

**PUBLIC USE DATASET
ANNOTATED eCRF**

**Therapeutic Hypothermia after Pediatric Cardiac Arrest
(THAPCA – Out of Hospital Trial)
CPCCRN Protocol Number 010
PECARN Protocol 007**

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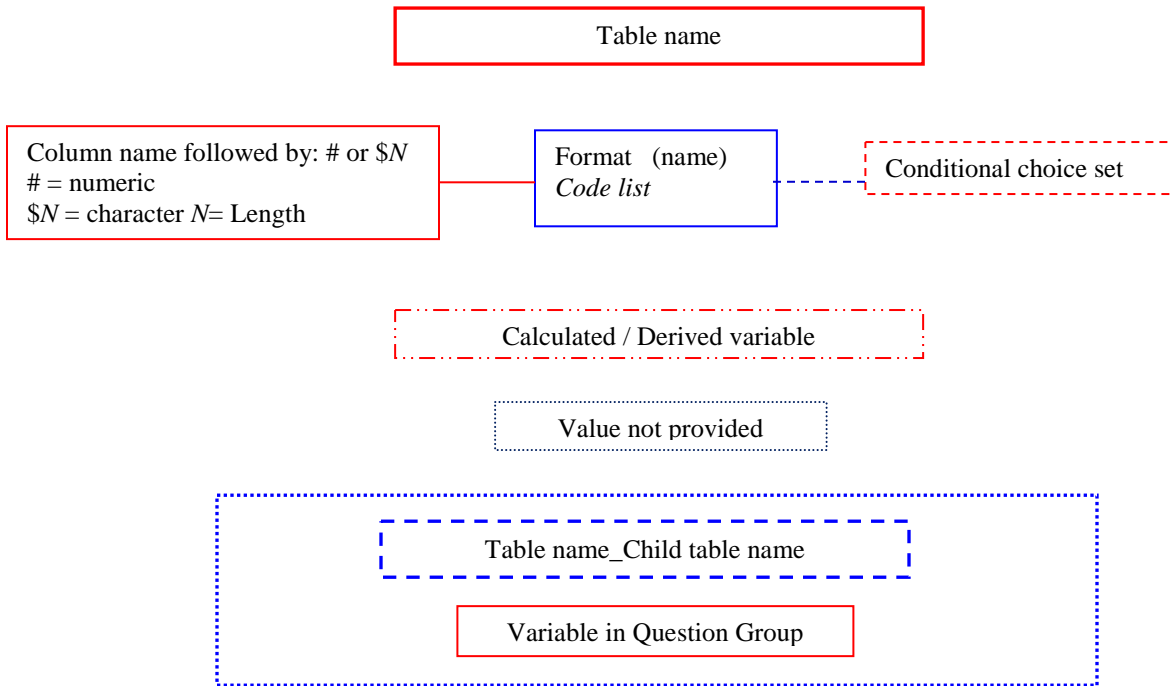
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Annotations key:



Notes:

SubjectID is a randomly generated ID number that uniquely identifies an enrolled (randomized) subject across datasets, it does not contain information about original site. For instances of multiple records per enrolled subject in a dataset, SubjectID and ItemGroupRepeatKey are used. Similarly, if there are multiple forms filled per subject, the variables StudyDay, Phase, Occurrence, StudyEvent, or VABSPPhase are used with SubjectID as needed.

All out of range and other questionable data has 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.

Randomization Day will be coded as 0 (Day 0) and all other dates will be recoded as number of days after Day 0.

Demographics (1 of 1)

SubjectID

Demographic Information

Subject...(0/5) -- Select to Jump --

Title: Subject Demographics

Birthdate of the subject
 Value not provided DD-MMM-YYYY

Gender of the subject
 Gender # gender
 1 = Male
 2 = Female

Race of the subject
 (select race) Race # race*
 2 = Asian
 3 = Black or African American
 5 = White
 97 = Unknown
 95 = Other

If "Other", describe: Value not provided

Ethnicity of the subject
 Ethnicity # ethnic
 1 = Hispanic or Latino
 2 = Not Hispanic or Latino
 97 = Stated as Unknown

*Note: Recoded values 1 and 4 (American Indian or Alaska Native and Native Hawaiian or Other Pacific Islander) as 95 (Other)

Derived variables included in the Demographics dataset:

Variable	Format	Type	Label	Algorithm / Notes
ageyrs		#	Age at Randomization (years)	Randomization Date - Birthdate

Eligibility (1 of 1)

SubjectID

Eligibility

Screeni...(0/4) Includi...(0/5) Excludi...(0/23) -- Select to Jump --

Title: Screening Information
Instructions: Only subjects that meet all inclusion criteria should be entered

Date and Time Screening Completed
Date: * DD-MMM-YYYY Time: * HH:MM

Patient's location at time of arrest
 *
DV6739G
1 = Out of hospital arrest
2 = In-hospital arrest: Non-study hospital
3 = In-hospital arrest: Study hospital

enter the date and time the consent was signed:
Date: DD-MMM-YYYY Time: HH:MM

Date and Time of randomization
Date: DD-MMM-YYYY Time: HH:MM

Assigned treatment group

DV6738G
1 = Hypothermia
2 = Normothermia

CardiacPatients_v2 (1 of 1)

SubjectID

Cardiac Patients

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

Title: Cardiac Patients

Did the patient have congenital heart disease?

(Select one) CHDYN #

If "Yes", did the patient have two ventricles?

(Select one) TwoVentrYN #

Was the etiology of the arrest primarily an arrhythmia (e.g. prolonged QT syndrome, ventricular tachycardia)?

(Select one) ArrhythmiaYN #

Did the patient have myocarditis or cardiomyopathy?

(Select one) CardiomyoYN #

Was this a post-operative cardiac surgery patient at the time of screening (i.e. had cardiac surgery during this hospitalization)?

(Select one) CardiacSurgYN #

If "Yes", did the patient have a Norwood procedure?

(Select one) NorwoodYN #

YNs
1 = Yes
0 = No

BLNeurobehavioral (1 of 1)

SubjectID

Baseline Neurobehavioral

The screenshot shows a clinical form titled "Baselin...(0/5)" with a dropdown menu for "-- Select to Jump --". The form contains several sections:

- Title: POPC, PCPC, VABS**
- Pediatric Overall Performance Category**: POPC score: (select one) * POPC #
- Pediatric Cerebral Performance Category**: PCPC score: (select one) * PCPC #
- Was the baseline VABS completed?**: Radio buttons for Yes and No * VABS_YN #
- If "Yes" enter the date and time VABS completed**: Date: VABSDay # DD-MMM-YYYY, Time: VABSTime \$6 HH:MM

Callouts provide definitions for DV6787G and DV6788G:

- DV6787G**: 1 = Good, 2 = Mild Disability, 3 = Moderate Disability, 4 = Severe Disability, 5 = Coma or vegetative state, 6 = Death
- DV6788G**: 1 = Normal, 2 = Mild Disability, 3 = Moderate Disability, 4 = Severe Disability, 5 = Coma or vegetative state, 6 = Death

A legend for VABS_YN # is also provided: YN, 1 = Yes, 0 = No.

FamilyHouseInfo (1 of 2)

SubjectID

Family and Household Information

The screenshot shows a data entry form titled "Family and Household Information". The form includes sections for "Caregiver Information" and "Subject's Residence and Global Function".

Caregiver Information:

- Initials: Value not provided
- Gender: (select gender) * **CaregiveGend #** (linked to DV6780G: 1 = Male, 2 = Female)
- Caregiver's relationship to the child: Relationship **CaregivRel #** (linked to DV6781G: 1 = Biological or adopted parent, 2 = Step parent, 3 = Foster parent, 4 = Grandparent, 5 = Other legal guardian, 95 = Other (specify), 98 = Question not answered)
- Caregiver's marital status: **CaregivMarit #** (linked to DV6782G: 1 = Married, 2 = Separated or divorced, 3 = Never married, 4 = Widowed, 98 = Question not answered)
- Caregiver's highest education received: **CaregivEdu #** (linked to DV6783G: 1 = No education, 2 = Some high school or less, 3 = High school graduate or GED, 4 = Vocational school or some college, 5 = College degree, 6 = Graduate or doctoral degree, 98 = Question not answered)
- What is the annual household income of the child's family?: **FamilyIncome #** (linked to DV6784G: 1 = Less than \$30,000, 2 = \$30,000 to < \$50,000, 3 = \$50,000 or more, 97 = Stated as unknown, 98 = Question not answered)

Subject's Residence and Global Function:

- Where has your child lived over the past 12 months (primary residence)? Primary residence (select) **ChildReside #** (linked to DV6785G: 1 = At home with parents/guardian, 2 = Foster care, 3 = Acute hospital, 4 = Inpatient rehabilitation hospital, 5 = Chronic care or skilled nursing facility, 95 = Other, 98 = Question not answered)
- Compared to children of the same age, were your child's home, school or social activities limited before his/her cardiac arrest?: **LimitedActiv #** (linked to DV6786G: 1 = Not limited, 2 = Limited a little, 3 = Limited a lot, 98 = Question not answered)

FamilyHouseInfo (2 of 2)

Caregiv...(0/10) FAD (0/12) -- Select to Jump --

Title: Family Assessment Device (FAD)

Page:

Family Assessment Device (FAD)

Planning family activities is difficult because we misunderstand each other.

Strongly agree Agree Disagree Strongly Disagree Question not answered

FADPlanning #

In times of crisis we turn to each other for support.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADCrisis #

We cannot talk to each other about sadness we feel.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADCantTalk #

Individuals in the family are accepted for what they are.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADFamAccept #

We avoid discussing our fears and concerns.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADNoDiscuss #

We express feelings to each other.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADExpress #

There are lots of bad feelings in our family.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADBadFeel #

We feel accepted for what we are.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADAreAccept #

Making decisions is a problem for our family.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADDecisions #

We are able to make decisions about how to solve problems.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADSolveProb #

We don't get along well together.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADGetAlong #

We confide in each other.

Strongly agree Agree Disagree Strongly Disagree Question not answered *

FADConfide #

DV6792G
1 = Strongly agree
2 = Agree
3 = Disagree
4 = Strongly Disagree
98 = Question not answered

Family Burden CHQ

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

Title: Family Burden - Child Health Questionnaire (CHQ)

Page:

Date questionnaire completed

QOLDay # * DD-MMM-YYYY

During the past 4 weeks, how MUCH emotional worry or concern did each of the following cause YOU:

Your child's physical health?

CHQ91a # *

Your child's emotional well-being or behavior?

CHQ91b # *

Your child's attention or learning abilities?

CHQ91c # *

DV495G
1 = None at all
2 = A little bit
3 = Some
4 = Quite a bit
5 = A lot
6 = Not answered

During the past 4 weeks, were you LIMITED in the amount of time YOU had for your own needs due to:

Your child's physical health?

CHQ92a # *

Your child's emotional well-being or behavior?

CHQ92b # *

Your child's attention or learning abilities?

CHQ92c # *

DV498G
1 = Yes- limited a lot
2 = Yes - limited some
3 = Yes - limited a little
4 = No - not limited
5 = Not answered

FamBurdenCHQ (2 of 2)

During the past 4 weeks, how often has your child's health or behavior:

Limited the types of activities you could do as a family?

CHQ93a # *

Interrupted various everyday family activities (eating, watching TV)?

CHQ93b # *

Limited your ability as a family to "pick up and go" on a moment's notice?

CHQ93c # *

Caused tension or conflict in your home?

CHQ93d # *

Been a source of disagreements or arguments in your family?

CHQ93e # *

Caused you to cancel or change plans (personal or work) at the last minute?

CHQ93f # *

DV496G
1 = Very often
2 = Fairly often
3 = Sometimes
4 = Almost never
5 = Never
6 = Not answered

Family Burden ITQOL

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

Title: Family Burden - Infant and Toddler Quality of Life Questionnaire (ITQOL)

Page: Mark CRF Complete

Date questionnaire completed

ITQOLDay # * DD-MMM-YYYY

During the previous 4 weeks, how MUCH anxiety or worry did each of the following cause YOU?

Child's feeding, eating, sleeping habits

ITQOL91a # *

Child's physical health

ITQOL91b # *

Child's emotional well-being or behavior

ITQOL91c # *

Child's learning abilities or cognitive development

ITQOL91d # *

Child's ability to interact with others

ITQOL91e # *

Child's behavior

ITQOL91f # *

Child's temperament

ITQOL91g # *

DV495G

1 = None at all

2 = A little bit

3 = Some

4 = Quite a bit

5 = A lot

6 = Not answered

FamBurdITQOL (2 of 2)

During the previous 4 weeks, were you LIMITED in the amount of time YOU had for your own personal needs due to problems with your child's personal needs?

Feeding, eating, sleeping habits

ITQOL92a #

Physical health

ITQOL92b #

Emotional well-being

ITQOL92c #

Learning abilities or cognitive development

ITQOL92d #

Ability to interact with others

ITQOL92e #


Behavior

ITQOL92f #

Temperament

ITQOL92g #

DV498G
1 = Yes- limited a lot
2 = Yes - limited some
3 = Yes - limited a little
4 = No - not limited
5 = Not answered

Mark CRF Complete 

[Return to top](#)

GestationalAge (1 of 1)

SubjectID

Gestational Age

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

Title: Gestational Age

Instructions: This form is required for subjects less than 5 years of age at the time of randomization.

Was the patient's gestational age at birth 38 weeks or less?

* If "No" or "Could not determine", skip the next question and save the form.

If "Yes", enter the patient's gestational age at birth:

Weeks

YNCND
1 = Yes
0 = No
93 = Could not determine

Baseline (1 of 3)

SubjectID

Baseline Assessments

Events 1 (0/1) Labs 1 (0/19) Labs 2 (0/24) -- Select to Jump --

Title: Event Review (Baseline evaluations)

Were any culture specimens obtained prior to randomization?

Y/N
1 = Yes
0 = No

BLCultureYN # Yes No * If "Yes", record on culture log

Events 1 (0/1) Labs 1 (0/19) Labs 2 (0/24) -- Select to Jump --

Title: Laboratory Tests (Baseline evaluations)

Were any complete blood counts (CBC) obtained prior to randomization?

Y/N
1 = Yes
0 = No

BLCBCYN # Yes No *

If "Yes", enter the most recent Hemoglobin, Platelet count and White blood cell count results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	Hemoglobin (g/dL)	Platelet count (10 ³ /microL)	White blood cell (10 ³ /microL)
BLCBCDay #	BLCBCTime \$6	BLHgb #	BLPlatelet #	BLWBC #

ADD

Baseline_CBC

SubjectID

ItemGroupRepeatKey

Were any of the following liver function tests (LFT) obtained prior to randomization?

Y/N
1 = Yes
0 = No

BLLFTYN # Yes No *

If "Yes", enter the most recent ALT, AST, LDH and Total bilirubin results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	ALT/SGPT (U/L)	AST/SGOT (U/L)	LDH (U/L)	Total bilirubin (mg/dL)
BLLFTDay #	BLLFTTime \$6	BLALT #	BLAST #	BLLDH #	BLBilirubin #

ADD

Baseline_Liver

SubjectID

ItemGroupRepeatKey

Were any blood coagulation tests obtained prior to randomization?

Y/N
1 = Yes
0 = No

BLCoagYN # Yes No *

If "Yes", enter the most recent PT, PTT and INR results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	PT (seconds)	PTT (seconds)	INR
BLCoagDay #	BLCoagTime \$6	BLPT #	BLPTT #	BLINR #

ADD

Baseline_Coags

SubjectID

ItemGroupRepeatKey

Baseline (2 of 3)

Events 1 (0/1) Labs 1 (0/19) Labs 2 (0/24) -- Select to Jump --

Title: Laboratory Tests (Baseline evaluations)

Were any of the following pancreatic enzyme tests obtained prior to randomization?

Yes No * **BLPanEnzYN #** YN
1 = Yes
0 = No

If "Yes", enter the most recent Amylase and Lipase results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	Amylase (U/L)	Lipase (U/L)		Baseline_Pancreas	SubjectID
BLPanEnzDay #	BLPanEnzTime \$6	BLAmylase #	BLLipase #	<input type="checkbox"/>		

ItemGroupRepeatKey

Were any of the following chemistry tests obtained prior to randomization?

Yes No * **BLOthChemYN #** YN
1 = Yes
0 = No

If "Yes", enter the most recent Magnesium, Ionized calcium, Total calcium, and Phosphate results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	Magnesium (mg/dL)	Ionized calcium (mmol/L)	Total calcium (mg/dL)	Phosphate (mg/dL)	Baseline_Chemistry	SubjectID
BLOthChemDay #	BLOthChemTm \$6	BLMagnesium #	BLIonizedCa #	BLTotalCa #	BLPhosphate #		

ItemGroupRepeatKey

Were any lactate tests obtained prior to randomization?

Yes No * **BLLactateYN #** YN
1 = Yes
0 = No

If "Yes", enter the most recent Lactate test results available prior to randomization

Date collected (DD-MMM-YYYY)	Time collected (HH:MM)	Lactate (mmol/L)		Baseline_Lactate	SubjectID
BLLactDay #	BLLactTime \$6	BLLactate #	<input type="checkbox"/>		

ItemGroupRepeatKey

Baseline (3 of 3)

Were any arterial blood gas (ABG) tests obtained prior to randomization? YN
1 = Yes
0 = No

Yes No * BLABGYN #

If "Yes", enter the most recent ABG test results available prior to randomization

Date collected:	BLABGDay #	<input type="text" value="DD-MMM-YYYY"/>
Time collected:	BLABGTime \$6	<input type="text" value="HH:MM"/>
pH:	BLABGpH #	
PaCO2:	BLABGPaCO2 #	<input type="text" value="mmHg"/>
PaO2:	BLABGPaO2 #	<input type="text" value="mmHg"/>
Saturation:	BLABGSat #	<input type="text" value="%"/>
HCO3 / Bicarbonate:	BLABGBicarb #	<input type="text" value="mmol/L"/>

ArrEtiol (1 of 4)

SubjectID

Etiology of Cardiac Arrest

◀ **Descrip...**(0/3) **Cardiov...**(0/3) **Neurolo...**(0/3) ▶ -- Select to Jump -- ▾

Title: Description of Arrest

Instructions: The purpose of questions in this section is to classify the single primary etiology for the cardiac arrest, as well as to provide a basic descriptive narrative about the arrest events.

Type a brief description of the events leading to the cardiac arrest

Brief description of cardiac arrest: *

Select the primary cause of the cardiac arrest (only one). *

Select single primary cause of cardiac arrest:

- Cardiovascular event
- Neurological event
- Congenital heart disease
- Respiratory event
- Multiple organ system failure (MOSF)
- Drug overdose
- Electrolyte imbalance
- Other
- Unknown

DV7096G

- 1 = Cardiovascular event
- 2 = Neurological event
- 3 = Congenital heart disease
- 4 = Respiratory event
- 5 = Multiple organ system failure (MOSF)
- 6 = Drug overdose
- 7 = Electrolyte imbalance
- 95 = Other
- 97 = Unknown

If "Other", specify: Required if "Other" was selected above.

ArrEtiol (2 of 4)

Descrip...(0/4)
Cardiov...(0/3)
Neurolo...(0/3)
-- Select to Jump --

Title: Cardiovascular

Instructions: The purpose of questions in this section is to identify whether cardiovascular events contributed to the cardiac arrest, and if yes, to indicate the specific type of event.

Page:

Was the cardiac arrest the result of a cardiovascular event?

Yes
 No *
 EtiolCardYN #
YN
1 = Yes
0 = No

If "Yes", select or enter the cardiovascular event(s) contributing to the cardiac arrest

Contributory cardiovascular event(s):	If "Other", specify:
(select all that apply) EtiolCardio #	Value not provided
<input type="button" value="ADD"/>	

ArrEtiol_EtiolCardio
SubjectID
ItemGroupRepeatKey

DV6764G

- 1 = Cardiac arrhythmia w/o history of Congenital Heart Disease (CHD)
- 2 = Hypovolemic shock (dehydration)
- 3 = Septic shock with hypotension
- 4 = Cardiomyopathy
- 5 = Hemorrhage
- 6 = Pulmonary hypertension
- 95 = Other

Cardiov...(0/3)
Neurolo...(0/3)
Congeni...(0/3)
-- Select to Jump --

Title: Neurological

Instructions: The purpose of questions in this section is to identify whether neurological events contributed to the cardiac arrest, and if yes, to indicate the specific type of event.

Page:

Was the cardiac arrest the result of a neurological event?

Yes
 No *
 EtiolNeuroYN #
YN
1 = Yes
0 = No

If "Yes", select or enter the neurological event(s) contributing to the cardiac arrest

Contributory neurological event(s):	If "Other", specify:
(select all that apply) EtiolNeuro #	Value not provided
<input type="button" value="ADD"/>	

ArrEtiol_EtiolNeuro
SubjectID
ItemGroupRepeatKey

DV6765G

- 1 = Seizure with apnea
- 95 = Other

ArrEtiol (3 of 4)

Neurolo...(0/3) Congeni...(0/3) Respira...(0/3) -- Select to Jump --

Title: Congenital Heart Disease

Instructions: The purpose of questions in this section is to identify whether congenital heart disease contributed to the cardiac arrest, and if yes, to indicate the specific type of contribution.

Page:

Was the cardiac arrest the result of congenital heart disease? YN
1 = Yes
0 = No

Yes No * EtiolCongYN #

If "Yes", select or enter the congenital heart disease(s) contributing to the cardiac arrest

Contributory congenital heart disease(s):	If "Other", specify:
(select) EtiolCongHrt #	Value not provided
ADD	

DV6766G

- 1 = Arrhythmia
- 2 = Hypoxemia
- 3 = Low cardiac output
- 4 = Postoperative during hospitalization
- 95 = Other

ArrEtiol_EtiolCongHrt

SubjectID

ItemGroupRepeatKey

Congeni...(0/3) Respira...(0/3) Miscell...(0/5) -- Select to Jump --

Title: Respiratory Event

Instructions: The purpose of questions in this section is to identify whether respiratory events contributed to the cardiac arrest, and if yes, to indicate the specific type of event.

Page:

Was the cardiac arrest the result of a respiratory event? YN
1 = Yes
0 = No

Yes No * EtiolRespYN #

If "Yes", select or enter the respiratory event(s) contributing to the cardiac arrest

Contributory respiratory event(s):	If "Other", specify:
EtiolResp #	Value not provided
ADD	

DV6767G

- 1 = ALTE (Acute Life Threatening Event) or SIDS like event
- 2 = Apnea
- 3 = Aspiration pneumonia (not drowning)
- 4 = Drowning (with or without aspiration)
- 5 = Respiratory asphyxia
- 6 = Endotracheal tube misplacement
- 7 = Respiratory failure (pneumonia, ARDS)
- 95 = Other

ArrEtiol_EtiolResp

SubjectID

ItemGroupRepeatKey

ArrEtiol (4 of 4)

Congeni...(0/3) Respira...(0/3) **Miscell...(0/5)** -- Select to Jump --

Title: Miscellaneous

Instructions: The purpose of questions in this section is to ask whether several miscellaneous types of events contributed to the cardiac arrest.

Page:

Multiple Organ System Failure (MOSF)
Was the cardiac arrest the result of multiple organ system failure?
 Yes No * EtiolMOSF #

Drug Overdose
Was the cardiac arrest the result of a drug overdose?
 Yes No * EtiolDrugOv #

Electrolyte Abnormality
Was the cardiac arrest the result of an electrolyte imbalance?
 Yes No * EtiolElectro #

Other Event (not previously listed)
Was the cardiac arrest the result of another event not listed previously?
 Yes No * OtherEtiol #

If "Yes", specify: Required if previous question was answered "Yes".

YN
1 = Yes
0 = No

OHCardiacArr (1 of 7)

SubjectID

Outside Hospital Cardiac Arrest

Cardiac...(0/14) Prehosp...(0/7) EMS Res...(0/7) -- Select to Jump --

Title: Cardiac Arrest Event

Date and time of cardiac arrest

Date: ArrestDay # * DD-MMM-YYYY Time known? Yes No * If "Yes" enter time: TimeArrest \$6 HH:MM

Duration of arrest prior to CPR: ArrestDur # * (best estimate)

Date and time of cardiopulmonary resuscitation started (chest compressions)

Date: CPRDay # * DD-MMM-YYYY Time known? Yes No * If "Yes" enter time: CPRTime \$6 HH:MM

Duration of chest compressions: CPRDuration # * (best estimate)

Return of Spontaneous Circulation (ROSC)

Date and time of ROSC

Date: ROSCDay # * DD-MMM-YYYY Time known? Yes No * If "Yes" enter time: ROSCTimeKnown \$6 HH:MM

If time of ROSC not known precisely:

If "No", estimated time: ROCTimeEst # HH:MM

Was cardiac arrest witnessed? Yes No Unable to determine *

Were chest compressions administered by bystander? Yes No Unable to determine *

YN
1 = Yes
0 = No

YN
1 = Yes
0 = No

YN
1 = Yes
0 = No

YNUD
1 = Yes
0 = No
94 = Unable to determine

DV7124G
1 = < 2 minutes
2 = 2 to 5 minutes
3 = > 5 to 10 minutes
4 = > 10 to 15 minutes
5 = > 15 to 20 minutes
6 = > 20 to 30 minutes
7 = > 30 to 40 minutes
8 = > 40 minutes
99 = Unable to determine

DV7093G
1 = < 2 minutes
2 = 2 to 5 minutes
3 = > 5 to 8 minutes
4 = > 8 to 11 minutes
5 = > 11 to 15 minutes
6 = > 15 to 20 minutes
7 = > 20 minutes
99 = Unable to determine

OHCardiacArr (2 of 7)

Cardiac...(0/14) Prehosp...(0/7) EMS Res...(0/7) -- Select to Jump --

Title: Prehospital Information

EMS Information
 Date and time of EMS arrival to the scene
 Date: **OHEMSDay #** * DD-MMM-YYYY Time: **OHEMSTime \$6** * HH:MM

Initial arrest rhythm noted by EMS
 Rhythm: (select one) * **RhythmEMS #**
 If "Other" describe: Value not provided

Were there other rhythms reported by EMS during chest compressions?
 Yes No * **CPRRhythYN #**
 YN
 1 = Yes
 0 = No

If "Yes", other rhythms reported during EMS chest compressions

Other rhythms:	If "Other" describe:	OHCardiacArr_CPRRhythmEM
CPRRhythm #	Value not provided	SubjectID
<input type="button" value="ADD"/>		ItemGroupRepeatKey

DV6762G
 1 = Asystole
 2 = Bradycardia
 3 = Pulseless electrical activity (PEA)
 4 = Sinus rhythm
 5 = Ventricular fibrillation
 6 = Ventricular tachycardia
 95 = Other

DV6761G
 1 = Asystole
 2 = Bradycardia
 3 = Pulseless electrical activity (PEA)
 4 = Ventricular fibrillation
 5 = Ventricular tachycardia
 95 = Other
 97 = Unknown

OHCardiacArr (3 of 7)

Prehosp...(0/7) EMS Res...(0/7) Rhythm ...(0/6) -- Select to Jump --

Title: Resuscitation Interventions by EMS and Transport

EMS Resuscitation

Number of defibrillation attempts by EMS?

Defibrillations: (select one) * OHDefibNuEMS #

Number of doses of epinephrine administered by EMS?

Doses epinephrine: (select one) * OHDoseEpiEMS #

Was intravenous or intraosseous access placed by EMS?

IV or IO established? Yes No Unable to determine * OHIVEMS #

Transport to Hospital

Was subject transported to first hospital by EMS?

Yes No * OHTranspEMS #

What was the first hospital the patient arrived at?

Type of hospital: (select one) * FirstHosp #

Date and time of arrival at first hospital, if not study hospital

Date: OH1stHospDay# DD-MMM-YYYY Time: OH1stHospTim \$6 HH:MM

DV7094G
 1 = 1
 2 = 2
 3 = 3
 4 = 4
 5 = 5
 6 = >5
 96 = None
 97 = Unknown

DV7095G
 1 = 1
 2 = 2
 3 = 3
 4 = 4
 5 = 5
 6 = 6
 7 = 7
 8 = 8
 9 = 9
 10 = 10
 11 = >10
 96 = None
 97 = Unknown

YNUD
 1 = Yes
 0 = No
 94 = Unable to determine

YN
 1 = Yes
 0 = No

DV7148G
 1 = Study hospital
 2 = Non-study hospital

OHCardiacArr (4 of 7)

YN
1 = Yes
0 = No
94 = Unable to determine

EMS Res...(0/7) Rhythm ...(0/6) Hospita...(0/6) -- Select to Jump

Title: Status on Arrival at Hospital

Were chest compressions still required at time of arrival at the first hospital? **OH1stHospCPR**

Yes No Unable to determine *

Rhythm on Arrival

Initial arrest rhythm reported at time of arrival at first hospital?

Rhythm: **RhythmHosp #** (if applicable)

If "Other" describe: Value not provided

Were there other reported rhythms during chest compressions at first hospital? **OthRhythm #**

Yes No *

If "Yes", other rhythms reported during hospital chest compressions

Other rhythms:	If "Other" describe:
CPRRhythmHos #	Value not provided

ADD

DV6761G
1 = Asystole
2 = Bradycardia
3 = Pulseless electrical activity (PEA)
4 = Ventricular fibrillation
5 = Ventricular tachycardia
95 = Other
97 = Unknown

YN
1 = Yes
0 = No

OHCardiacArr_CPRRhythm2

SubjectID

ItemGroupRepeatKey

DV6762G
1 = Asystole
2 = Bradycardia
3 = Pulseless electrical activity (PEA)
4 = Sinus rhythm
5 = Ventricular fibrillation
6 = Ventricular tachycardia
95 = Other

OHCardiacArr (5 of 7)

Rhythm...(0/6) Other C...(0/3) Hospita...(0/6) -- Select to Jump --

Title: Other Cardiac Arrest Event

Instructions: Record cardiac arrest events requiring at least 2 minutes of chest compressions, and a resulting ROSC of at least 20 minutes, that occurred after the qualifying arrest, but prior to randomization.

Did the patient have additional cardiac arrest events after the qualifying arrest but prior to randomization?

Yes No *

OthCAYN #

YN
1 = Yes
0 = No

If "Yes", enter the date and time of each cardiac arrest event

Date (DD-MMM-YYYY)	Time (HH:MM)
OthCADay #	OthCATm \$6

ADD

OHCardiacArr_OtherOHHospCA

SubjectID

ItemGroupRepeatKey

OHCardiacArr (6 of 7)

Rhythm ...(0/6) Hospita...(0/6) Admissi...(0/6) -- Select to Jump --

Title: Hospital Based Resuscitation Information

Number of defibrillation attempts at hospital?
 * DefibHosp #

Number of doses of epinephrine administered at hospital?
 * EpinephHosp #

Were open chest compressions performed?
 Yes No * OpenChestCPR #

Was ECMO used following cardiac arrest and prior to randomization?
 Yes No * ECMO #

If "Yes", provide date and time ECMO was started
Start date: ECMOStartDay # DD-MMM-YYYY Start time: ECMOStartTim \$6 HH:MM

DV7094G
1 = 1
2 = 2
3 = 3
4 = 4
5 = 5
6 = >5
96 = None
97 = Unknown

DV7095G
1 = 1
2 = 2
3 = 3
4 = 4
5 = 5
6 = 6
7 = 7
8 = 8
9 = 9
10 = 10
11 = >10
96 = None
97 = Unknown

YN
1 = Yes
0 = No

Rhythm ...(0/6) Hospita...(0/6) Admissi...(0/6) -- Select to Jump --

Title: Study Hospital Admission Information

Dates and times at study hospital

Date and time of arrival at study hospital

Date: * DD-MMM-YYYY Time: * HH:MM

Date and time of study hospital admission

Date: * DD-MMM-YYYY Time: * HH:MM

Date and time of PICU admission

Date: * DD-MMM-YYYY Time: * HH:MM

ReviewSystem (1 of 4)

SubjectID

Review of Systems

One (0/18) Two (0/16) -- Select to Jump --

Title: Review of Systems Section One
Instructions: Indicate Normal, Abnormal, or Unknown for every system. If abnormal, then you must provide a description

Date and Time of Review of Systems
Date: **RevSystDay #** * DD-MMM-YYYY Time: **RevSysTime \$6** * HH:MM

HEENT review **HEENT #**
HEENT: Normal * Abnormal Unknown
If "Abnormal", provide description: Value not provided

Cardiovascular review **Cardiovasc #**
Cardiovascular: Normal * Abnormal Unknown
If "Abnormal", provide description: Value not provided

Respiratory or pulmonary review **RespPulm #**
Respiratory: Normal * Abnormal Unknown
If "Abnormal", provide description: Value not provided

Gastrointestinal review **Gastrointest #**
Gastrointestinal: Normal * Abnormal Unknown
If "Abnormal", provide description: Value not provided

DV6776G
1 = Normal
2 = Abnormal
97 = Unknown

ReviewSystem (2 of 4)

Hepatic review	Hepatic #	Hepatic: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description:	Value not provided
Genitourinary review	Genitourin #	Genitourinary: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description:	Value not provided
Renal review	RenalSymptom #	Renal: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description:	Value not provided
Neurologic review	NeuroloSymp #	Neurologic: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description:	Value not provided

DV6776G
1 = Normal
2 = Abnormal
97 = Unknown

ReviewSystem (3 of 4)

One (0/18) Two (0/16) -- Select to Jump --

Title: Review of Systems Section Two

Instructions: Indicate Normal, Abnormal, or Unknown for every system. If abnormal, then you must provide a description

Psychiatric review **Psychiatric #**

Psychiatric: Normal * Abnormal Unknown

If "Abnormal", provide description: Value not provided

Endocrine review **Endocrine #**

Endocrine: Normal * Abnormal Unknown

If "Abnormal", provide description: Value not provided

Hematologic review **Hematologic #**

Hematologic: Normal * Abnormal Unknown

If "Abnormal", provide description: Value not provided

Musculoskeletal review **Musculoskel #**

Musculoskeletal: Normal * Abnormal Unknown

If "Abnormal", provide description: Value not provided

DV6776G
1 = Normal
2 = Abnormal
97 = Unknown

ReviewSystem (4 of 4)

Dermatologic review	Dermatologic #
Dermatologic: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description: <div style="border: 1px dashed gray; padding: 5px; text-align: center;">Value not provided</div>
Allergies	Allergies #
Allergies: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description: <div style="border: 1px dashed gray; padding: 5px; text-align: center;">Value not provided</div>
Immunologic review	Immune #
Immunologic: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description: <div style="border: 1px dashed gray; padding: 5px; text-align: center;">Value not provided</div>
Alcohol or drug abuse review	AlcoholDrug #
Alcohol/Drug abuse: <input type="radio"/> Normal * <input type="radio"/> Abnormal <input type="radio"/> Unknown	If "Abnormal", provide description: <div style="border: 1px dashed gray; padding: 5px; text-align: center;">Value not provided</div>

DV6776G
1 = Normal
2 = Abnormal
97 = Unknown

PhysExam (1 of 3)


SubjectID

Physical Examination

Basic I...(0/4) Body Sy...(0/8) Body Sy...(0/9) -- Select to Jun

Title: Basic Information

Basic Information

Date of physical exam  * DD-MMM-YYYY

Time of physical exam * HH:MM

Height: * (cm)

Weight: * (kg)

PhysExam (2 of 3)

Basic I...(0/4) Body Sy...(0/8) Body Sy...(0/9) -- Select to Jump --

Title: Body System/Site (Part 1)

Instructions: Indicate Normal, Abnormal, or Not Assessed for every site. If abnormal, then you must provide a description

HEENT Examination Findings HEENTPE #

If 'Abnormal' is selected, description is required.

HEENT (select one) * Description:(Required if Abnormal) Value not provided

Cardiovascular Examination Findings CardioPE #

If 'Abnormal' is selected, description is required.

Cardiovascular (select one) * Description:(Required if Abnormal) Value not provided

Lung Examination Findings LungsPE #

If 'Abnormal' is selected, description is required.

Lungs (select one) * Description:(Required if Abnormal) Value not provided

Abdomen and GI Examination Findings AbdGIPE #

If 'Abnormal' is selected, description is required.

Abdomen/GI (select one) * Description:(Required if Abnormal) Value not provided

DV6779G
1 = Normal
2 = Abnormal
3 = Not Assessed

PhysExam (3 of 3)

Basic I...(0/4) Body Sy...(0/8) Body Sy...(0/9) -- Select to Jump --

Title: Body System/Site (Part 2)
Instructions: Indicate Normal, Abnormal, or Not Assessed for every site. If abnormal, then you must provide a description.

Extremities and Musculoskeletal Examination Findings
If 'Abnormal' is selected, description is required.

Extremities (select one) * Description:(Required if Abnormal) Value not provided

Neurologic Examination Findings
If 'Abnormal' is selected, description is required.

Neurologic (select one) * Description:(Required if Abnormal) Value not provided

Skin Examination Findings
If 'Abnormal' is selected, description is required.

Skin (select one) * Description:(Required if Abnormal) Value not provided

Lymph Nodes and Hematology Examination Findings
If 'Abnormal' is selected, description is required.

Lymph Nodes / Hematology (select one) * Description:(Required if Abnormal) Value not provided

Additional Comments about the Physical Examination (optional)
Additional comments about the physical examination Value not provided

DV6779G
1 = Normal
2 = Abnormal
3 = Not Assessed

PreArrest (1 of 6)

SubjectID

Pre-Arrest Status

Diagnos...(0/18) Diagnos...(0/18) Severit...(0/6) -- Select to Jump --

Title: Pre-Arrest Conditions

Did patient have a pre-existing prenatal condition?

Yes No * PreExPrenat #

YN
1 = Yes
0 = No

If "Yes", select or enter all prenatal conditions that apply:

Prenatal conditions	If "Other", describe:
(one condition per row, add as many rows as needed)	Value not provided
ADD Prenatal #	

DV6741G
1 = Apnea of prematurity (estimated gestational age is <36 weeks)
95 = Other

PreArrest_Prenatal
SubjectID
ItemGroupRepeatKey

Did patient have a pre-existing lung or airway disease?

Yes No * PreExLung #

YN
1 = Yes
0 = No

If "Yes", select or enter all lung and / or airway diseases that apply:

Lung or Airway Disease	If "Other", describe:
(one condition per row, add as many rows as needed)	Value not provided
ADD LungDisease #	

PreArrest_LungDisease
SubjectID
ItemGroupRepeatKey

DV6742G
1 = Asthma or history of Reactive Airway Disease (RAD)
2 = Bronchopulmonary Dysplasia (BPD) or Chronic Lung Disease (CLD)
3 = Home oxygen required
4 = Tracheostomy
95 = Other

PreArrest (2 of 6)

Did patient have a pre-existing congenital heart disease?

Yes No *

PreExCongHrt #

YN
1 = Yes
0 = No

If "Yes", select or enter all congenital heart diseases that apply:

Congenital Heart Disease	If "Other", describe:
(one condition per row, add as many rows as needed)	Value not provided
ADD	

CongenHeart #

PreArrest_CongenHeart

SubjectID

ItemGroupRepeatKey

DV6743G

- 1 = Anomalous pulmonary venous return
- 2 = Anomalous coronary artery (ALCAPA)
- 3 = Aortic stenosis
- 4 = Atrial septal defect (ASD)
- 5 = Atrial ventricular septal defect (AVSD)
- 6 = Coartation of the Aorta / Interrupted Aortic Arch
- 7 = Congenital arrhythmias
- 8 = Double outlet right ventricle (DORV)
- 9 = Hypertrophic cardiomyopathy
- 10 = Hypoplastic left heart (HLHS)
- 11 = Patent ductus arteriosus (PDA)
- 12 = Pulmonary atresia with intact septum
- 13 = Pulmonary atresia with VSD
- 14 = Pulmonary stenosis
- 15 = Single ventricle
- 16 = Tetralogy of Fallot
- 17 = Transposition of great arteries
- 18 = Tricuspid atresia
- 19 = Truncus arteriosus
- 20 = Ventricular septal defect (VSD)
- 95 = Other

PreArrest (3 of 6)

Did patient have a pre-existing acquired heart disease?

Yes No * **PreExAcqHrt #**

YN
1 = Yes
0 = No

If "Yes", select or enter all acquired heart diseases that apply:

Acquired Heart Disease	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> AcquiredHrt #	Value not provided <input type="button" value="X"/>

DV6744G
1 = Cardiomyopathy
2 = Myocarditis
95 = Other

PreArrest_AcquiredHrt
SubjectID
ItemGroupRepeatKey

Did patient have pre-existing arrhythmia?

Yes No * **PreExArrhyth #**

YN
1 = Yes
0 = No

If "Yes", select or enter all arrhythmias that apply:

Arrhythmia	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Arrhythmia #	Value not provided <input type="button" value="X"/>

DV6745G
1 = Atrial (SVT, flutter/fib, JET)
2 = Ventricular (VT, VF, Torsades)
3 = AV block
95 = Other

PreArrest_Arrhythmia
SubjectID
ItemGroupRepeatKey

Did patient have a pre-existing immunocompromised condition or is taking an immunosuppressive medication?

Yes No * **PreExImmuno #**

YN
1 = Yes
0 = No

If "Yes", select or enter any immunocompromised conditions and / or immunosuppressive medications that apply:

Immunocompromised Condition or Medication	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Immunocomp #	Value not provided <input type="button" value="X"/>

DV6746G
1 = Chronic steroids
2 = Cancer or leukemia
95 = Other

PreArrest_Immunocomp
SubjectID
ItemGroupRepeatKey

PreArrest (4 of 6)

Diagnos...(0/18) Diagnos...(0/18) Severit...(0/6) -- Select to Jump --

Title: Pre-Arrest Conditions

Did patient have a pre-existing transplant?
 Yes No * **PreExTranspl #** YN
1 = Yes
0 = No

Did patient have a pre-existing gastrointestinal disorder?
 Yes No * **PreExGastro #** YN
1 = Yes
0 = No

If "Yes", select or enter all gastrointestinal conditions that apply:

Gastrointestinal	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Gastro #	Value not provided <input type="button" value="X"/>

DV6748G
1 = Gastroesophageal reflux
95 = Other

PreArrest_Gastro
SubjectID
ItemGroupRepeatKey

Did patient have a pre-existing endocrine condition?
 Yes No * **PreExEndo #** YN
1 = Yes
0 = No

If "Yes", select or enter all endocrine conditions that apply:

Endocrine	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Endocrine #	Value not provided <input type="button" value="X"/>

DV6749G
1 = Diabetes
95 = Other

PreArrest_Endocrine
SubjectID
ItemGroupRepeatKey

PreArrest (5 of 6)

Did patient have a pre-existing renal condition? YN
1 = Yes
0 = No

Yes No * PreExRenal #

If "Yes", select or enter all renal conditions that apply:

Renal Condition	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Renal #	Value not provided <input type="button" value="X"/>

DV6750G
 1 = Chronic renal failure
 2 = Acute renal failure
 95 = Other

PreArrest_Renal
 SubjectID
 ItemGroupRepeatKey

Did patient have a pre-existing neurologic condition? YN
1 = Yes
0 = No

Yes No * PreExNeuro #

If "Yes", select or enter all neurologic conditions that apply:

Neurologic Condition	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Neurologic #	Value not provided <input type="button" value="X"/>

DV6755G
 1 = Known developmental delay/mental retardation
 2 = Seizures
 95 = Other

PreArrest_Neurologic
 SubjectID
 ItemGroupRepeatKey

Did patient have any other significant pre-existing medical condition? YN
1 = Yes
0 = No

Yes No * PreExMisc #

If "Yes", please select or enter any other significant medical conditions not listed previously that apply:

Miscellaneous	If "Other", describe:
(one condition per row, add as many rows as needed) <input type="button" value="ADD"/> Misc #	Value not provided <input type="button" value="X"/>

DV6756G
 1 = Cyanotic heart disease (baseline sat < 85%)
 2 = Pulmonary hypertension
 3 = Failure to thrive
 95 = Other

PreArrest_Misc
 SubjectID
 ItemGroupRepeatKey

PreArrest (6 of 6)

Diagnos...(0/18) | Diagnos...(0/18) | Severit...(0/6) | -- Select to Jump --

Title: Severity Indicators and Pre-arrest medications

Was the patient receiving supplemental oxygen when the arrest occurred?
 Yes No * PASuppOx #

Did the patient have a tracheostomy when the arrest occurred?
 Yes No * PATracheost #

Was the patient on mechanical ventilation when the arrest occurred?
 Yes No * PAMechVent #

Did the patient have a surgically placed gastric or small bowel feeding tube when the arrest occurred?
 Yes No * PAFeedTube #

Were medications taken within 24 hours prior to cardiac arrest?
 Yes No * MedsYN #

If "Yes", list all prescriptions and OTC medications taken within 24 hours of cardiac arrest:

Name of medication	
Value not provided	X
ADD	

YN
 1 = Yes
 0 = No

PreArrest_PreArrMeds
 SubjectID
 ItemGroupRepeatKey

Derived variables included in the PreArrest_PreArrMeds dataset:

Variable	Format	Type	Label	Algorithm / Notes
codedmedname		\$	Coded Medication Name	Verbatim terms were coded using MedDRA version 13
code		\$	RxNorm Code	Verbatim terms were coded using RxNorm version 02/01/2010

Preinterven_VS

SubjectID

ItemGroupRepeatKey

Pre-intervention Vital Signs

◀ VitalSi...(0/6) Electro...(0/9) ▶ -- Select to Jump -- ▾

Title: Pre-intervention Vital Signs
Enter the most recent Vital Sign values collected prior to randomization, and all values collected between randomization and start of intervention

Date (DD-MMM-YYYY)	Time (HH:MM)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Mean BP (mmHg)	Heart Rate (bpm)	
<input type="text" value="BLVSDay #"/>	<input type="text" value="BLVSTm \$6"/>	<input type="text" value="BLSystBP #"/>	<input type="text" value="BLDiastBP #"/>	<input type="text" value="BLMeanBP #"/>	<input type="text" value="BLHeartRate #"/>	<input type="button" value="X"/>
<input type="button" value="ADD"/>						

Preinterven_Elytes

SubjectID

ItemGroupRepeatKey

Pre-intervention Electrolytes

VitalSi...(0/6) Electro...(0/9) -- Select to Jump --

Title: Pre-intervention Electrolytes
Enter the most recent Electrolytes values collected prior to randomization, and all values collected between randomization and start of intervention

Date (DD-MMM-YYYY)	Time (HH:MM)	Sodium (mmol/L)	Potassium (mmol/L)	Bicarbonate (mmol/L)	Chloride (mmol/L)	BUN (mg/dL)
BLLytesDay #	BLLytesTm \$6	BLSodium #	BLPotassium #	BLBicarbonate #	BLChloride #	BLBUNitrogen

ADD

Creatinine (mg/dL)	Glucose (mg/dL)
BLCreatinine #	BLGlucose #

HGIntervenSumm (1 of 2)

SubjectID

Hypothermia Intervention Summary

THG (0/10) ET (0/5) -- Select to Jump --

Title: Intervention Summary: Therapeutic Hypothermia Group

Instructions: Record summary information throughout the duration of per-protocol temperature control.

Induction Phase
Date and time active temperature control is initiated

Date: DD-MMM-YYYY Time: HH:MM

Maintenance Phase
Date and time temperature is maintained in the 32.0-34.0 °C range for one hour

Date: DD-MMM-YYYY Time: HH:MM

Re-warming Phase
Date and time rewarming begins

Date: DD-MMM-YYYY Time: HH:MM

Normothermia Phase
Date and time temperature is maintained in the 36.0-37.5 °C range for 1 hour

Date: DD-MMM-YYYY Time: HH:MM

End of Intervention
Date and time active temperature control is discontinued

Date: DD-MMM-YYYY Time: HH:MM

HGIntervenSumm (2 of 2)

THG (0/10) ET (0/5) -- Select to Jump --

Title: Intervention Discontinued Early or Not Initiated

Instructions: Record information related to early discontinuation or non initiated temperature control

Intervention Discontinued Early or Not Initiated

Was the active temperature control permanently discontinued prior to 120 hours or never initiated?

Yes * No

AT_DCEarly #

YN
1 = Yes
0 = No

If "Yes" provide the date and time of decision to discontinue or not initiate active temperature control

Date of decision: AT_Day # DD-MMM-YYYY Time of decision: AT_Time \$6 HH:MM

If "Yes" to above (discontinued early or not initiated), select reason to discontinue or not initiate active temperature control:

(select reason) AT_DCReas #

Value not provided

DV7130G
1 = Death (complete a Death Information Form)
2 = Investigator determination
3 = Technical failure and no backup available
4 = Parents withdrew consent (complete a Withdrawal of Consent Form)

Derived variables included in the HGIntervenSumm dataset:




Variable	Format	Type	Label	Algorithm / Notes
TrtDiscReason	TRTDISCREASON 1=Improving 2=Worsening 90=Other	#	Treatment discontinued reason categorized by medical monitor	

NGIntervenSumm (1 of 2)

SubjectID

Normothermia Intervention Summary

◀ TNG (0/6) ET (0/5) ▶ -- Select to Jump -- ▾

Title: Intervention Summary: Therapeutic Normothermia Group	
Instructions: Record summary information throughout the duration of temperature control.	
Induction Phase	
Date and time active temperature control is initiated	
Date: <input type="text" value="IntervDay #"/>  DD-MMM-YYYY	Time: <input type="text" value="IntervTime \$6"/> HH:MM
Maintenance Phase	
Date and time target temperature is maintained in the 36.0-37.5°C range for 1 hour	
Date: <input type="text" value="TargTempDay #"/>  DD-MMM-YYYY	Time: <input type="text" value="TargTempTime \$6"/> HH:MM
End of Intervention	
Date and time active temperature control is discontinued	
Date: <input type="text" value="IntDiscDay #"/>  DD-MMM-YYYY	Time: <input type="text" value="IntDiscTime \$6"/> HH:MM

TNG (0/6) ET (0/5) -- Select to Jump --

Title: Intervention Discontinued Early or Not Initiated

Intervention Discontinued Early or Not Initiated

Was the active temperature control permanently discontinued prior to 120 hours or never initiated?

Yes * No

AT_DCEarly #

YN
1 = Yes
0 = No

If "Yes" provide the date and time of decision to discontinue or not initiate active temperature control

Date of decision: AT_Day # DD-MMM-YYYY Time of decision: AT_Time \$6 HH:MM

If "Yes" to above (discontinued early or not initiated), select reason to discontinue or not initiate active temperature control:

(select reason) AT_DCReas #

For all reasons other than "Death", provide description of the reason to discontinue or not initiate active temperature control

Value not provided

DV7130G
1 = Death (complete a Death Information Form)
2 = Investigator determination
3 = Technical failure and no backup available
4 = Parents withdrew consent (complete a Withdrawal of Consent Form)

Derived variables included in the NGIntervenSumm dataset:

Variable	Format	Type	Label	Algorithm / Notes
TrtDiscReason	TRTDISCREASON 1=Improving 2=Worsening 90=Other	#	Treatment discontinued reason categorized by medical monitor	

TempMonitor

SubjectID

ItemGroupRepeatKey

Phase

Blanketrol Temperature Log

Instructions: Record temperatures every 15 minutes, from initiation of temperature control until the target temperature range (32.0 - 34.0 °C) is maintained for one hour.
All temperatures should be recorded in degrees Celsius, to a tenth of a degree. (i.e. 32.4)

Use this section for subjects who are NOT on ECMO and are having temperature control with Blanketrol.
Esophageal and either bladder or rectal temperatures are required.

Date (DD-MMM-YYYY)	Time (HH:MM)	Blanketrol Water Temp. (°C)	Blanketrol Set Point Temp. (°C)	Esophageal Temp. (°C)	Bladder Temp. (°C)	Rectal Temp. (°C)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

ADD

TpDay #	TpTm \$6	H2OTp #	SetPtTp #	EsoTp #	BladTp #	RecTp #
---------	----------	---------	-----------	---------	----------	---------

TempECMO

SubjectID

ItemGroupRepeatKey

Phase

ECMO Temperature Log

Use this section for subjects who are on ECMO and are not having temperature control with Blanketrol.
ECMO set point circuit temp and either ECMO blood/circuit temp, esophageal, bladder, or rectal temperatures are required.

Date (DD-MMM-YYYY)	Time (HH:MM)	ECMO Set Point Circuit Temp. (°C)	ECMO Blood/Circuit Temp. (°C)	Esophageal Temp. (°C)	Bladder Temp. (°C)	Rectal Temp. (°C)
ECMOTpDay # <input type="text"/>	ECMOTpTm \$6 <input type="text"/>	ECMOTp # <input type="text"/>	ECMObloodTp # <input type="text"/>	ECMOEsoTp # <input type="text"/>	ECMOBladTp <input type="text"/>	ECMORecTp # <input type="text"/>

VitalSigns

SubjectID

ItemGroupRepeatKey

Phase

Vital Signs Log

Date (DD-MMM-YYYY)	Time (HH:MM)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Mean BP (mmHg)	Heart Rate (bpm)
VSDay # <input type="text"/>	VSTime \$6 <input type="text"/>	SystBP # <input type="text"/>	DiastBP # <input type="text"/>	MeanBP # <input type="text"/>	HeartRate # <input type="text"/>
<input type="button" value="ADD"/>					

Electrolytes

SubjectID

ItemGroupRepeatKey

Phase

Electrolytes Log

Date (DD-MMM-YYYY)	Time (HH:MM)	Sodium (mmol/L)	Potassium (mmol/L)	Bicarbonate (mmol/L)	Chloride (mmol/L)	BUN (mg/dL)
ElectroLabDay #	EletroTm \$6	Sodium #	Potassium_K #	Bicarbonate #	Chloride #	BUNitrogen #

ADD

than every 6 hours, then all results should be entered.

Creatinine (mg/dL)	Glucose (mg/dL)
Creatinine #	Glucose #

PrimaryProbe (1 of 1)

SubjectID

Primary Probe Log

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

Title: Primary Probe Log

Instructions: Enter the temperature source that was used at start of study intervention. Document each time the primary probe location changed during intervention.

Which temperature source was used as the primary probe at start of study intervention?

(Select one) * ProbeStart #

Did the primary probe location change anytime during intervention?

(Select one) ProbeChange #

If 'Yes', enter the date, time and new location of the primary probe. Enter each time the primary probe location was changed:

Date (DD-MMM-YYYY)	Time (HH:MM)	Primary Probe	PrimaryProbe_Location
ProbeLocDay #	ProbeLocTime \$6	PrimaryProbe #	SubjectID

ADD

PrimProb
 1 = Esophageal
 2 = Bladder
 3 = Rectal
 4 = ECMO Blood/Circuit

YNs
 1 = Yes
 0 = No

PrimProb
 1 = Esophageal
 2 = Bladder
 3 = Rectal
 4 = ECMO Blood/Circuit

ETTempMonitor (1 of 1)

SubjectID

ItemGroupRepeatKey

Early Termination Temp Log

Tempera...(0/5) -- Select to Jump --

Title: Early Termination of Intervention Temperature Log

Instructions: Record temperatures every 4 hours, from termination of temperature control, until 120 hours after the initiation of temperature control. All temperatures should be recorded in degrees Celsius, to a tenth of a degree. (i.e. 32.4)

Date (DD-MMM-YYYY)	Time (HH:MM)	Temp. (°C)	Route	If "Other", describe route:
<input type="text" value="ETTpDay #"/>	<input type="text" value="ETTpTm \$6"/>	<input type="text" value="ETTp #"/>	<ul style="list-style-type: none"><input type="radio"/> Axillary<input type="radio"/> Tympanic<input type="radio"/> Rectal<input type="radio"/> Esophageal<input type="radio"/> Bladder<input type="radio"/> Oral<input type="radio"/> ECMO Blood/Circuit<input type="radio"/> Other	<input type="text" value="Value not provided"/>

ADD

ETTpRoute #

DV6822G

- 1 = Axillary
- 2 = Tympanic
- 3 = Rectal
- 4 = Esophageal
- 5 = Bladder
- 6 = Oral
- 7 = ECMO Blood/Circuit
- 95 = Other

Day0 (1 of 5)

SubjectID

Day 0

Events 1 (0/10) Events 2 (0/9) Labs 1 (0/16) -- Select to Jump --

Title: Event Review (Study Day 0)
 Subtitle: These questions apply to the time period after randomization through 23:59 of that day

Study date (on study Day 0)
 StudyDay # * DD-MMM-YYYY

Were there any new adverse events experienced on this day?
 (AEs can only occur after randomization)
 Yes No * (If "Yes", record on AE log) AE #

Were any culture specimens obtained between randomization and 23:59 on this day?
 Yes No * (If "Yes", record on culture log) CultureYN #

Did the patient undergo any surgeries to treat bleeding between randomization and 23:59 on this day?
 Yes No * SurgeryYN #

Did the patient undergo ECMO cannulation or decannulation, surgically placed feeding tube, or tracheotomy between randomization and 23:59 on this day?
 Yes No * (If "Yes", record on procedure log) ProcYN #

Did the patient receive any blood products between randomization and 23:59 on this day?
 Yes No * BloodProdYN #

If "Yes", enter all blood products administered from randomization through 23:59 of that day

Time administered (HH:MM)	Type of blood product	Amount of blood product (ml)
BloodProdTm \$6	BloodProdTyp #	BloodProdAmt #
<input type="button" value="ADD"/>		

Did the patient experience a cardiac arrest requiring chest compressions between randomization and 23:59 on this day?
 Yes No * (If "Yes", record on AE log) CAYN #

Legend:
 YN
 1 = Yes
 0 = No

Legend:
 YN
 1 = Packed red blood cells (PRBC)
 2 = Platelets
 3 = Fresh frozen plasma (FFP)
 4 = Cryoprecipitate

Annotations:
 BloodProductsDay0to7
 SubjectID
 StudyDay
 ItemGroupRepeatKey

Day0 (2 of 5)

Events 1 (0/10)

Events 2 (0/9)

Labs 1 (0/16)

-- Select to Jump --

Title: Event Review (Study Day 0)

Subtitle: These questions apply to the time period after randomization through 23:59 of that day

Did the patient experience any previously undocumented and serious arrhythmias between randomization and 23:59 on this day?

Yes No * (If new, record on AE log)

ArrhyYN #

YN
1 = Yes
0 = No

DV6789G

1 = Atrial (SVT, flutter/fib, JET)
2 = Ventricular (VT > 30 sec, VF, Torsades)
3 = Asystole
4 = PEA
95 = Other

If "Yes", enter all arrhythmias identified from randomization through 23:59 of that day

Start time of arrhythmia	Type of arrhythmia experienced	Description of other types of arrhythmia
ArrhythTm \$6	ArrhythYes #	Value not provided

ADD

Arrhythmiaday0to7

SubjectID

StudyDay

ItemGroupRepeatKey

Was correct esophageal probe placement confirmed by chest x-ray between randomization and 23:59 on this day?

Yes No *

CXRYN #

YN
1 = Yes
0 = No

Did the patient experience a clinical seizure between randomization and 23:59 on this day?

Yes No *

ClinicalSz #

If "Yes", type of clinical seizure (select one)

ClinSzYes #

DV6790G

1 = Probable clinical diagnosis which resulted in initiation of anticonvulsant treatment
2 = Possible clinical diagnosis (no anticonvulsant treatment initiated but specific diagnostic testing [e.g., EEG] may have been ordered)

Did the patient experience an electrographic seizure between randomization and 23:59 on this day?

Yes No No EEG monitoring done on this day *

ElectroSz #

SeizYN

1 = Yes
0 = No
3 = No EEG monitoring done on this day

If "Yes", type of electrographic seizure (select one)

ElectroSzYes #

DV6791G

1 = Definite electroencephalographic seizure ("ictal") activity described
2 = Abnormal recording but without definite EEG confirmation of seizure activity

Day0 (3 of 5)

Events 2 (0/9) Labs 1 (0/16) Labs 2 (0/20) -- Select to Jump --

Title: Laboratory Tests (Study Day 0)
Subtitle: These questions apply to the time period after randomization through 23:59 of that day

Were any complete blood counts (CBCs) obtained between randomization and 23:59 on this day?
 Yes No * **CBCYN #** YN
1 = Yes
0 = No

If "Yes", record all Hemoglobin, Platelet counts and White blood cell counts collected after randomization through 23:59 of that day

Time collected (HH:MM)	Hemoglobin (g/dL)	Platelet count (10 ³ /microl)	White blood cell (10 ³ /microl)
CBCTime \$6	Hgb #	Platelet #	WBC #

ADD StudyDay ItemGroupRepeatKey CBCDay0to5 SubjectID

Were any of the following liver function tests (LFTs) obtained between randomization and 23:59 on this day?
 Yes No * **LFTYN #** YN
1 = Yes
0 = No

If "Yes", record all ALT, AST, LDH and Total bilirubin results collected after randomization through 23:59 of that day

Time collected (HH:MM)	ALT/SGPT (U/L)	AST/SGOT (U/L)	LDH (U/L)	Total bilirubin (mg/dL)
LFTTime \$6	ALT #	AST #	LDH #	Bilirubin #

ADD StudyDay ItemGroupRepeatKey LiverDay0to5 SubjectID

Were any blood coagulation tests obtained between randomization and 23:59 on this day?
 Yes No * **CoagYN #** YN
1 = Yes
0 = No

If "Yes", record all PT, PTT and INR results collected after randomization through 23:59 of that day

Time collected (HH:MM)	PT (seconds)	PTT (seconds)	INR
CoagTime \$6	PT #	PTT #	INR #

ADD StudyDay ItemGroupRepeatKey CoagulationDay0to5 SubjectID

Day0 (4 of 5)

Events 2 (0/9) Labs 1 (0/16) Labs 2 (0/20) -- Select to Jump --

Title: Laboratory Tests (Study Day 0)
 Subtitle: These questions apply to the time period after randomization through 23:59 of that day

Were any of the following pancreatic enzyme tests obtained between randomization and 23:59 on this day?
 Yes No * PanEnzYN #

YN
 1 = Yes
 0 = No

If "Yes", record all Amylase and Lipase results collected after randomization through 23:59 of that day

Time collected (HH:MM)	Amylase (U/L)	Lipase (U/L)
PanEnzTime \$6	Amylase #	Lipase #

ADD

StudyDay SubjectID
 ItemGroupRepeatKey

Were any of the following chemistry tests obtained between randomization and 23:59 on this day?
 Yes No * OthChemYN #

YN
 1 = Yes
 0 = No

If "Yes", record all Magnesium, Ionized calcium, Total calcium, and Phosphate results collected after randomization through 23:59 of that day

Time collected (HH:MM)	Magnesium (mg/dL)	Ionized calcium (mmol/L)	Total calcium (mg/dL)	Phosphate (mg/dL)
OthChemTm \$6	Magnesium #	IonizedCa #	TotalCa #	Phosphate #

ADD

ChemistryDay0to5
 SubjectID
 StudyDay ItemGroupRepeatKey

Were any lactate tests obtained between randomization and 23:59 on this day?
 Yes No * lactateYN #

YN
 1 = Yes
 0 = No

If "Yes", record all Lactate test results collected after randomization through 23:59 of that day

Time collected (HH:MM)	Lactate (mmol/L)
LactTime \$6	Lactate #

ADD

LactateDay0to3
 SubjectID
 StudyDay ItemGroupRepeatKey

Were any arterial blood gas analyses obtained between randomization and start of active temperature control on this day?

Yes No *

ABGYN #

YN

1 = Yes

0 = No

If "Yes", enter the ABG collected closest to but prior to start of active temperature control:

Time collected: HH:MM

pH:

PaCO2: mmHg

PaO2: mmHg

Saturation: %

HCO3 / Bicarbonate: mmol/L

Day 1
Day 2
Day 3

Events 1 (0/9) Events 2 (0/11) Labs 1 (0/16) -- Select to Jump --

Title: Event Review (Study Day 1)
 Subtitle: All questions apply to Day 1 : the first day after the day of randomization, from 00:00 to 23:59

Study date (on study Day 1)
 StudyDay # * DD-MMM-YYYY

Were there any new adverse events experienced on this day?
 Yes No * (If "Yes", record on AE log) AE #

Were any culture specimens obtained on this day?
 Yes No * (If "Yes", record on culture log) CultureYN #

Did the patient undergo any surgeries to treat bleeding on this day?
 Yes No * SurgeryYN #

Did the patient undergo ECMO cannulation or decannulation, surgically placed feeding tube, or tracheotomy on this day?
 Yes No * (If "Yes", record on procedure log) ProcYN #

Did the patient receive any blood products on this day?
 Yes No * BloodProdYN #

If "Yes", enter all blood products administered on this study day

Type of blood product	Amount of blood product (ml)
BloodProdTyp #	BloodProdAmt #

ADD

BloodProductsDay0to7
 SubjectID

StudyDay ItemGroupRepeatKey

Did the patient experience a cardiac arrest requiring chest compressions on this day?
 Yes No * (If "Yes", record on AE log) CAYN #

YN
1 = Yes
0 = No

YN
1 = Yes
0 = No

DV6839G
 1 = Packed red blood cells (PRBC)
 2 = Platelets
 3 = Fresh frozen plasma (FFP)
 4 = Cryoprecipitate

Day1, Day2, Day3 (2 of 5)

Events 1 (0/9) Events 2 (0/11) Labs 1 (0/16) -- Select to Jump --

Title: Event Review (Study Day 1)
Subtitle: All questions apply to Day 1 : the first day after the day of randomization, from 00:00 to 23:59

Did the patient experience any previously undocumented and serious arrhythmias?
 Yes No * (If new, record on AE log)

ArrhyYN #

YN
1 = Yes
0 = No

If "Yes", enter all arrhythmias identified on this study day

Type of arrhythmia experienced	Description of other types of arrhythmia
ArrhythYes #	Value not provided
<input type="button" value="ADD"/>	

DV6789G
 1 = Atrial (SVT, flutter/fib, JET)
 2 = Ventricular (VT > 30 sec, VF, Torsades)
 3 = Asystole
 4 = PEA
 95 = Other

Arrhythmiaday0to7
 StudyDay
 SubjectID
 ItemGroupRepeatKey

Was correct esophageal probe placement confirmed by chest x-ray on this study day?
 Yes No *

CXRYN #

YN
1 = Yes
0 = No

DV6790G
 1 = Probable clinical diagnosis which resulted in initiation of anticonvulsant treatment
 2 = Possible clinical diagnosis (no anticonvulsant treatment initiated but specific diagnostic testing [e.g., EEG] may have been ordered)

Did the patient experience a clinical seizure on this day?
 Yes No *

ClinicalSz #

If "Yes", type of clinical seizure (select one) ClinicalSzYes # (If new, record on AE log)

Did the patient experience an electrographic seizure on this day?
 Yes No No EEG monitoring done on this day *

ElectroSz #

SeizYN
 1 = Yes
 0 = No
 3 = No EEG monitoring done on this

If "Yes", type of electrographic seizure (select one) ElectroSzYes # (If new, record on AE log)

Was subject receiving any form of renal replacement therapy?
 Yes No *

DialyticYN #

DV6791G
 1 = Definite electroencephalographic seizure ("ictal") activity described
 2 = Abnormal recording but without definite EEG confirmation of seizure activity

Fluid Input and Urine Output
 Total fluid input: FluidsTotal # * mL
 Total urine output: FluidsOut # * mL

YN
1 = Yes
0 = No

Day1, Day2, Day3 (3 of 5)

Events 2 (0/11) Labs 1 (0/16) Labs 2 (0/20) -- Select to Jump --

Title: Laboratory Tests (Study Day 1)
 Subtitle: All questions apply to Day 1 : the first day after the day of randomization, from 00:00 to 23:59
 Instructions: New abnormal laboratory results that are considered clinically significant by the PI should also be entered on the AF log

Were any complete blood counts obtained on this day?
 Yes No * **CBCYN #** YN
1 = Yes
0 = No

If "Yes", record all Hemoglobin, Platelet counts and White blood cell counts collected on this study day

Time collected (HH:MM)	Hemoglobin (g/dL)	Platelet count (10 ³ /microl)	White blood cell (10 ³ /microl)	
CBCTime \$6	Hgb #	Platelet #	WBC #	StudyDay

ADD CBCDay0to5 SubjectID ItemGroupRepeatKey

Were any of the following liver function tests (LFTs) obtained on this day?
 Yes No * **LFTYN #** YN
1 = Yes
0 = No

If "Yes", record all ALT, AST, LDH and Total bilirubin results collected on this study day

Time collected (HH:MM)	ALT/SGPT (U/L)	AST/SGOT (U/L)	LDH (U/L)	Total bilirubin (mg/dL)	
LFTTime \$6	ALT #	AST #	LDH #	Bilirubin #	StudyDay

ADD LiverDay0to5 SubjectID ItemGroupRepeatKey

Were any blood coagulation tests obtained on this day?
 Yes No * **CoagYN #** YN
1 = Yes
0 = No

If "Yes", record all PT, PTT and INR results collected on this study day

Time collected (HH:MM)	PT (seconds)	PTT (seconds)	INR	
CoagTime \$6	PT #	PTT #	INR #	StudyDay

ADD CoagulationDay0to5 SubjectID ItemGroupRepeatKey

Day1, Day2, Day3 (4 of 5)

Events 2 (0/11) Labs 1 (0/16) Labs 2 (0/20) -- Select to Jump --

Title: Laboratory Tests (Study Day 1)
 Subtitle: All questions apply to Day 1 : the first day after the day of randomization, from 00:00 to 23:59
 Instructions: New abnormal laboratory results that are considered clinically significant by the PI should also be entered on the AE log

Were any of the following pancreatic enzyme tests obtained on this day?
 Yes No * PanEnzYN # YN
1 = Yes
0 = No

If "Yes", record all Amylase and Lipase results collected on this study day

Time collected (HH:MM)	Amylase (U/L)	Lipase (U/L)
PanEnzTime \$6	Amylase #	Lipase #

ADD

PancreasDay0to5
 StudyDay SubjectID
 ItemGroupRepeatKey

Were any of the following chemistry tests obtained on this day?
 Yes No * OthChemYN # YN
1 = Yes
0 = No

If "Yes", record all Magnesium, Ionized calcium, Total calcium, and Phosphate results collected on this study day

Time collected (HH:MM)	Magnesium (mg/dL)	Ionized calcium (mmol/L)	Total calcium (mg/dL)	Phosphate (mg/dL)
OthChemTm \$6	Magnesium #	IonizedCa #	TotalCa #	Phosphate #

ADD

ChemistryDay0to5
 StudyDay ItemGroupRepeatKey SubjectID

Were any lactate tests obtained on this day?
 Yes No * lactateYN # YN
1 = Yes
0 = No

If "Yes", record all Lactate test results collected on this study day

Time collected (HH:MM)	Lactate (mmol/L)
LactTime \$6	Lactate #

LactateDay0to3
 StudyDay ItemGroupRepeatKey SubjectID

Day1, Day2, Day3 (5 of 5)

Were any arterial blood gas analyses obtained on this day?	
<input type="radio"/> Yes <input type="radio"/> No *	<input type="text" value="ABGYN #"/>
If "Yes", enter the ABG collected closest to 8:00am on this study day	
Time collected:	<input type="text" value="ABGTime \$6"/> HH:MM
pH:	<input type="text" value="ABGpH #"/>
PaCO2:	<input type="text" value="ABGPaCO2 #"/> mmHg
PaO2:	<input type="text" value="ABGPaO2 #"/> mmHg
Saturation:	<input type="text" value="ABGSat #"/> %
HCO3 / Bicarbonate:	<input type="text" value="ABGBicarb #"/> mmol/L

YN
1 = Yes
0 = No

Day4, Day5 (1 of 4)

SubjectID

Day 4
Day 5

Events 1 (0/9) Events 2 (0/11) Labs 1 (0/16) -- Select to Jump --

Title: Event Review (Study Day 4)
 Subtitle: All questions apply to Day 4 : the fourth day after the day of randomization, from 00:00 to 23:59

Study date (on study Day 4)
 StudyDay # [calendar icon] * DD-MMM-YYYY

Were there any new adverse events experienced on this day?
 Yes No * (If "Yes", record on AE log) AE #

Were any culture specimens obtained on this day?
 Yes No * (If "Yes", record on culture log) CultureYN #

Did the patient undergo any surgeries to treat bleeding on this day?
 Yes No * SurgeryYN #

Did the patient undergo ECMO cannulation or decannulation, surgically placed feeding tube, or tracheotomy on this day?
 Yes No * (If "Yes", record on procedure log) ProcYN #

Did the patient receive any blood products on this day?
 Yes No * BloodProdYN #

If "Yes", enter all blood products administered on this study day

Type of blood product	Amount of blood product (ml)
BloodProdTyp #	BloodProdAmt #
[ADD]	

BloodProductsDay0to7
 SubjectID
 StudyDay ItemGroupRepeatKey

Did the patient experience a cardiac arrest requiring chest compressions on this day?
 Yes No * (If "Yes", record on AE log) CAYN #

DV6839G
 1 = Packed red blood cells (PRBC)
 2 = Platelets
 3 = Fresh frozen plasma (FFP)
 4 = Cryoprecipitate

YN
 1 = Yes
 0 = No

YN
 1 = Yes
 0 = No

Day4, Day5 (2 of 4)

Events 1 (0/9) Events 2 (0/11) Labs 1 (0/16) -- Select to Jump --

Title: Event Review (Study Day 4)
 Subtitle: All questions apply to Day 4 : the fourth day after the day of randomization, from 00:00 to 23:59

Did the patient experience any previously undocumented and serious arrhythmias?
 Yes No * (If new, record on AE log) **ArrhyYN #** YN
1 = Yes
0 = No

If "Yes", enter all arrhythmias identified on this study day

Type of arrhythmia experienced	Description of other types of arrhythmia
ArrhythYes #	Value not provided

ADD

DV6789G
 1 = Atrial (SVT, flutter/fib, JET)
 2 = Ventricular (VT > 30 sec, VF, Torsades)
 3 = Asystole
 4 = PEA
 95 = Other

ArrhythmiaDay0to7
StudyDay
SubjectID
ItemGroupRepeatKey

Was correct esophageal probe placement confirmed by chest x-ray on this study day?
 Yes No * **CXRYN #** YN
1 = Yes
0 = No

Did the patient experience a clinical seizure on this day?
 Yes No * **ClinicalSz #** YN
1 = Yes
0 = No

If "Yes", type of clinical seizure (select one) **ClinicalSzYes #** (If new, record on AE log)

Did the patient experience an electrographic seizure on this day?
 Yes No No EEG monitoring done on this day * **ElectroSz #** SeizYN
1 = Yes
0 = No
3 = No EEG monitoring done on this day

If "Yes", type of electrographic seizure (select one) **ElectroSzYes #** (If new, record on AE log)

Was subject receiving any form of renal replacement therapy?
 Yes No * **DialyticYN #** YN
1 = Yes
0 = No

Fluid Input and Urine Output
 Total fluid input **FluidsTotal #** * mL Total urine output **FluidsOut #** * mL

DV6790G
 1 = Probable clinical diagnosis which resulted in initiation of anticonvulsant treatment
 2 = Possible clinical diagnosis (no anticonvulsant treatment initiated but specific diagnostic testing [e.g., EEG] may have been ordered)

DV6791G
 1 = Definite electroencephalographic seizure ("ictal") activity described
 2 = Abnormal recording but without definite EEG confirmation of seizure activity

Day4, Day5 (3 of 4)

Events 2 (0/11) Labs 1 (0/16) Labs 2 (0/10) -- Select to Jump --

Title: Laboratory Tests (Study Day 4)
 Subtitle: All questions apply to Day 4 : the fourth day after the day of randomization, from 00:00 to 23:59
 Instructions: New abnormal laboratory results that are considered clinically significant by the PI should also be entered on the AE log

Were any complete blood counts obtained on this day?
 Yes No * **CBCYN #** YN
1 = Yes
0 = No

If "Yes", record all Hemoglobin, Platelet counts and White blood cell counts collected on this study day

Time collected (HH:MM)	Hemoglobin (g/dL)	Platelet count (10 ³ /microl)	White blood cell (10 ³ /microl)
CBCTime \$6	Hgb #	Platelet #	WBC #

ADD StudyDay CBCDay0to5
SubjectID ItemGroupRepeatKey

Were any of the following liver function tests (LFTs) obtained on this day?
 Yes No * **LFTYN #** YN
1 = Yes
0 = No

If "Yes", record all ALT, AST, LDH and Total bilirubin results collected on this study day

Time collected (HH:MM)	ALT/SGPT (U/L)	AST/SGOT (U/L)	LDH (U/L)	Total bilirubin (mg/dL)
LFTTime \$6	ALT #	AST #	LDH #	Bilirubin #

ADD StudyDay LiverDay0to5
SubjectID ItemGroupRepeatKey

Were any blood coagulation tests obtained on this day?
 Yes No * **CoagYN #** YN
1 = Yes
0 = No

If "Yes", record all PT, PTT and INR results collected on this study day

Time collected (HH:MM)	PT (seconds)	PTT (seconds)	INR
CoagTime \$6	PT #	PTT #	INR #

ADD StudyDay CoagulationDay0to5
SubjectID ItemGroupRepeatKey

Day4, Day5 (4 of 4)

Events 2 (0/11) Labs 1 (0/16) Labs 2 (0/10) -- Select to Jump --

Title: Laboratory Tests (Study Day 4)
Subtitle: All questions apply to Day 4 : the fourth day after the day of randomization, from 00:00 to 23:59
Instructions: New abnormal laboratory results that are considered clinically significant by the PI should also be entered on the AE log

Were any of the following pancreatic enzyme tests obtained on this day?

Yes No * PanEnzYN # YN
1 = Yes
0 = No

If "Yes", record all Amylase and Lipase results collected on this study day

Time collected (HH:MM)	Amylase (U/L)	Lipase (U/L)	
PanEnzTime \$6	Amylase #	Lipase #	X

ADD StudyDay ItemGroupRepeatKey PancreasDay0to5 SubjectID

Were any of the following chemistry tests obtained on this day?

Yes No * OthChemYN # YN
1 = Yes
0 = No

If "Yes", record all Magnesium, Ionized calcium, Total calcium, and Phosphate results collected on this study day

Time collected (HH:MM)	Magnesium (mg/dL)	Ionized calcium (mmol/L)	Total calcium (mg/dL)	Phosphate (mg/dL)	
OthChemTm \$6	Magnesium #	IonizedCa #	TotalCa #	Phosphate #	X

ADD StudyDay ItemGroupRepeatKey ChemistryDay0to5 SubjectID

Day6, Day7 (1 of 3)

SubjectID

Day 6
Day 7

Events 1 (0/9) Events 2 (0/13) -- Select to Jump --

Title: Event Review (Study Day 6)
Subtitle: All questions apply to Day 6 : the sixth day after the day of randomization, from 00:00 to 23:59

Study date (on study Day 6)
StudyDay # * DD-MMM-YYYY

Were there any new adverse events experienced on this day?
 Yes No * (If "Yes", record on AE log) AE #

Were any culture specimens obtained on this day?
 Yes No * (If "Yes", record on culture log) CultureYN #

Did the patient undergo any surgeries to treat bleeding on this day?
 Yes No * SurgeryYN #

Did the patient undergo ECMO cannulation or decannulation, surgically placed feeding tube, or tracheotomy on this day?
 Yes No * (If "Yes", record on procedure log) ProcYN #

Did the patient receive any blood products on this day?
 Yes No BloodProdYN #

If "Yes", enter all blood products administered on this study day

Type of blood product	Amount of blood product (ml)
BloodProdTyp #	BloodProdAmt #

ADD

BloodProductsDay0to7

SubjectID

StudyDay

ItemGroupRepeatKey

Did the patient experience a cardiac arrest requiring chest compressions on this day?
 Yes No * (If "Yes", record on AE log) CAYN #

YN
1 = Yes
0 = No

YN
1 = Yes
0 = No

DV6839G
1 = Packed red blood cells (PRBC)
2 = Platelets
3 = Fresh frozen plasma (FFP)
4 = Cryoprecipitate

Day6, Day7 (2 of 3)

Events 1 (0/9) | Events 2 (0/13) | -- Select to Jump --

Title: Event Review (Study Day 6)
 Subtitle: All questions apply to Day 6 : the sixth day after the day of randomization, from 00:00 to 23:59

Did the patient experience any previously undocumented and serious arrhythmias?
 Yes No * (If new, record on AE log) **ArrhyYN #**

YN
 1 = Yes
 0 = No

If "Yes", enter all arrhythmias identified on this study day

Type of arrhythmia experienced	Description of other types of arrhythmia
ArrhythYes #	Value not provided

ADD

DV6789G
 1 = Atrial (SVT, flutter/fib, JET)
 2 = Ventricular (VT > 30 sec, VF, Torsades)
 3 = Asystole
 4 = PEA
 95 = Other

ArrhythmiaDay0to7
StudyDay
SubjectID
ItemGroupRepeatKey

Did the patient experience a clinical seizure on this day?
 Yes No * **ClinicalSz #**

YN
 1 = Yes
 0 = No

If "Yes", type of clinical seizure (select one) **ClinicalSzYes #**

DV6790G
 1 = Probable clinical diagnosis which resulted in initiation of anticonvulsant treatment
 2 = Possible clinical diagnosis (no anticonvulsant treatment initiated but specific diagnostic testing [e.g., EEG] may have been ordered)

Did the patient experience an electrographic seizure on this day?
 Yes No No EEG monitoring done on this day * **ElectroSz #**

If "Yes", type of electrographic seizure (select one) **ElectroSzYes #** (If new, record on AE log)

SeizYN
 1 = Yes
 0 = No
 3 = No EEG monitoring done on this day

DV6791G
 1 = Definite electroencephalographic seizure ("ictal") activity described
 2 = Abnormal recording but without definite EEG confirmation of seizure activity

Day6, Day7 (3 of 3)

Minimum temperature on this day

Route

- Axillary *
- Tympanic
- Rectal
- Esophageal
- Bladder
- Oral
- ECMO Blood/Circuit
- Other

TempSiteMin #

If "Other", describe route: Value not provided

DV6822G
1 = Axillary
2 = Tympanic
3 = Rectal
4 = Esophageal
5 = Bladder
6 = Oral
7 = ECMO Blood/Circuit
95 = Other

Temperature

TempMin # * (degrees Celsius)

Maximum temperature on this day

Route

- Axillary *
- Tympanic
- Rectal
- Esophageal
- Bladder
- Oral
- ECMO Blood/Circuit
- Other

TempSiteMax #

If "Other", describe route: Value not provided

DV6822G
1 = Axillary
2 = Tympanic
3 = Rectal
4 = Esophageal
5 = Bladder
6 = Oral
7 = ECMO Blood/Circuit
95 = Other

Temperature

TempMax # * (degrees Celsius)

Day8, Day9, Day 10 (1 of 1)

SubjectID

Day 8
Day 9
Day 10

Events 1 (0/9) -- Select to Jump --

Title: Event Review (Study Day 8)
Subtitle: All questions apply to Day 8 : the eighth day after the day of randomization, from 00:00 to 23:59

Study date (on study Day 8)
StudyDay # * DD-MMM-YYYY

Were there any new adverse events experienced on this day?
 Yes No * (If "Yes", record on AE log) AE #

Did the patient undergo ECMO cannulation or decannulation, surgically placed feeding tube, or tracheotomy on this day?
 Yes No * (If "Yes", record on procedure log) ProcYN #

Minimum temperature on this day
Route
 Axillary *
 Tympanic
 Rectal
 Esophageal
 Bladder
 Oral
 ECMO Blood/Circuit
 Other
If "Other", describe route: Value not provided

Temperature
TempMin # * (degrees Celsius)

Maximum temperature on this day
Route
 Axillary *
 Tympanic
 Rectal
 Esophageal
 Bladder
 Oral
 ECMO Blood/Circuit
 Other
If "Other", describe route: Value not provided

Temperature
TempMax # * (degrees Celsius)

YN
1 = Yes
0 = No

DV6822G
1 = Axillary
2 = Tympanic
3 = Rectal
4 = Esophageal
5 = Bladder
6 = Oral
7 = ECMO Blood/Circuit
95 = Other

AdverseEvents (1 of 1)

SubjectID ItemGroupRepeatKey

Adverse Event Log

Adverse... (0/12) -- Select to Jump --

Title: Adverse Events Log

Instructions: An Adverse Event (AE) is an untoward medical occurrence experienced by a subject. An event constitutes a diagnosis, a set of related signs or symptoms, or a single sign or symptom temporally associated with the use of an intervention whether or not it is... In this study, any event that occurs after the time of randomization that is not documented on the Baseline Review of Systems or Baseline Physical Exam Form is considered an AE. Abnormal laboratory test are considered AE's if they are also considered clinically significant by the Principal Investigator.

Name of Event	Start date (DD-MMM-YYYY)	Outcome	Stop date (DD-MMM-YYYY) (not required if Outcome is "symptom persists")	Intensity	Action taken
Value not provided	AESTartDay #	AEOOutcome #	AESTopDay #	AEIntensity #	AEAction #
	DV6826G 1 = Death 2 = Recovered (patient returned to baseline) 3 = Recovered with sequelae 4 = Symptom persists			DV6827G 1 = Mild 2 = Moderate 3 = Severe	DV6828G 1 = Concomitant medication started, changed, or discontinued 2 = Surgery or other procedure 3 = Both the above 98 = None 99 = Other (describe)
If Action taken is "Other" describe other action taken	Action taken to study intervention	Relationship to study intervention (investigator's assessment)	Was this event expected?	Is this a serious adverse event?	Is this an expected SAE that can be classified as part of the subset that requires reporting to the DCC?
Value not provided	AEInterAction #	AERelation #	AEEExpected #	SAE_YN #	SAE_Subset #
	DV7119G 1 = Temperature control discontinued 2 = Temperature control interrupted 3 = Temperature control modified 98 = None	DV6829G 1 = Probably related 2 = Possibly related 3 = Not related	DV6830G 1 = Expected 2 = Not expected	YN 1 = Yes 0 = No	

Derived variables included in the AdverseEvents dataset:

Variable	Format	Type	Label	Algorithm / Notes
aelltcode		#	MedDRA Lower Term ID Number	Verbatim terms were coded using MedDRA version 13
aellt		\$	MedDRA Lower Level Term	

ConMeds (1 of 1)

SubjectID

ItemGroupRepeatKey

Concomitant Medications

The screenshot shows a web form titled "Concomitant Medications" with the instruction: "Record concomitant medications administered from the time of randomization through day 7 or Hospital Discharge, whichever is earlier." The form contains a table with the following columns: Medication name, Start date (DD-MMM-YYYY), Continuing at end of Day 7/hospital discharge?, Stop date (DD-MMM-YYYY), Given in relation to AE?, and If "Yes", provide reason. Annotations include: "Value not provided" for Medication name; "MedStartDay #" for Start date; "MedCont #" for Continuing at end of Day 7/hospital discharge? with a legend "YN 1 = Yes 0 = No"; "MedStopDay #" for Stop date; "MedRelatedAE #" for Given in relation to AE? with a legend "YN 1 = Yes 0 = No"; and "Value not provided" for the reason field.

Derived variables included in the ConMeds dataset:

Variable	Format	Type	Label	Algorithm / Notes
codedmedname		\$	Coded Medication Name	
code		\$	RxNorm Code	Verbatim terms were coded using RxNorm version 02/01/2010

CultureLog (1 of 1)

SubjectID

ItemGroupRepeatKey

Culture Log

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

Title: Microbiological cultures log

Instructions: Enter all cultures collected within 12 hours of randomization through Day 7.
Final results for all cultures collected during this period should be entered.
For positive cultures, upload a de-identified PDF of the microbiology report that is labeled with the Patient ID number .

Cultures Log

Collection Date (DD-MMM-YYYY)	Collection Time (HH:MM)	Specimen Type	Result date (DD-MMM-YYYY)	Final result	Upload de-identified positive micro report
CultureDay #	CultureTime \$6	SpecType #	CultResultDay #	CultResult #	Value not provided <input type="button" value="Click to upload file"/>

DV6844G
1 = Blood
2 = Urine
3 = Respiratory
4 = CSF
5 = Other wound and deep tissue

DV7143G
1 = New infection
2 = Continuing infection
3 = Not an infection (contaminant or colonization)
4 = Not an infection (negative culture)

ProcedureLog (1 of 1)

SubjectID

ItemGroupRepeatKey

Procedure Log

Procedu...(0/2) -- Select to Jump --

Title: Procedure Log
Instructions: Procedures should be recorded from randomization through the initial hospital discharge.
Only the following procedures should be entered:
ECMO initiation
ECMO decannulation
Surgically placed feeding tube
Tracheostomy placement
Tracheostomy decannulation

Procedure Log

Date of Procedure (DD-MMM-YYYY)	Type of Procedure	
ProcDay #	(select procedure)	X
<input type="button" value="ADD"/>	ProcLog #	

DV7115G
1 = ECMO initiation
2 = ECMO decannulation
3 = Surgically placed feeding tube
4 = Tracheostomy placement
5 = Tracheostomy decannulation

PICU Discharge (1 of 1)

SubjectID

Initial PICU Discharge

Initial...(0/10) -- Select to Jump --

Title: Initial PICU Discharge Information
 Instructions: Complete when the first PICU discharge occurs after randomization

Date and Time of PICU Discharge
 Date: PICUDschDay # * DD-MMM-YYYY Time: PICUDschTime \$6 HH:MM

Location to where subject was discharged
 (select one) PICUDschLoc # * If "Not applicable (subject died)" stop here

If "Other" specify location: Value not provided

Pediatric Overall Performance Category
 POPC score: (select one) POPC #

Pediatric Cerebral Performance Category
 PCPC score: (select one) PCPC #

Glasgow Coma Score

Eye opening
 (select one) GCSEye #

Best verbal response
 (select one) GCSVerbal #

Best motor response
 (select one) GCSMotor #

Total GCS Score GCSTotal # (calculated automatically on save)

DV6853G
 1 = Home or foster care
 2 = Acute inpatient rehabilitation unit (in same or separate hospital)
 3 = Chronic care or skilled nursing facility
 4 = Step down or floor unit in same hospital
 5 = Not applicable (patient died)
 95 = Other

DV6787G
 1 = Good
 2 = Mild Disability
 3 = Moderate Disability
 4 = Severe Disability
 5 = Coma or vegetative state
 6 = Death

DV6788G
 1 = Normal
 2 = Mild Disability
 3 = Moderate Disability
 4 = Severe Disability
 5 = Coma or vegetative state
 6 = Death

Eye
 1 = 1
 2 = 2
 3 = 3
 4 = 4

Verbal
 1 = 1
 2 = 2
 3 = 3
 4 = 4
 5 = 5

Motor
 1 = 1
 2 = 2
 3 = 3
 4 = 4
 5 = 5
 6 = 6

HospDischarge (1 of 2)

SubjectID

Hospital Discharge

Hospita...(0/14) -- Select to Jump --

Title: Hospital Discharge
Instructions: Complete when the first hospital discharge occurs after randomization

Date of Hospital Discharge
Date: * DD-MMM-YYYY

Location to where patient was discharged
 * If "Not applicable (subject died)" stop here

If "Other", specify location:

Pediatric Overall Performance Category
POPC score:

Pediatric Cerebral Performance Category
PCPC score:

Glasgow Coma Score

Eye opening: **Eye**
1 = 1
2 = 2
3 = 3
4 = 4

Best verbal response: **Verbal**
1 = 1
2 = 2
3 = 3
4 = 4
5 = 5

Best motor response: **Motor**
1 = 1
2 = 2
3 = 3
4 = 4
5 = 5
6 = 6

Total GCS Score: (calculated automatically on save)

DV6856G
1 = Home or foster care
2 = Another acute care hospital
3 = Acute inpatient rehabilitation unit
4 = Chronic care or skilled nursing facility
5 = Not applicable (patient died)
95 = Other

DV6787G
1 = Good
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

DV6788G
1 = Normal
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

HospDischarge (2 of 2)

Severity Indicators

Was the subject receiving supplemental oxygen at the time of hospital discharge?

HospSuppOx #

Did the subject have a tracheostomy present at hospital discharge?

HospTracheo #

Was the subject discharged on mechanical ventilation?

HospMechVent #

Did the subject have a surgically placed gastric or small bowel feeding tube at the time of hospital discharge?

HospFeedTube #

Child Assent

Was child assent obtained at hospital discharge?

ChildAssent #

YN
1 = Yes
0 = No

DV7114G
1 = Yes, child gave assent
2 = Child refused assent
3 = Child unable to provide assent

Day28VitalStatus (1 of 1)

SubjectID

Day 28 Vital Status

Day 28 ... (0/2) -- Select to Jump --

Title: Day 28 Vital Status

Instructions: This form is required for all randomized subjects.

This form must be completed on or after Day 28, which is 29 calendar days from the day of randomization. If the subject dies prior to Day 28, this form can be completed at time of death.

What was the subject's status on Day 28?

"Alive" if it was verified the subject was alive on Day 28

"Deceased" if it was verified the subject died on or prior to Day 28

"Could not be determine" if you have exhausted all possible avenues to determine the status on Day 28

Alive Deceased Could not determine *

SubjectStat #

Enter the date that the subject's vital status was verified.

If the vital status could not be determined, enter the date the subject was last known or last documented to be alive.

StatusDay # * DD-MMM-YYYY

DV6850G
1 = Alive
2 = Deceased (complete death form)
3 = Could not determine

Withdrawal (1 of 1)

SubjectID

Withdrawal of Consent

Withdrawal of Consent (0/5) -- Select to Jump --

Title: Withdrawal of Consent

Date and Time of withdrawal of consent

Date: * DD-MMM-YYYY Time: * HH:MM

During which phase of the study was parental permission withdrawn?

(select one) *

For withdrawals during the intervention phase, which elements of consent were withdrawn?

(select one)

For withdrawals after the intervention phase, what elements of consent were withdrawn?

(select one)

DV7152G

- 1 = Intervention phase
- 2 = Post-intervention pre-discharge
- 3 = Prior to Month 3 Follow-up (after hospital discharge)
- 4 = Prior to Month 12 Follow-up (after Month 3 Follow-up)

DV7131G

- 1 = Parent withdrew permission from intervention only, but agrees to continue study assessments and data collection through Month 12 (end of study)
- 2 = Parent withdrew permission to participate in study intervention and assessments, but agrees to data collection through Month 12 (end of study)
- 3 = Parent withdrew permission to participate in study intervention, assessments, data collection and any contact or follow-up

DV7151G

- 1 = Parent withdrew permission to participate in study assessments, but agrees to data collection through Month 12 (end of study)
- 2 = Parent withdrew permission to participate in study assessments, data collection and any contact or follow-up

DeathInfo (1 of 1)

SubjectID

Death Information

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

Title: Death Information

Date and Time of death

Date: * DD-MMM-YYYY Time known? Yes No * If "Yes" enter time: HH:MM

Cause of death

*

If "Other" describe:

DeathTimeYN #

YN
1 = Yes
0 = No

DV6861G
1 = Cardiovascular failure / futility
2 = Neurologic brain death declared
3 = Respiratory failure / futility
4 = Withdrawal for poor neurologic prognosis
5 = Withdrawal for other system failure
95 = Other (describe)
97 = Unknown

Month3Status (1 of 1)

SubjectID

3-Month Follow-up Status

3-Month...(0/4) -- Select to Jump --

Title: Subject Follow-up Status at Month 3

Instructions: Two to four weeks prior to 3-months post randomization, contact the family to obtain the status of the subject.
If "Alive", fax the THAPCA Contact Information Form to KKI.
If "Deceased", complete the Death Information Form.
If "Could not determine", all attempts should be documented, and contact must be attempted again at the Month 12 Follow-up.
Please refer to the THAPCA Manual of Operations for more detailed instructions.

Follow-up Status at Month 3

Date the subject status was verified

Date: * DD-MMM-YYYY

Subject status

Alive
 Deceased (complete death form)
 Could not determine

*

DV6850G
1 = Alive
2 = Deceased (complete death form)
3 = Could not determine

If "Subject status" is "Could not determined" enter the last date the subject was known to be alive.

Date: DD-MMM-YYYY

If "Subject status" is "Alive" enter the date when the Contact Information Form was faxed to Kennedy Krieger

Date: DD-MMM-YYYY

Month3KKI (1 of 2)

SubjectID

3-Month Follow-up KKI

3-Month...(0/15) -- Select to Jump --

Title: Information collected by KKI at 3-Month follow-up

Date and Time of KKI Follow-up

Date: * DD-MMM-YYYY Time: * HH:MM

Primary Location of Patient Over Previous Month

Location: *

If "Other" describe location:

Vineland Adaptive Behavior Scale (VABS)

Was a VABS completed during the KKI follow-up?

Yes * No

If "No", indicate reason:

If "Other", describe reason:

DV6848G

- 1 = Home or foster care
- 2 = Acute care hospital
- 3 = Acute inpatient rehabilitation unit
- 4 = Chronic care or skilled nursing facility
- 5 = Not applicable (patient died)
- 95 = Other
- 97 = Unknown

YN

- 1 = Yes
- 0 = No

DV7142G

- 1 = Unable to contact primary caregiver
- 2 = Primary caregiver declined participation
- 95 = Other

Severity Indicators

Is patient receiving supplemental oxygen?

Yes * No

FUSuppOx #

Does patient have tracheostomy in place?

Yes * No

FUTracheo #

Does patient require mechanical ventilation?

Yes * No

FUMechVent #

Does patient have a surgically placed feeding tube?

Yes * No

FUFeedTube #

Global Function

Compared to children of the same age, are your child's home, school or social activities limited now?

(select one) *

LimitedAct #

Thinking about your child since cardiac arrest, has he or she (select below):

(select one) *

FUSkills #

Pediatric Overall Performance Category

POPC score: (select one) *

POPC #

Pediatric Cerebral Performance Category

PCPC score: (select one) *

PCPC #

Legend:

YN
1 = Yes
0 = No

DV6862G
1 = Not limited
2 = Limited a little
3 = Limited a lot

DV6863G
1 = Gained a lot of new skills
2 = Gained a few new skills
3 = Stayed the same
4 = Lost a few skills
5 = Lost a lot of skills

POPC
1 = Good
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

PCPC
1 = Normal
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

Month12Status (1 of 1)

SubjectID

12-Month Follow-up Status

12-Mont...(0/4) -- Select to Jump --

Title: Subject Follow-up Status at Month 12

Instructions: Two to four weeks prior to 12-months post randomization, contact the family to obtain the status of the subject.
If "Alive", fax the THAPCA Contact Information Form to KKI.
If "Deceased", complete the Death Information Form.
If "Could not determine", all attempts should be documented.
Please refer to the THAPCA Manual of Operations for more detailed instructions.

Follow-up Status at Month 12

Date the subject status was verified

Date: * DD-MMM-YYYY

Subject status

Alive *

Deceased (complete death form)

Could not determine

If "Subject status" is "Could not determined" enter the last date the subject was known to be alive.

Date: DD-MMM-YYYY

If "Subject status" is "Alive" enter the date when the Contact Information Form was faxed to Kennedy Krieger

Date: DD-MMM-YYYY

DV6850G
1 = Alive
2 = Deceased (complete death form)
3 = Could not determine

Month12KKI (1 of 2)

SubjectID

12-Month Follow-up KKI

12-Mont...(0/15) -- Select to Jump --

Title: Information collected by KKI at 12-Month follow-up

Date and Time of KKI Follow-up

Date: * DD-MMM-YYYY Time: * HH:MM

Primary Location of Patient Over Previous Month

Location:

If "Other" describe location:

Vineland Adaptive Behavior Scale (VABS)

Was a VABS completed during the KKI follow-up?

Yes No

If "No", indicate reason:

If "Other", describe reason:

DV6848G

- 1 = Home or foster care
- 2 = Acute care hospital
- 3 = Acute inpatient rehabilitation unit
- 4 = Chronic care or skilled nursing facility
- 5 = Not applicable (patient died)
- 95 = Other
- 97 = Unknown

YN

- 1 = Yes
- 0 = No

DV7142G

- 1 = Unable to contact primary caregiver
- 2 = Primary caregiver declined participation
- 95 = Other

Severity Indicators

Is patient receiving supplemental oxygen?

Yes No

FUSuppOx #

Does patient have tracheostomy in place?

Yes No

FUTracheo #

Does patient require mechanical ventilation?

Yes No

FUMechVent #

Does patient have a surgically placed feeding tube?

Yes No

FUFeedTube #

Global Function

Compared to children of the same age, are your child's home, school or social activities limited now?

(select one) ▼ LimitedAct #

Thinking about your child since cardiac arrest, has he or she (select below):

(select one) ▼ FUSkills #

Pediatric Overall Performance Category

POPC score: (select one) ▼ POPC #

Pediatric Cerebral Performance Category

PCPC score: (select one) ▼ PCPC #

Legend:

YN
1 = Yes
0 = No

DV6862G
1 = Not limited
2 = Limited a little
3 = Limited a lot

DV6863G
1 = Gained a lot of new skills
2 = Gained a few new skills
3 = Stayed the same
4 = Lost a few skills
5 = Lost a lot of skills

POPC
1 = Good
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

PCPC
1 = Normal
2 = Mild Disability
3 = Moderate Disability
4 = Severe Disability
5 = Coma or vegetative state
6 = Death

Month12OnSite (1 of 1)

SubjectID

12-Month Follow-up Onsite Evaluations

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

Title: Status of Month 12 Onsite Evaluations

Instructions: Please refer to the THAPCA Manual of Operations for more detailed instructions.

For children less than 5years 9months the neurobehavioral battery consists only of the Mullen Scales of Early Learning

PRCA Neurological Outcome Measure

Was this examination completed?

Yes * No

Neuro_YN #

YN
1 = Yes
0 = No

If no, select reason: (select one) Other, specify: Value not provided

Neuro_NDRes #

Neurobehavioral Battery

Was this examination completed?

Yes * No

NBehav_YN #

YN
1 = Yes
0 = No

If no, select reason: NBehav_NDRes # Other, specify: Value not provided

NCRes
1 = KKI determined as not necessary
2 = Unable to contact
3 = Unwilling to come in
4 = Unable to come in
95 = Other, specify

NDRes
1 = Unable to contact
2 = Unwilling to come in
3 = Unable to come in
95 = Other, specify

Neurobehavioral Battery It 5yo 9months

Mullen ... (0/20) -- Select to Jump --

Title: For patients less than 5 years 9 months of age

Date of neurobehavioral assessment

Date: * DD-MMM-YYYY

Name of supervising psychologist

*

Name of tester

*

1. Visual Reception (raw score):

2. Visual Reception (t score):

or is the Visual Reception t score less than 20 (select one)

1 = Yes
0 = No

3. Fine Motor (raw score):

4. Fine Motor (t score):

or is the Fine Motor t score less than 20 (select one)

1 = Yes
0 = No

5. Receptive Language (raw score):

6. Receptive Language (t score):

or is the Receptive Language t score less than 20 (select one)

1 = Yes
0 = No

NeuroBatlt6 (2 of 2)

7. Expressive Language (raw score):

ELangrRaw #

8. Expressive Language (t score):

ELangrT #

or is the Expressive Language t score less than 20 (select one) ▼

ELangrTlt20 #

YN
1 = Yes
0 = No

9. Early Learning Composite (standard score):

ELCompSc #

or is the Early Learning Composite standard score less than 49 (select one) ▼

ELCompSclt49 #

YN
1 = Yes
0 = No

Explanation for any missing data

Value not provided

NeuroBat6to16 (1 of 7)

SubjectID

Neurobehavioral Battery 6-16yo

Page 1 (0/14) Page 2 (0/14) Page 3 (0/13) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
 Subtitle: Children ages 6 - 16 years old
 Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Date of neurobehavioral assessment
 Date: * DD-MMM-YYYY

Name of supervising psychologist
 *

Name of tester
 *

Wechsler Abbreviated Scale of Intelligence (WASI)
 Vocabulary
 t score:

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Matrix Reasoning
 t score:

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Full Scale IQ - 2 Test Composite
 standard score:

MRes
 1 = Responsiveness/Cognition, Motor
 2 = Motor
 3 = Vision/Hearing
 4 = Behavioral
 5 = Communication
 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Wechsler Intelligence Scale for Children (WISC-IV) Digit Span subtest

Digit Span Forward

scaled score: **WISCdsf #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

WISCdsfMD \$13

Digit Span Backward

scaled score: **WISCdsb #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

WISCdsbMD \$13

Digit Span Total

scaled score: **WISCdsT #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

WISCdsTMD \$13

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

- MDRes
1 = Responsiveness/Cognition, Motor
2 = Motor
3 = Vision/Hearing
4 = Behavioral
5 = Communication
6 = External factors not related to the child's ability
(i.e. fire alarm, family had to leave, etc.)

Page 1 (0/14) Page 2 (0/14) Page 3 (0/13) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
Subtitle: Children ages 6 - 16 years old
Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Wechsler Intelligence Scale for Children (WISC-IV) Coding subtest

Coding

scaled score: **WISCCode #**

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) **WISCCodeMD \$13** (select all that apply)

California Verbal Learning Test for Children

List A Total Trials

t score: **CVLTTot #**

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) **CVLTTotMD \$13** (select all that apply)

List A Short-Delay Free Recall

z score: **CVLTSFre #**

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) **CVLTSFreMD \$13** (select all that apply)

List A Short-Delay Cued Recall

z score: **CVLTSCue #**

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) **CVLTSCueMD \$13** (select all that apply)

NeuroBat6to16 (4 of 7)

List A Long-Delay Free Recall	
z score:	CVLTLFre #
Explanation for missing data:	<p>Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)</p> <p>CVLTLFreMD \$13</p> <p>(select all that apply)</p>
List A Long-Delay Cued Recall	
z score:	CVLTLCue #
Explanation for missing data:	<p>Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)</p> <p>CVLTLCueMD \$13</p> <p>(select all that apply)</p>
Correct Recognition Hits	
z score:	CVLTRecog #
Explanation for missing data:	<p>Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)</p> <p>CVLTRecogMD \$13</p> <p>(select all that apply)</p>

- MDRes
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Page 2 (0/14) Page 3 (0/13) Page 4 (0/9) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
 Subtitle: Children ages 6 - 16 years old
 Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Ray Osterreith Complex Figure Test (Meyers and Meyers Administration and Scoring System)

Total accuracy for Copy

raw score: **ROCFCopy #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROCFCopyMD \$13

Total accuracy for Immediate Recall

t score: **ROCFImRe #** or is the Immediate Recall t score less than lowest calculable t score (select one) **ROCFImReF #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROCFImReMD \$13

Total accuracy for Delayed Recall

t score: **ROCFDeRe #** or is the Delayed Recall t score less than lowest calculable t score (select one) **ROCFDeReF #**

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROCFDeReMD \$13

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

YN
 1 = Yes
 0 = No

YN
 1 = Yes
 0 = No

NeuroBat6to16 (6 of 7)

Recognition total correct

t score: ROCFRecT # or is the Recognition t score less than lowest calculable t score (select one) ROCFRecTF #

Explanation for missing data: ROCFRecTMD \$13 (select all that apply)

Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Controlled Oral Word Association (COWA)

Total number of words for three trials

raw score: COWATot #

Explanation for missing data: COWATotMD \$13 (select all that apply)

Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

YN
 1 = Yes
 0 = No

MDRes
 1 = Responsiveness/Cognition, Motor
 2 = Motor
 3 = Vision/Hearing
 4 = Behavioral
 5 = Communication
 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Page 2 (0/14) Page 3 (0/13) Page 4 (0/9) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
 Subtitle: Children ages 6 - 16 years old
 Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Grooved Pegboard Test
 Time to place all pegs in board - dominant hand

raw score: (conds)

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Time to place all pegs in board - non-dominant hand

raw score: (seconds)

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Beery Test of Visuomotor Integrations (VMI)
 Total accuracy score

standard score: or is the standard score less than lowest calculable standard score (select one)

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

If unreliable is selected, explain any unreliable test score:

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

GPegDomMD \$13

GPegNonDMD \$13

YN
 1 = Yes
 0 = No

VMITotMD \$13

NeuroBatgte17 (1 of 7)

SubjectID

Neurobehavioral Battery 17 years and older

Page 1 (0/12) Page 2 (0/14) Page 3 (0/13) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery

Subtitle: Ages 17 years and older

Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Date of neurobehavioral assessment

Date: * DD-MMM-YYYY

Name of supervising psychologist

*

Name of tester

*

Wechsler Abbreviated Scale of Intelligenece (WASI)

Vocabulary

t score:

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Matrix Reasoning

t score:

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Full Scale IQ - 2 Test Composite

standard score:

- MDRes
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

NeuroBatgte17 (2 of 7)

Wechsler Adult Intelligence Scale (WAIS - III) Digit Span subtest

Digit Span Backward

scaled score:

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Digit Span Total

scaled score:

Explanation for missing data: (select all that apply)

- Responsiveness/Cognition
- Motor
- Vision/Hearing
- Behavioral
- Communication
- External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

NeuroBatgte17 (3 of 7)

Page 1 (0/12) Page 2 (0/14) Page 3 (0/13) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
Subtitle: Ages 17 years and older
Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response
Wechsler Adult Intelligence Scale (WAIS - III) Digit Symbol Coding subtest
Coding

scaled score:

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

(select all that apply)

California Verbal Learning Test - Second Edition
1-5 Free Recall Total

t score:

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

(select all that apply)

Short-Delay Free Recall

z score:

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

(select all that apply)

Short-Delay Cued Recall

z score:

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

(select all that apply)

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

NeuroBatgte17 (4 of 7)

Long-Delay Free Recall

z score: CVLT2LFre #

Explanation for missing data: Responsiveness/Cognition (select all that apply)
Motor CVLT2LFreMD \$13
Vision/Hearing
Behavioral
Communication
External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Long-Delay Cued Recall

z score: CVLT2LCue #

Explanation for missing data: Responsiveness/Cognition (select all that apply)
Motor CVLT2LCueMD \$13
Vision/Hearing
Behavioral
Communication
External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Long Delay yes/no Recognition Hits

z score: CVLT2LRecog #

Explanation for missing data: Responsiveness/Cognition (select all that apply)
Motor CVLT2LRecogMD \$13
Vision/Hearing
Behavioral
Communication
External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

- MDRes
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Page 2 (0/14) Page 3 (0/13) Page 4 (0/9) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
 Subtitle: Ages 17 years and older
 Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Ray Osterreith Complex Figure Test (Meyers and Meyers Administration and Scoring System)

Total accuracy for Copy

raw score: **ROFCopy #**

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROFCopyMD \$13

Total accuracy for Immediate Recall

t score: **ROCFImRe #** or is the Immediate Recall t score less than lowest calculable t score (select one) **ROCFImReF #**

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROCFImReMD \$13

Total accuracy for Delayed Recall

t score: **ROCFDeRe #** or is the Delayed Recall t score less than lowest calculable t score (select one) **ROCFDeReF #**

Explanation for missing data: (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

ROCFDeReMD \$13

- MDRes**
- 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

YN
 1 = Yes
 0 = No

YN
 1 = Yes
 0 = No

NeuroBatgte17 (6 of 7)

Recognition total correct

t score: or is the Recognition t score less than lowest calculable t score (select one)

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) (select all that apply)

Controlled Oral Word Association (COWA)

Total number of words for three trials

raw score:

Explanation for missing data: Responsiveness/Cognition Motor Vision/Hearing Behavioral Communication External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.) (select all that apply)

YN
1 = Yes
0 = No

MDRes
1 = Responsiveness/Cognition, Motor
2 = Motor
3 = Vision/Hearing
4 = Behavioral
5 = Communication
6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

NeuroBatgte17 (7 of 7)

Page 2 (0/14) Page 3 (0/13) Page 4 (0/9) -- Select to Jump --

Title: 12-Month Neurobehavioral Battery
 Subtitle: Ages 17 years and older
 Instructions: For select all that apply questions: Use Ctrl + Click to select more than one response

Grooved Pegboard Test
 Time to place all pegs in board - dominant hand

raw score: GPegDom # (seconds)

Explanation for missing data: GPegDomMD \$13 (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Time to place all pegs in board - non-dominant hand

raw score: (seconds) GPegNonD #

Explanation for missing data: GPegNonDMD \$13 (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

Beery Test of Visuomotor Integrations (VMI)
 Total accuracy score

standard score: VMITot # or is the standard score less than lowest calculable standard score (select one) VMITotF #

YN
 1 = Yes
 0 = No

Explanation for missing data: VMITotMD \$13 (select all that apply)
 Responsiveness/Cognition
 Motor
 Vision/Hearing
 Behavioral
 Communication
 External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

- MDRes**

 - 1 = Responsiveness/Cognition, Motor
 - 2 = Motor
 - 3 = Vision/Hearing
 - 4 = Behavioral
 - 5 = Communication
 - 6 = External factors not related to the child's ability (i.e. fire alarm, family had to leave, etc.)

PRCAYoung (1 of 3)

SubjectID

PRCA Neurological Outcome Measure (Up to 3years old)

Title: PRCA Neurological Outcome Measure	
Subtitle: Infant version (Up to 3 years old)	
Instructions: Enter a value for each item: Normal, Abnormal, or Not Done (includes items that are not age appropriate). If Abnormal enter the severity of abnormality (1-mild; 2-moderate; 3-severe).	
Identifying Data	
Date of assessment	
Date:	<input type="text" value="AssessDay #"/> <input type="button" value="Calendar"/> * DD-MMM-YYYY
Location of assessment:	<input type="text" value="AssessLoc #"/> NuroLoc 1 = In-patient 2 = Out-patient Clinic
<input type="radio"/> In-patient *	
<input type="radio"/> Out-patient Clinic	

PRCAYoung (2 of 3)

Title: PRCA Neurological Outcome Measure - Scoring Sheet

Subtitle: Infant version (Up to 3 years old)

Instructions: Enter a value for each item: Normal, Mild Abnormality, Moderate Abnormality, Severe Abnormality, or Not Done (includes items that are not age appropriate or that were not assessed).

Sensorimotor Deficit - score each side separately

Left side: (select one) **SenMotorL #** Right side: (select one) **SenMotorR #**

For items scored in Sensorimotor Deficits Left and Right, identify all the types of Sensorimotor Deficits that you observed (Ctrl + Click to select more than one)

Abnormality of tone **SenMotorDef \$13**

- Quadriparesis
- Hemiparesis
- Sensory deficit
- Global delay in gross motor skill attainment
- Global delay in fine motor skill attainment

SenMot

- 1 = Abnormality of tone
- 2 = Quadriparesis
- 3 = Hemiparesis
- 4 = Sensory deficit
- 5 = Global delay in gross motor skill attainment
- 6 = Global delay in fine motor skill attainment

Other motor or sensory deficits (includes cranial nerve deficits)

(select one) **OthSMDef #**

For items scored in Other motor or sensory deficit, identify all the types of Sensorimotor Deficits that you observed (Ctrl + Click to select more than one)

- Vision impairment
- Difficulty with drinking, chewing or swallowing
- Ataxia
- Movement disorder
- Other, describe:

OthSMDSpc \$12

OthDef

- 1 = Vision impairment
- 2 = Difficulty with drinking, chewing or swallowing
- 3 = Ataxia
- 4 = Movement disorder
- 90 = Other, describe:

Other, describe: Value not provided

NuroScr

- 0 = None
- 1 = Mild but no impact on function
- 2 = Moderate with some functional limitations
- 3 = Severe or profound with missing function

OthDef

- 1 = Vision impairment
- 2 = Difficulty with drinking, chewing or swallowing
- 3 = Ataxia
- 4 = Movement disorder
- 90 = Other, describe:

PRCAYoung (3 of 3)

Language Deficit - Production (including dysarthria)	(select one) LangDefProd # <input type="button" value="v"/>	NuroScr 0 = None 1 = Mild but no impact on function 2 = Moderate with some functional limitations 3 = Severe or profound with missing function
Language Deficit - Comprehension	(select one) LangDefComp # <input type="button" value="v"/>	
Cognitive Deficit	(select one) CognDef # <input type="button" value="v"/>	CogBeh 0 = None 1 = Mild (little impact on daily function) 2 = Moderate with some functional limitations 3 = Severe or profound with missing function
Behavioral Deficit	(select one) BehavDef # <input type="button" value="v"/>	
For Cognitive and Behavioral Deficits, describe the deficits that you observed:		
<div style="border: 1px solid black; padding: 5px; min-height: 100px;">Value not provided</div>		
Other comments regarding scoring:		
<div style="border: 1px solid black; padding: 5px; min-height: 100px;">Value not provided</div>		

PRCAOlder (1 of 3)

SubjectID

PRCA Neurological Outcome Measure (Children Aged 3 Years and Older)

Title: PRCA Neurological Outcome Measure	
Subtitle: Children aged 3 years and older	
Instructions: Enter a value for each item: Normal, Abnormal, or Not Done (includes items that are not age appropriate). If Abnormal enter the severity of abnormality (1-mild; 2-moderate; 3-severe).	
Identifying Data	
Date of assessment	
Date: <input type="text" value="AssessDay #"/>	<input type="text" value="DD-MMM-YYYY"/> *
Location of assessment:	
<input type="radio"/> In-patient *	<input type="radio"/> Out-patient Clinic
<input type="text" value="AssessLoc #"/>	NuroLoc 1 = In-patient 2 = Out-patient Clinic

Title: PRCA Neurological Outcome Measure - Scoring Sheet

Subtitle: Children aged 3 years and older

Instructions: Enter a value for each item: Normal, Abnormal, or Not Done (includes items that are not age appropriate). If Abnormal enter the severity of abnormality (1-mild; 2-moderate; 3-severe).

Sensorimotor Deficit - score each side separately

Left side: (select one) **SenMotorL #** Right side: (select one) **SenMotorR #**

For items scored in Sensorimotor Deficits Left and Right, identify all the types of Sensorimotor Deficits that you observed (Ctrl + Click to select more than one)

- Abnormality of tone
- Quadruparesis
- Hemiparesis
- Sensory deficit
- Global delay in gross motor skill attainment
- Global delay in fine motor skill attainment

SenMotorDef \$13

- SenMot**
- 1 = Abnormality of tone
- 2 = Quadruparesis
- 3 = Hemiparesis
- 4 = Sensory deficit
- 5 = Global delay in gross motor skill attainment
- 6 = Global delay in fine motor skill attainment

NuroScr
0 = None
1 = Mild but no impact on function
2 = Moderate with some functional limitations
3 = Severe or profound with missing function

Other motor or sensory deficits (includes cranial nerve deficits)

(select one) **OthSMDef #**

For items scored in Other motor or sensory deficit, identify all the types of Sensorimotor Deficits that you observed (Ctrl + Click to select more than one)

- Vision impairment
- Difficulty with drinking, chewing or swallowing
- Ataxia
- Movement disorder
- Other, describe:

OthSMDSpc \$12

- OthDef**
- 1 = Vision impairment
- 2 = Difficulty with drinking, chewing or swallowing
- 3 = Ataxia
- 4 = Movement disorder
- 90 = Other, describe:

Other, describe: **Value not provided**

PRCAOlder (3 of 3)

Language Deficit - Production (including dysarthria)	(select one) LangDefProd #	NuroScr 0 = None 1 = Mild but no impact on function 2 = Moderate with some functional limitations 3 = Severe or profound with missing function
Language Deficit - Comprehension	(select one) LangDefComp #	
Cognitive Deficit	(select one) CognDef #	CogScr 0 = None 1 = Mild 2 = Moderate 3 = Severe or profound with missing function
Behavioral Deficit	(select one) BehavDef #	
For Cognitive and Behavioral Deficits, describe the deficits that you observed:		BehvScr 0 = None 1 = Mild, no impact on academic or social function 2 = Moderate with some functional limitations 3 = Severe or profound with missing function
Value not provided		
Other comments regarding scoring:		
Value not provided		

Month12VitalStatus (1 of 1)

SubjectID

12-Month Vital Status

12-Mont...(0/2) -- Select to Jump --

Title: 12-Month Vital Status

Instructions: This form is required if the subject's vital status was not confirmed on or after the one year anniversary of randomization, by neither the Month 12 KKI follow-up nor the on-site evaluations.

What was the subject's status on the one-year anniversary date of randomization?

"Alive" if it was verified the subject was alive at one year

"Deceased" if it was verified the subject died on or prior to one year

"Could not be determine" if all efforts have been exhausted to determine the status at one year

Alive Deceased Could not determine *

SubjectStatus #

DV6850G
1 = Alive
2 = Deceased (complete death form)
3 = Could not determine

Enter the date that the subject's vital status was verified.

If the vital status could not be determined, enter the date the subject was last known or last documented to be alive.

StatusDay # * DD-MMM-YYYY

Vineland Adaptive Behavior Scale (VABS)

Variable	Format	Type	Label	Algorithm / Notes
subjectid		#	Subject ID	Randomly generated ID number that uniquely identifies an enrolled (randomized) subject across datasets
VABSTestDay		#	Day of VABS Test (relative to randomization date)	VABS Test Date – Randomization Date
VABSPhase		\$	VABS Study Phase	= "BASELINE" for Baseline VABS = "IIIMOS" for Month 3 VABS = "XIIMOS" for Month 12 VABS
VABSAge		\$	Age at time of VABS-II Assessment (Years:Months)	Age variable output from VABS Scoring Software
REC_RAW		#	Receptive Raw Score	Output from VABS Scoring Software
REC_VSCALE		#	Receptive v-Scale Score	Output from VABS Scoring Software
REC_ADAPT_LEVEL		\$	Receptive Adaptive Level	Output from VABS Scoring Software
EXP_RAW		#	Expressive Raw Score	Output from VABS Scoring Software
EXP_VSCALE		#	Expressive v-Scale Score	Output from VABS Scoring Software
EXP_ADAPT_LEVEL		\$	Expressive Adaptive Level	Output from VABS Scoring Software
WRN_RAW		#	Written Raw Score	Output from VABS Scoring Software
WRN_VSCALE		#	Written v-Scale Score	Output from VABS Scoring Software
WRN_ADAPT_LEVEL		\$	Written Adaptive Level	Output from VABS Scoring Software
COM_SUM_VSCALES_FOR_DOMAIN		#	Communication Domain Sum of the Subdomain v-Scale Scores	Output from VABS Scoring Software
COM_STD_SCORE		#	Communication Domain Standard Score	Output from VABS Scoring Software
COM__ILE_RANK		\$	Communication Domain Percentile Rank	Output from VABS Scoring Software
COM_ADAPT_LEVEL		\$	Communication Domain Adaptive Level	Output from VABS Scoring Software

VABS (2 of 3)

Variable	Format	Type	Label	Algorithm / Notes
PER_RAW		#	Personal Raw Score	Output from VABS Scoring Software
PER_VSCALE		#	Personal v-Scale Score	Output from VABS Scoring Software
PER_ADAPT_LEVEL		\$	Personal Adaptive Level	Output from VABS Scoring Software
DOM_RAW		#	Domestic Raw Score	Output from VABS Scoring Software
DOM_VSCALE		#	Domestic v-Scale Score	Output from VABS Scoring Software
DOM_ADAPT_LEVEL		\$	Domestic Adaptive Level	Output from VABS Scoring Software
CMM_RAW		#	Community Raw Score	Output from VABS Scoring Software
CMM_VSCALE		#	Community v-Scale Score	Output from VABS Scoring Software
CMM_ADAPT_LEVEL		\$	Community Adaptive Level	Output from VABS Scoring Software
DLS_SUM_VSCALES_FOR_DOMAIN		#	Daily Living Skills Domain Sum of the Subdomain v-Scale Scores	Output from VABS Scoring Software
DLS_STD_SCORE		#	Daily Living Skills Domain Standard Score	Output from VABS Scoring Software
DLS__ILE_RANK		\$	Daily Living Skills Domain Percentile Rank	Output from VABS Scoring Software
DLS_ADAPT_LEVEL		\$	Daily Living Skills Domain Adaptive Level	Output from VABS Scoring Software
IPR_RAW		#	Interpersonal Relations Raw Score	Output from VABS Scoring Software
IPR_VSCALE		#	Interpersonal Relations v-Scale Score	Output from VABS Scoring Software
IPR_ADAPT_LEVEL		\$	Interpersonal Relations Adaptive Level	Output from VABS Scoring Software
PL_RAW		#	Play and Leisure Time Raw Score	Output from VABS Scoring Software
PL_VSCALE		#	Play and Leisure Time v-Scale Score	Output from VABS Scoring Software
PL_ADAPT_LEVEL		\$	Play and Leisure Time Adaptive Level	Output from VABS Scoring Software
CS_RAW		#	Coping Skills Raw Score	Output from VABS Scoring Software

VABS (3 of 3)

Variable	Format	Type	Label	Algorithm / Notes
CS_VSCALE		#	Coping Skills v-Scale Score	Output from VABS Scoring Software
CS_ADAPT_LEVEL		\$	Coping Skills Adaptive Level	Output from VABS Scoring Software
SOC_SUM_VSCALES_FOR_DOMAIN		#	Socialization Domain Sum of the Subdomain v-Scale Scores	Output from VABS Scoring Software
SOC_STD_SCORE		#	Socialization Domain Standard Score	Output from VABS Scoring Software
SOC__ILE_RANK		\$	Socialization Domain Percentile Rank	Output from VABS Scoring Software
SOC_ADAPT_LEVEL		\$	Socialization Domain Adaptive Level	Output from VABS Scoring Software
GMS_RAW		#	Gross Motor Skills Raw Score	Output from VABS Scoring Software
GMS_VSCALE		#	Gross Motor Skills v-Scale Score	Output from VABS Scoring Software
GMS_ADAPT_LEVEL		\$	Gross Motor Skills Adaptive Level	Output from VABS Scoring Software
FMS_RAW		#	Fine Motor Skills Raw Score	Output from VABS Scoring Software
FMS_VSCALE		#	Fine Motor Skills v-Scale Score	Output from VABS Scoring Software
FMS_ADAPT_LEVEL		\$	Fine Motor Skills Adaptive Level	Output from VABS Scoring Software
MS_SUM_VSCALES_FOR_DOMAIN		#	Motor Skills Domain Sum of the Subdomain v-Scale Scores	Output from VABS Scoring Software
MS_STD_SCORE		#	Motor Skills Domain Standard Score	Output from VABS Scoring Software
MS__ILE_RANK		\$	Motor Skills Domain Percentile Rank	Output from VABS Scoring Software
MS_ADAPT_LEVEL		\$	Motor Skills Domain Adaptive Level	Output from VABS Scoring Software
ABC_SUM_ALL_DOM_STD_SCORES		#	Adaptive Behavior Composite Sum of All Domain Standard Scores	Output from VABS Scoring Software
ABC_STD_SCORE		#	Adaptive Behavior Composite Standard Score	Output from VABS Scoring Software
ABC__ILE_RANK		\$	Adaptive Behavior Composite Percentile Rank	Output from VABS Scoring Software
ABC_ADAPT_LEVEL		\$	Adaptive Behavior Composite Adaptive Level	Output from VABS Scoring Software

Outcomes (1 of 14)

Outcomes

Variable	Format	Type	Label	Algorithm / Notes
SubjectID		#	Subject ID	Randomly generated ID number that uniquely identifies an enrolled (randomized) subject across datasets
TreatRand	TREATMENT 1 = Hypothermia 2 = Normothermia 3 = Treatment not initiated	#	Treatment Assigned	= 1 if subject was randomized to Hypothermia = 2 if subject was randomized to Normothermia
TreatRec	TREATMENT	#	Treatment Received	= 1 if subject received Hypothermia = 2 if subject received Normothermia = 3 if subject received neither treatment
AgeYrs		#	Age at Randomization (years)	Randomization Date - Birthdate
AgeGroup	AGEGROUP 1 = < 2 years 2 = 2-11 years 3 = >= 12 years	#	Age Group at Randomization	= 1 if AgeYrs < 2 = 2 if 2 <= AgeYrs < 12 = 3 if AgeYrs >= 12
Gender	GENDER 1 = Male 2 = Female	#	Sex	Copied from Demographics dataset
PreExNone	YN 1 = Yes 0 = No	#	Patient had no pre-existing condition	= 1 if PreExPrenat, PreExLung, PreExCongHrt, PreExAcqHrt, PreExArrhyth, PreExImmuno, PreExTranspl, PreExGastro, PreExEndo, PreExRenal, PreExNeuro, and PreExMisc (all from PreArrest dataset) are all No = 0 if any of these variables are Yes
PreExLung	YN	#	Did patient have a pre-existing lung or airway disease?	Copy from PreArrest dataset
PreExNeuro	YN	#	Did patient have a pre-existing neurologic condition?	Copy from PreArrest dataset

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Variable	Format	Type	Label	Algorithm / Notes
PreExGastro	YN	#	Did patient have a pre-existing gastrointestinal disorder?	Copy from PreArrest dataset
PreExPrenat	YN	#	Did patient have a pre-existing prenatal condition?	Copy from PreArrest dataset
PreExCongHrt	YN	#	Did patient have a pre-existing congenital heart disease?	Copy from PreArrest dataset
PreExOther	YN	#	Patient had pre-existing condition other than lung/airway, neurologic, gastrointestinal disorder, prenatal, or congenital heart disease	= 1 if PreExAcqHrt is Yes OR PreExArrhyth is Yes OR PreExImmuno is Yes OR PreExTranspl is Yes OR PreExEndo is Yes OR PreExRenal is Yes OR PreExMisc is Yes (all from PreArrest dataset) = 0 if ALL of these variables are No
CACauseCat	CACAUSECAT 1 = Cardiovascular event 4 = Respiratory event 95 = Other 97 = Unknown	#	Primary etiology of cardiac arrest	= 95 if ArrEtiol.PrimaryCause is "Neurological event", "Congenital heart disease event", "Multiple organ system failure (MOSF)", "Drug overdose", or "Electrolyte imbalance" = ArrEtiol.PrimaryCause otherwise
OHArrWitness	YNUD 1 = Yes 0 = No 94 = Unable to determine	#	Was the cardiac arrest witnessed?	Copy from OHCardiacArr dataset
OH CPRBystand	YNUD	#	Were chest compressions administered by bystander?	Copy from OHCardiacArr dataset
CARhythmEMSHosp	CARHYTHM 1 = Asystole 2 = Bradycardia 3 = Pulseless electrical activity (PEA) 4 = Ventricular fibrillation or tachycardia 97 = Unknown	#	Initial cardiac arrest rhythm noted by EMS or hospital	Based on RhythmEMS, RhythmHosp, OHTranspEMS, and RhythmOther (all from OHCardiacArr dataset). Used rhythm recorded at hospital if subject was not transported by EMS. Study PIs recategorized "Other" rhythm entries.
CAtoCPR		#	Time between cardiac arrest and start of compressions (minutes)	Time of CPR – time of arrest (from OHCardiacArr dataset). NULL if either variable is NULL.

Outcomes (3 of 14)

Variable	Format	Type	Label	Algorithm / Notes
CPRtoROSC		#	Time between start of compressions and ROSC/ROC (minutes)	Time of ROSC – time of CPR (from OHCardiacArr dataset). NULL if either variable is NULL.
FirstHosp	DV7148G 1 = Study Hospital 2 = Non-study hospital	#	What was the first hospital the patient arrived at?	Copy from OHCardiacArr dataset
OH1stHospCPR	YNUD	#	Were chest compressions still required at time of arrival at the first hospital?	Copy from OHCardiacArr dataset
DosesEpiEMS		#	Number of doses of epinephrine administered by EMS (>10 coded as 11, Unknown coded as NULL)	= 0 if OHCardiacArr.OHTranspEMS is No = NULL else if OHCardiacArr.OHDoseEpiEMS is (NULL or Unknown) = 0 else if OHCardiacArr.OHDoseEpiEMS is None = OHCardiacArr.OHDoseEpiEMS otherwise
DosesEpiHosp		#	Number of doses of epinephrine administered at hospital (>10 coded as 11, Unknown coded as NULL)	= NULL if OHCardiacArr.EpinephHosp is (NULL or Unknown) = 0 else if OHCardiacArr.EpinephHosp is None = OHCardiacArr.EpinephHosp otherwise
DosesEpiTotal		#	Total number of doses of epinephrine administered by EMS and at hospital	DosesEpiEMS + DosesEpiHosp
SurviveM12	YESNOUNKNOWN 1 = Yes 0 = No 97 = Unknown	#	Survival at 12 months	= 0 if subject died on or prior to the one-year anniversary of their cardiac arrest per the death date = 1 else if subject is known to be alive on or after the one-year anniversary of their cardiac arrest per any of the 12 month follow-up datasets = 97 otherwise
PrimaryEndpoint	YESNOUNKNOWN	#	Survival at 12 months with VABS >= 70	= 1 if SurviveM12 is Yes AND Month 12 VABS >= 70 = 0 if SurviveM12 is No = 0 if Month 12 VABS < 70 = 97 otherwise
Primary	YN 1 = Yes 0 = No	#	Eligible for primary analysis?	= 1 if baseline VABS >= 70 = 1 if baseline VABS is NULL AND (baseline POPC='Good' or 'Mild Disability) AND (baseline PCPC ='Normal' or 'Mild Disability) = 0 otherwise

Outcomes (4 of 14)

Variable	Format	Type	Label	Algorithm / Notes
M12VabsOutcome		#	Alternative VABS status at 12 months outcome	= -2000 if SurviveM12 is No = -1000 if SurviveM12 is Yes AND the Month 12 VABS is the lowest possible for age = Month 12 VABS otherwise
M12VabsOutcomeCat	M12VABSOUTCOME 0 = Death 1 = Profound disability (VABS < 45 or lowest possible) 2 = Moderate to severe disability (VABS 45-69) 3 = Good functional status (VABS >= 70)	#	Categorical VABS status at 12 months	= 0 if SurviveM12 is No = 1 if M12VabsOutcome < 45 = 2 if 45 <= M12VabsOutcome <= 69 = 3 if M12VabsOutcome >= 70
DeltaVabs		#	Change in neurobehavioral function as assessed by VABS from pre-arrest to 12 months.	= -2000 if SurviveM12 is No = -1000 if SurviveM12 is Yes AND the Month 12 VABS is the lowest possible for age = Month 12 VABS – baseline VABS if SurviveM12 is Yes AND both VABS scores are not NULL = NULL otherwise
DeltaVabsCat	DELTA 0 = Death 1 = Lowest possible VABS score 2 = VABS decreased > 30 points 3 = VABS decreased 16-30 points 4 = VABS decreased no more than 15 points or improved	#	Categorical change in neurobehavioral function as assessed by VABS from pre-arrest to 12 months	= 0 if SurviveM12 is No = 1 if DeltaVabs = -1000 = 2 if DeltaVabs <= -30 = 3 if -30 <= DeltaVabs <= -16 = 4 if DeltaVabs >= -15

Variable	Format	Type	Label	Algorithm / Notes
BloodAll	YESNOWITHDREW -1 = Unknown (patient withdrew) 1 = Yes 0 = No	#	Any blood product use within 7 days of randomization	<p>= -1 if NO blood products were used after randomization through Day 7 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if any blood products were used after randomization through Day 7</p> <p>= 0 else if NO blood products were used after randomization through Day7</p> <p>Note:In the raw data, SubjectID 49 is indicated to have packed red blood cells on Day 7. However, the amount entered is 0. There were no other blood products used for this subject. Therefore, BloodAll=No for SubjectID 49.</p>
BloodCryo	YESNOWITHDREW	#	Any cryoprecipitate use within 7 days of randomization	<p>= -1 if NO cryoprecipitate was used after randomization through Day 7 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if any cryoprecipitate was used after randomization through Day 7</p> <p>= 0 else if NO cryoprecipitate was used after randomization through Day7</p>
BloodFFP	YESNOWITHDREW	#	Any fresh frozen plasma (FFP) use within 7 days of randomization	<p>= -1 if NO fresh frozen plasma (FFP) was used after randomization through Day 7 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if any fresh frozen plasma (FFP)was used after randomization through Day 7</p> <p>= 0 else if NO fresh frozen plasma (FFP)was used after randomization through Day7</p>

Variable	Format	Type	Label	Algorithm / Notes
BloodPRBC	YESNOWITHDREW	#	Any packed red blood cell/whole blood use within 7 days of randomization	<p>= -1 if NO packed red blood cells (PRBC) were used after randomization through Day 7 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if any packed red blood cells (PRBC) were used after randomization through Day 7</p> <p>= 0 else if NO packed red blood cells (PRBC) were used after randomization through Day7</p> <p>Note:In the raw data, SubjectID 49 is indicated to have packed red blood cells on Day 7. However, the amount entered is 0. There were no other blood products used for this subject. Therefore, BloodPRBC=No for SubjectID 49.</p>
BloodPlat	YESNOWITHDREW	#	Any platelet use within 7 days of randomization	<p>= -1 if NO platelets were used after randomization through Day 7 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if any platelets were used after randomization through Day 7</p> <p>= 0 else if NO platelets were used after randomization through Day7</p>
Arrhy	YESNOWITHDREW	#	Any serious arrhythmias within 7 days of randomization	<p>= -1 if there are NO serious arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection</p> <p>= 1 else if there are any serious arrhythmias occurring after randomization through day 7</p> <p>= 0 else if there are NO serious arrhythmias occurring after randomization through day 7</p>

Outcomes (7 of 14)

Variable	Format	Type	Label	Algorithm / Notes
ArrhyAsystole	YESNOWITHDREW	#	Any Asystole arrhythmias within 7 days of randomization	= -1 if there are NO serious Asystole arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if there are any serious Asystole arrhythmias occurring after randomization through day 7 = 0 else if there are NO serious Asystole arrhythmias occurring after randomization through day 7
ArrhyAtrial	YESNOWITHDREW	#	Any Atrial (SVT, atrial flutter, JET) arrhythmias within 7 days of randomization	= -1 if there are NO serious Atrial arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if there are any serious Atrial arrhythmias occurring after randomization through day 7 = 0 else if there are NO serious Atrial arrhythmias occurring after randomization through day 7
ArrhyPEA	YESNOWITHDREW	#	Any PEA arrhythmias within 7 days of randomization	= -1 if there are NO serious PEA arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if there are any serious PEA arrhythmias occurring after randomization through day 7 = 0 else if there are NO serious PEA arrhythmias occurring after randomization through day 7

Outcomes (8 of 14)

Variable	Format	Type	Label	Algorithm / Notes
ArrhyVentricular	YESNOWITHDREW	#	Any Ventricular (sustained VT greater than 30 seconds, VF, Torsades) arrhythmias within 7 days of randomization	= -1 if there are NO serious Ventricular arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if there are any serious Ventricular arrhythmias occurring after randomization through day 7 = 0 else if there are NO serious Ventricular arrhythmias occurring after randomization through day 7
ArrhyOther	YESNOWITHDREW	#	Any other type of arrhythmias within 7 days of randomization	= -1 if there are NO serious Other arrhythmias occurring after randomization through day 7, AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if there are any serious Other arrhythmias occurring after randomization through day 7 = 0 else if there are NO serious Other arrhythmias occurring after randomization through day 7
InfectionN		#	Number of culture-proven infection within 7 days of randomization	Number of new, culture-proven infections occurring after randomization date/time through day 7 according to the culture log
Infection	YESNOWITHDREW	#	Any culture-proven infection within 7 days of randomization	= -1 if infection = 0 AND the patient withdrew permission to collect data prior to completing all 8 days of data collection = 1 else if infection > 0 = 0 else if infection = 0

Outcomes (9 of 14)

Variable	Format	Type	Label	Algorithm / Notes
DaysData		#	Days of expected daily data collection including Days 0-7	= Number of days from randomization to the earliest of day 7, hospital discharge, death, or withdrawal. Day of randomization and (day 7, day of hospital discharge, or day of death) are included in this calculation. In cases of withdrawal, date of withdrawal is included in the calculation if daily form was created for that day (ie, data was collected on withdraw date)
Death28	VITALSTATUS -1 = Could not be determined 1 = Deceased 0 = Alive	#	Patient vital status at Day 28	= 1 if patient died on or prior to Day 28 = 0 else if patient is verified to be alive on Day 28 = -1 if vital status on Day 28 could not be determined
OneYearAvailableReas	ONEYEARAVAILBLEREAS 1 = Unable to obtain vital status 2 = Vital status known, unable to obtain VABS	#	Reason one year data is unavailable	= 1 if SurviveM12 is Unknown = 2 else if SurviveM12 is Yes AND Month 12 VABS is NULL = NULL otherwise
timeToDeathM12		#	Time to death/censor by Month 12 (days)	= (Death date – cardiac arrest date) if SurviveM12 is No = (One-year cardiac arrest anniversary date – cardiac arrest date) if SurviveM12 is Yes = (Last date patient known to be alive – cardiac arrest date) if SurviveM12 is Unknown
censorDeathM12	YESNO 1 = Yes 0 = No	#	Censored for 12 month mortality	= 0 if SurviveM12 is No = 1 if SurviveM12 is Yes OR Unknown
FirstTempNew		#	First reported temperature	Earliest recorded temperature. If more than one temperature recorded at the same (earliest) time, the following order of preference is used to select the temperature: temperature recorded by the primary probe at that time (reference primary probe form), ECMO blood/circuit temperature, esophageal temperature, bladder temperature, rectal temperature.
FirstABGpH		#	First reported ph	First non-missing BLABGpH value from the Baseline dataset

Outcomes (10 of 14)

Variable	Format	Type	Label	Algorithm / Notes
FirstABGPaCO2		#	First reported PaCO2 (mmHg)	First non-missing BLABGPaCO2 value from the Baseline dataset
FirstABGPaO2		#	First reported PaO2 (mmHg)	First non-missing BLABGPaO2 value from the Baseline dataset
FirstABGSat		#	First reported Saturation (%)	First non-missing BLABGSat value from the Baseline dataset
FirstABGBicarb		#	First reported Bicarbonate (mmol/L)	First non-missing BLABGBicarb value from the Baseline dataset
Firstlactate		#	First reported Lactate (mmol/L)	First non-missing BLLactate value from the Baseline_Lactate dataset
FirstSodium		#	First reported Serum sodium concentration (mmol/L)	First non-missing BLSodium value from the PreInterven_Elytes dataset
FirstPotassium		#	First reported Serum potassium concentration (mmol/L)	First non-missing BLPotassium value from the PreInterven_Elytes dataset
FirstBicarbonate		#	First reported Serum bicarbonate concentration (mmol/L)	First non-missing BLBicarbonate value from the PreInterven_Elytes dataset
FirstChloride		#	First reported Serum chloride concentration (mmol/L)	First non-missing BLChloride value from the PreInterven_Elytes dataset
FirstBUNitrogen		#	First reported Serum BUN concentration (mmol/L)	First non-missing BLBUNitrogen value from the PreInterven_Elytes dataset
FirstCreatinine		#	First reported Serum creatinine concentration (mmol/L)	First non-missing BLCreatinine value from the PreInterven_Elytes dataset
Firstglucose		#	First reported Serum glucose concentration (mmol/L)	First non-missing BLGlucose value from the PreInterven_Elytes dataset
Firstmagnesium		#	First reported Magnesium (mg/dL)	First non-missing BLMagnesium value from the Baseline_Chemistry dataset
Firstionizedca		#	First reported Ionized calcium (mmol/L)	First non-missing BLLonizedCa value from the Baseline_Chemistry dataset
Firsttotalca		#	First reported Total calcium (mg/dL)	First non-missing BLTotalCa value from the Baseline_Chemistry dataset
Firstphosphate		#	First reported Phosphate (mg/dL)	First non-missing BLPhosphate value from the Baseline_Chemistry dataset
FirstALT		#	First reported ALT/SGPT (U/L)	First non-missing BLALT value from the Baseline_Liver dataset
FirstAST		#	First reported AST/SGOT (U/L)	First non-missing BLAST value from the Baseline_Liver dataset

Outcomes (11 of 14)

Variable	Format	Type	Label	Algorithm / Notes
FirstBilirubin		#	First reported Total Bilirubin (mg/dL)	First non-missing BLBilirubin value from the Baseline_Liver dataset
FirstPT		#	First reported PT (seconds)	First non-missing BLPT value from the Baseline_Coags dataset
FirstPTT		#	First reported PTT (seconds)	First non-missing BLPTT value from the Baseline_Coags dataset
FirstINR		#	First reported INR	First non-missing BLINR value from the Baseline_Coags dataset
FirstAmylase		#	First reported Amylase (U/L)	First non-missing BLAmylase value from the Baseline_Pancreas dataset
FirstLipase		#	First reported Lipase (U/L)	First non-missing BLLipase value from the Baseline_Pancreas dataset
FirstHgb		#	First reported Hemoglobin (g/dL)	First non-missing BLHgb value from the Baseline_CBC dataset
FirstPlatelet		#	First reported Platelet count (10 ³ /microL)	First non-missing BLPlatelet value from the Baseline_CBC dataset
FirstWBC		#	First reported White blood cell (10 ³ /microL)	First non-missing BLWBC value from the Baseline_CBC dataset
BLVabs		#	Pre-cardiac arrest VABS Adaptive Behavior Composite Score	= ABC_STD_SCORE from the VABS dataset where VABSPhase = "BASELINE"
BLPCPC	PCPCDER 1 = Normal = 1 2 = Mild disability = 2 3 = Moderate disability = 3 4 = Severe disability = 4 5 = Coma or vegetative state = 5	#	Pre-cardiac arrest PCPC	=PCPC from the BLNeurobehavioral dataset
BLPOPC	POPCDER 1 = Good = 1 2 = Mild disability = 2 3 = Moderate disability = 3 4 = Severe disability = 4 5 = Coma or vegetative state = 5	#	Pre-cardiac arrest POPC	=POPC from the BLNeurobehavioral dataset

Outcomes (12 of 14)

Variable	Format	Type	Label	Algorithm / Notes
PrimaryRe	PRIMARYRE 1 = Baseline VABS<70 2 = No VABS, POPC, nor PCPC 3 = No VABS, POPC/PCPC>=3	#	Why not eligible for primary analysis	= NULL if Primary is Yes = 1 if BLVabs<70 = 2 if BLVabs is NULL AND (BLPCPC is NULL OR BLPOPC is NULL) = 3 if BLVabs is NULL AND (BLPOPC>2 OR BLPCPC>2)
HOSPDCStat	HOSPITALVITALSTATUS 0 = Alive 1 = Deceased	#	Vital Status at Hospital Discharge	= 1 if HospDsSchDate from HospDischarge dataset=DeathDT from DeathInfo dataset AND HospDsSchLoc from HospDischarge dataset="Not applicable (patient died)"
DeathRe	DV6861G 1 = Cardiovascular failure/futility 2 = Neurologic brain death declared 3 = Respiratory failure/futility 4 = Withdrawal for poor neurologic prognosis 5 = Withdrawal for other system failure 95 = Other 97 = Unknown	#	Cause of Death	= DeathReason from DeathInfo dataset
ELCompScCat	ELCOMPSCCAT 1 = Lowest possible score 2 = 49 - 69 (well below average) 3 = 70 - 84 (below average) 4 = 85 - 115 (average) 5 = > 115 (above average)	#	Early learning composite category	= 1 if NeurobatIt6.ELCompScIt49 is Yes and for one subject identified by KKI = 2 if 49 <= NeurobatIt6.ELCompSc <= 69 = 3 if 70 <= NeurobatIt6.ELCompSc <= 84 = 4 if 85 <= NeurobatIt6.ELCompSc <= 115 = 5 if 115 < NeurobatIt6.ELCompSc

Outcomes (13 of 14)

Variable	Format	Type	Label	Algorithm / Notes
WASIFAIQCat	WASIRANGE 1 = Lowest possible score 2 = 55 - 69 (well below average) 3 = 70 - 84 (below average) 4 = 85 - 115 (average) 5 = > 115 (above average)	#	Intelligence domain: Full-scale IQ score category	= 1 if month12onsite.Nbehav_NDRes = "KKI determined as not necessary" and for one subject identified by KKI = 2 if 55 <= Neurobat6to16.WASIFull <= 69 = 2 if 55 <= Neurobatgte17.WASIFull <= 69 = 3 if 70 <= Neurobat6to16.WASIFull <= 84 = 3 if 70 <= Neurobatgte17.WASIFull <= 84 = 4 if 85 <= Neurobat6to16.WASIFull <= 115 = 4 if 85 <= Neurobatgte17.WASIFull <= 115 = 5 if 115 < Neurobat6to16.WASIFull = 5 if 115 < Neurobatgte17.WASIFull
mullwasicat	MULLWASICAT 1 = Lowest possible score 2 = < 70 (well below average) 3 = 70 - 84 (below average) 4 = 85 - 115 (average) 5 = > 115 (above average)	#	Mullen or WASI score category (all ages combined)	= ELCompScCat if ELCompScCat is not NULL = WASIFAIQCat if WASIFAIQCat is not NULL
Hypokalemia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Hypokalemia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Hypokalemia" = 0 otherwise
Hyperkalemia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Hyperkalemia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Hyperkalemia" = 0 otherwise
Hypoglycemia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Hypoglycemia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Hypoglycemia" = 0 otherwise
Hyperglycemia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Hyperglycemia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Hyperglycemia" = 0 otherwise

Outcomes (14 of 14)

Variable	Format	Type	Label	Algorithm / Notes
Hypophosphatemia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Hypophosphatemia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Hypophosphatemia" = 0 otherwise
Neutropenia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Neutropenia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Neutropenia" = 0 otherwise
Thrombocytopenia	YN	#	During first 5 days, patient had at least one reported AE with MedDRA lower level term of 'Thrombocytopenia'	= 1 if subject has a record in the adverseevents dataset where AESTartDay <= 5 AND AELLT="Thrombocytopenia" = 0 otherwise
ClinElectroSz	YN	#	During first 5 days, patient had a clinical or electrographic seizure	= 1 if ClinicalSz = Yes or ElectroSz = Yes in any of the Day0, Day1, Day2, Day3, Day4, or Day5 datasets = 0 otherwise
RepeatCA5days	YN	#	During first 5 days, patient had a repeat cardiac arrest	= 1 if CAYN = Yes in any of the Day0, Day1, Day2, Day3, Day4, or Day5 datasets = 0 otherwise
Dialytic	YN	#	During first 5 days, patient received any form of renal replacement therapy	= 1 if DialyticYN = Yes in any of the Day0, Day1, Day2, Day3, Day4, or Day5 datasets = 0 otherwise

Temperature

Variable	Format	Type	Label	Algorithm / Notes
SubjectID		#	Subject ID	Randomly generated ID number that uniquely identifies an enrolled (randomized) subject across datasets
Temp		#	Primary Temperature (°C)	Temperature recorded in the temperature logs for the temperature route indicated to be the primary probe location (according to the primary probe form) at the time of the temperature collection
Time		#	Time from treatment initiation (hours)	Temperature date/time – Treatment Initiation date/time