)

High SvO2: SvO2GoalHigh, # (%)

SvO2NotChg, # ☐ Not changed from previous study day☐ Not set SvO2NotDone, #

## SaO2

Low SaO2: SaO2GoalLow, # (%)

High SaO2: SaO2GoalHigh, # (%)

SaO2NotChg, # ☐ Not changed from previous study day☐ Not set SaO2NotDone, #NotChg  
2=Not changed from  
previous study dayNotSet  
99=Not Set

Blood (1 of 2)

## ECMO Blood Product &amp; Medication Information:

PudID #

Occurrence #

ItemGroupRepeatKey #

Blood (0/14)

BloodMe...(0/10)

-- Select to Jump --

## Title: Blood Product Information

Date: BLOODDAY, # (DD-MMM-YYYY)

Was whole blood given on this study day?

WholeBloodGiven, # If yes, provide details

Total non-priming amount given: WholeBloodAmount, # (mL) Total priming amount: WholeBloodPrime, # (mL)

Were packed red blood cells (PRBC) given on this study day?

PRBCGiven, # If yes, provide details

Total non-priming amount given: PRBCAmount, # (mL) Total priming amount: PRBCPrime, # (mL)

Was fresh frozen plasma (FFP) given on this study day?

PlasmaGiven, # If yes, provide details

Total non-priming amount given: PlasmaAmount, # (mL) Total priming amount: PlasmaPrime, # (mL)

Were platelets given on this study day?

PlateletsGiven, # If yes, provide details

Total amount given: PlateletsAmount, # (mL)

Was cryoprecipitate given on this study day?

CryoGiven, # If yes, provide details

Total amount given: CryoAmount, # (mL)

YesNo  
1=Yes  
0=No

Blood (2 of 2)

## ECMO Blood Product &amp; Medication Information:

PudID #

Occurrence #

ItemGroupRepeatKey #

◀ Blood (0/14) BloodMe...(0/10) ▶ -- Select to Jump -- ▼

**Title: ECMO Related Medications**

Was heparin held on this study day?

HeparinHeld, # ▼

If yes, for how many hours was heparin held? HeparinHeldHours, # (hours)

Was Antithrombin III (ATIII) given on this study day?

ATIIIGiven, # ▼ if yes, provide details

Total dose: ATIIIDose, # (IU)

Was Novoseven given on this study day?

NovoGiven, # ▼ if yes, provide details

Total dose: NovoDose, # (mg)

Was Amicar given on this study day?

AmicarGiven, # ▼ if yes, provide details

Total dose: AmicarDose, # (mg)

Was Amicar given via infusion? (select one) ▼ AmicarInfusion, #

Was an Amicar loading dose given prior to infusion? (select one) ▼ AmicarLoadDose, #

YesNo  
1=Yes  
0=No

YesNo  
1=Yes  
0=No

Organ (1 of 1)

## ECMO Organ Systems:

PudID #

Occurrence #

ItemGroupRepeatKey #

OrganSy...(0/6) -- Select to Jump --

**Title: Organ System Failure Information**

Instructions: Refer to the worksheets and manual of operations (MOO) for instructions on how to record these data elements.

Study date: ORGANFAILDAY, # (DD-MMM-YYYY)

Which of the following organ systems are failed today:

Neurologic:	(select one)	NeuroSystem, #	YesNo 1=Yes 0=No
Cardiovascular:	(select one)	CardioSystem, #	
Renal:	(select one)	RenalSystem, #	
Pulmonary:	(select one)	PulmSystem, #	
Hepatic:	(select one)	HepaticSystem, #	