University of Utah
Central Data Management Coordinating Center

ANNOTATED eCRF FOR PUBLIC USE DATASETS

Measuring Opioid Tolerance Induced by Fentanyl (or Other Opioids)
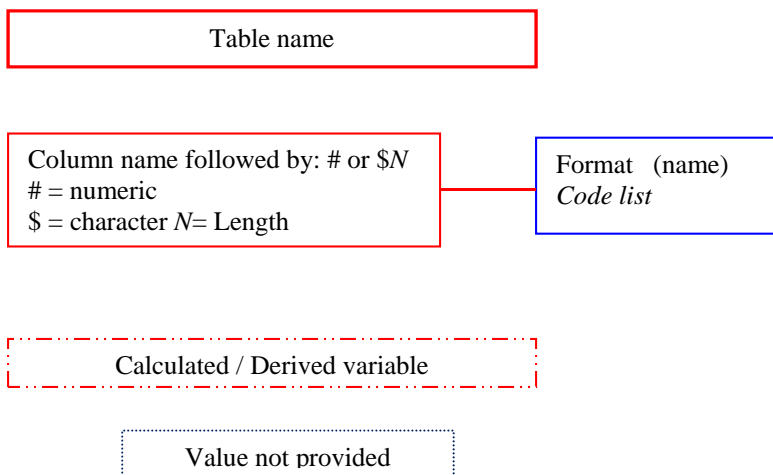
MOTIF Study

CPCCRN Protocol Number 026

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Arkansas Children's Hospital

Table of Contents

Annotations key:

Table name

Column name followed by: # or N # = numeric $ = character N= Length

Format   (name)   *Code list*

Calculated / Derived variable

Value not provided

Notes:

Variable names for dates were modified from, for example, eventdate to eventday. Labels were modified to read "Day . . . (relative to study entry)." Study entry is the same as the first dose date, or date of first opioid infusion. For daily data, there is also a "study day" defined as Day 1 - Day 14. Study Day 1 is the day of study entry, so corresponds to day 0 for any recoded dates.

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

Demographics
Unique ID = SubjectID

Demographics Data	Enrollment Data

Essential Identifying Info (Birthdate, Sex, Race) ---- * Indicates required fields

*Patient ID	SubjectID #	* Date of Birth (use 4 digits for year)	AgeInMonths #	Estimated DOB?	Value not provided
Initials	Value not provided	*Sex	SEX $1	*Race	RACE #
Hispanic/Latino Ethnicity?	HISPANIC_ETHNICITY #	Race Other	OTHER_RACE $50	Test Patient?	Value not provided

Date Created	Value not provided

DV6484G
-1 = Hispanic or Latino
0 = Not Hispanic or Latino
1 = Unknown

DV403G
1 = American Indian or Alaska Native
2 = Asian
3 = Black or African American
4 = Native Hawaiian or Other Pacific Islander
5 = White
6 = Unknown
7 = Other

Save	Show Printable version	Exit Demographics/Enrollment

Study Entry

Unique ID = SubjectID

SubjectID #

Study Entry	
Date of PICU admission	PICUAdmitDay #
Time of PICU admission	PICUAdmitTime $5
Height (cm)	HeightCM #
Date first continuous IV infusion of morphine or fentanyl was started	FrstDoseDay #
Time first continuous IV infusion of morphine or fentanyl was started	FrstDoseTm $5
Date mechanical ventilation started	VentStDay #
Time mechanical ventilation started	VentStTime $5
Operative Status	OperativeStatus #
Postoperative type	PostOpType2 #
Other Surgery please describe	SurgeryOther $150
Primary Diagnostic Category	PrimDiag_1 #
Other primary diagnostic category	PrimDiag_1Oth $255

DV6478G
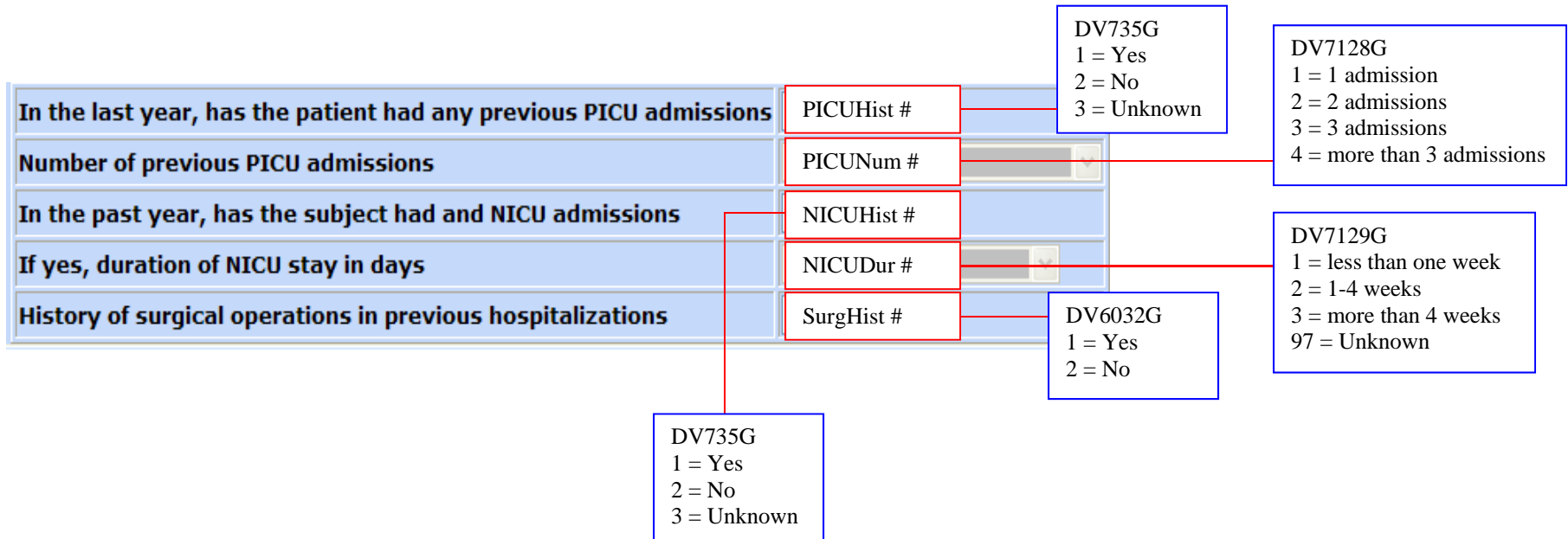0 = Not postoperative
1 = Postoperative

DV6479G
0 = Cardiac surgery
1 = Neurosurgery
2 = Orthopedic surgery
3 = Transplant surgery
4 = Trauma surgery
5 = Other surgery

DV7116G
1 = Asthma (reactive airway disease)
2 = Cancer
3 = Cardiac arrest w/in 24 hours (closed heart compressions)
4 = Chromosomal abnormality (not hereditary)
5 = Diabetes
7 = Gastroesophageal reflux
8 = Cardiovascular disease acquired
9 = Cardiovascular disease congenital
11 = Hypoxic-ischemic encephalopathy (acute, not static)
12 = Medical device malfunction
13 = Meningitis
14 = Pneumonia/bronchiolitis
15 = Seizures (includes complications of seizure therapy)
16 = Sepsis
17 = Shock
19 = Transplant
20 = Trauma
21 = Respiratory Distress/Failure
98 = None
99 = Other

In the last year, has the patient had any previous PICU admissions	PICUHist #
In the past year, has the subject had and NICU admissions	NICUHist #
If yes, duration of NICU stay in days	NICUDur #
History of surgical operations in previous hospitalizations	SurgHist #

Number of previous PICU admissions — PICUNum #

DV735G
1 = Yes
2 = No
3 = Unknown

DV7128G
1 = 1 admission
2 = 2 admissions
3 = 3 admissions
4 = more than 3 admissions

DV7129G
1 = less than one week
2 = 1-4 weeks
3 = more than 4 weeks
97 = Unknown

DV6032G
1 = Yes
2 = No

DV735G
1 = Yes
2 = No
3 = Unknown

Derived variables included in the STUDYENTRY dataset:

Variable	Type	Label	Algorithm / Notes
PRISMIIICalcS	#	PRISM III Score	Based on the first 12 hours of PICU admission

Secondary Diagnostic Category

Unique ID = SubjectID, Repeat_instance

SubjectID #   Repeat_instance #

Secondary Diagnostic Catergory

Secondary Diagnostic Category	Other secondary diagnostic category
SecDiag_1 #	SecDiag_1Oth $100

Add record   Delete record

DV7116G
1 = Asthma (reactive airway disease)
2 = Cancer
3 = Cardiac arrest w/in 24 hours (closed heart compressions)
4 = Chromosomal abnormality (not hereditary)
5 = Diabetes
7 = Gastroesophageal reflux
8 = Cardiovascular disease acquired
9 = Cardiovascular disease congenital
11 = Hypoxic-ischemic encephalopathy (acute, not static)
12 = Medical device malfunction

13 = Meningitis
14 = Pneumonia/bronchiolitis
15 = Seizures (includes complications of seizure therapy)
16 = Sepsis
17 = Shock
19 = Transplant
20 = Trauma
21 = Respiratory Distress/Failure
98 = None
99 = Other

Chronic Diagnostic Category

Unique ID = SubjectID, Repeat_instance

SubjectID #

Repeat_instance #

Chronic Diagnostic Catergory

Chronic Diagnoses		Other diagnoses	
	ChronicDiag_1 #	ChronicDiag_1Oth $100	

Add record   Delete record

DV7117G
1 = Bronchopulmonary dysplasia (BPD)
2 = Cancer (oncologic disease)
3 = Cerebral palsy
4 = Chromosomal anomalies (not hereditary conditions)
5 = Congenital heart disease
6 = Diabetes
8 = Hydrocephalus
9 = Intraventricular hemorrhage (from perinatal period)
10 = Mental retardation
11 = Meningomyelocele/spina bifida
12 = Short gut syndrome
13 = Static encephalopathy
14 = Transplant
98 = None
99 = Other

STUDYDAY1 (1 of 5)

Study Day 1
Unique ID = SubjectID

SubjectID #   StudyDay #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Day 1 - From the start time of the first continuous IV infusion of morphine or fentanyl to 23:59

Date	Day #
Weight (kg)	WeightKG #
Weight (kg) on which infusion rate was calculated	DrgWeightKG #

Continuous IV infusions of morphine

Was morphine administered by continuous IV infusion on this study day   CIVMorphYN #

Time started	Time stopped	Infusion rate (mg/kg/hour)
Refer to DCIVMORPH dataset		

[Add record] [Delete record]

DV6032G
1 = Yes
2 = No

Boluses of morphine

Were any morphine boluses administered on this study day   BMorphYN #

Time administered	Dose administered (mg)
Refer to DBMORPH dataset	

[Add record] [Delete record]

DV6032G
1 = Yes
2 = No

MOTIF Annotated PUD eCRF

Continuous IV infusions of fentanyl

Was fentanyl administered by continuous IV infusion on this study day   CIVFentYN #

DV6032G
1 = Yes
2 = No

Time started	Time stopped	Infusion rate (mcg/kg/hour)
Refer to DCIVFENT dataset		

[Add record]   [Delete record]

Boluses of fentanyl

Were any fentanyl boluses administered on this study day   BFentYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mcg)
Refer to DBFENT dataset	

[Add record]   [Delete record]

STUDYDAY1 (3 of 5)

Continuous IV infusions of Midazolam

Was midazolam administered by continuous IV infusion on this study day | CIVMidazYN #

DV6032G
1 = Yes
2 = No

Time started	Time stopped	Infusion rate (mg/kg/hour)
Refer to DCIVMIDAZ dataset		

[Add record] [Delete record]

Boluses of midazolam

Were any midazolam boluses administered on this study day | BMidazYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mg)
Refer to DBMIDAZ dataset	

[Add record] [Delete record]

Boluses of lorazepam

Were any lorazepam boluses administered on this study day   BLorazYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mg)
Refer to DBLORAZ dataset	

Add record   Delete record

MOTIF Annotated PUD eCRF

Othe Sedative Drugs

Were any other sedatives administered on this study day — SedatYN #

DV6032G
1 = Yes
2 = No

Select all sedative drugs administered | **Other, specify**

Refer to DSEDATIVES dataset

[Add record] [Delete record]

Othe Analgesic Drugs

Were any other analgesics administered on this study day — AnalgYN #

DV6032G
1 = Yes
2 = No

Select all analgesic drugs administered | **Other, specify**

Refer to DANALGESICS dataset

[Add record] [Delete record]

DAILYDATA (1 of 7)

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Daily Data Collection
Unique ID = SubjectID, StudyDay

SubjectID #

Daily Data Collection

Study Day	StudyDay #
Date	Day #
Weight (kg)	WeightKG #
Weight (kg) on which infusion rate was calculated	DrgWeightKG #

Daily agitation assessments

Were muscle relaxants used on this study day	MuscRel #
Were physical restraints used on this study day	PhyRest #
Did inadvertent or unplanned dislodgement of an endotracheal tube occur on this study day	ETTDisc #
Did inadvertent or unplanned dislodgement of a central venous line occur on this study day	CVLDisc #
Did inadvertent or unplanned dislodgement of an arterial line occur on this study day	ALDisc #
Did inadvertent or unplanned dislodgement of a thoracostomy tube occur on this study day	ThoraDisc #
Did inadvertent or unplanned dislodgement of a peripheral venous line occur on this study day	IVDisc #
Did inadvertent or unplanned dislodgement of a surgical drain occur on this study day	SurgDrDisc #
Did inadvertent or unplanned dislodgement of a urinary catheter occur on this study day	UCDisc #

DV6032G
1 = Yes
2 = No

DV6266G
1 = Yes
2 = No
94 = Not Applicable

Other daily assessments

Did the patient undergo a surgical procedure on this study day	SurgProcs #
Surgical type	SurgType #
Other surgical type	OthSurgType $150

DV6032G
1 = Yes
2 = No

DV6479G
0 = Cardiac surgery
1 = Neurosurgery
2 = Orthopedic surgery
3 = Transplant surgery
4 = Trauma surgery
5 = Other surgery

Invasive procedure - Any procedure that breaks the skin barrier or mucous membrane barrier or involves the placement of a medical device (catheter, probe, electrode, drain, prosthetic, or anything else) into a body orifice or body cavity, other than momentary suctioning of the nose, mouth, endotracheal tube, or tracheostomy tube.

Did the patient undergo any invasive procedures on this study day	InvasProc #
How many procedures	NumInvProcs #
Did the patient have a creatinine > 1.2 mg/dL on this study day	ElevCreat #
Did the patient require dialysis or continuous renal replacement therapy on this study day	DialysisYN #
Did the patient have hepatic dysfunction associated with an INR > 2.0 on this study day	ElevINR #

DV6032G
1 = Yes
2 = No

DV6266G
1 = Yes
2 = No
94 = Not Applicable

DV6032G
1 = Yes
2 = No

DV6266G
1 = Yes
2 = No
94 = Not Applicable

Continuous IV infusions of morphine

Was morphine administered by continuous IV infusion on this study day   CIVMorphYN #

Time started	Time stopped	Infusion rate (mg/kg/hour)
Refer to DCIVMORPH dataset		

DV6032G
1 = Yes
2 = No

[Add record] [Delete record]

Boluses of morphine

Were any morphine boluses administered on this study day   BMorphYN #

Time administered	Dose administered (mg)
Refer to DBMORPH dataset	

DV6032G
1 = Yes
2 = No

[Add record] [Delete record]

MOTIF Annotated PUD eCRF

Continuous IV infusions of fentanyl

Was fentanyl administered by continuous IV infusion on this study day   CIVFentYN #

DV6032G
1 = Yes
2 = No

Time started	Time stopped	Infusion rate (mcg/kg/hour)
Refer to DCIVFENT dataset		

[Add record] [Delete record]

Boluses of fentanyl

Were any fentanyl boluses administered on this study day   BFentYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mcg)
Refer to DBFENT dataset	

[Add record] [Delete record]

DAILYDATA (5 of 7)

Continuous IV infusions of midazolam

Was midazolam administered by continuous IV infusion on this study day | CIVMidazYN #

DV6032G
1 = Yes
2 = No

Time started	Time stopped	Infusion rate (mg/kg/hour)
Refer to DCIVMIDAZ dataset		

Add record   Delete record

Boluses of midazolam

Were any midazolam boluses administered on this study day | BMidazYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mg)
Refer to DBMIDAZ dataset	

Add record   Delete record

DAILYDATA (6 of 7)

Boluses of lorazepam

Were any lorazepam boluses administered on this study day | BLorazYN #

DV6032G
1 = Yes
2 = No

Time administered	Dose administered (mg)

Refer to DBLORAZ dataset

Add record   Delete record

MOTIF Annotated PUD eCRF

Othe Sedative Drugs

Were any other sedatives administered on this study day | SedatYN #

DV6032G
1 = Yes
2 = No

Select all sedative drugs administered

Other, specify

Refer to DSEDATIVES dataset

Add record   Delete record

Othe Analgesic Drugs

Were any other analgesics administered on this study day | AnalgYN #

DV6032G
1 = Yes
2 = No

Select all analgesic drugs administered

Other, specify

Refer to DANALGESICS dataset

Add record   Delete record

DCIVMORPH (1 of 1)

Continuous IV Infusions of Morphine
Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Time started	Time stopped	Infusion rate (mg/kg/hour)
MStartTime $5	MStopTime $5	Mrate #

Add record   Delete record

DBMORPH (1 of 1)

Boluses of Morphine
Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Time administered	Dose administered (mg)
MBolusTime $5	MBolusDose #

Add record   Delete record

DCIVFENT (1 of 1)

Continuous IV Infusions of Fentanyl
Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Repeat_instance #

Time started	Time stopped	Infusion rate (mcg/kg/hour)
FStartTime $5	FStopTime $5	Frate #

Add record   Delete record

Boluses of Fentanyl

Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Time administered	Dose administered (mcg)
FBolusTime $5	FBolusDose #

Add record   Delete record

DCIVMIDAZ (1 of 1)

Continuous IV Infusions of Midazolam
Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Time started	Time stopped	Infusion rate (mg/kg/hour)
MidStartTime $5	MidStopTime $5	Midrate #

Add record   Delete record

DBMIDAZ (1 of 1)

Boluses of Midazolam

Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Repeat_instance #

Time administered	Dose administered (mg)
MidBolusTime $5	MidBolusDose #

Add record   Delete record

Boluses of Lorazepam

Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #   StudyDay #   Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Time administered	Dose administered (mg)
LorBolusTime $5	LorBolusDose #

Add record   Delete record

DSEDATIVES (1 of 1)

Other Sedative Drugs
Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #   StudyDay #   Repeat_instance #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Select all sedative drugs administered   **Other, specify**

Sed_Name #   Sed_Other $50

Add record   Delete record

DV7055G
1 = Ketamine
2 = Propofol
3 = Chloral hydrate
4 = Chlorpheniramine
5 = Clonazepam
6 = Diazepam
7 = Droperidol
8 = Etomidate
9 = Haloperidol
10 = Hydroxyzine
11 = Methohexital
12 = Pentobarbital
13 = Phenobarbital
14 = Promethazine
15 = Thiopental
98 = Other, specify

DANALGESICS (1 of 1)

Other Analgesic Drugs

Unique ID = SubjectID, StudyDay, Repeat_instance

SubjectID #

StudyDay #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Repeat_instance #

Select all analgesic drugs administered

Other, specify

Angecs_Name #

Angecs_Other $50

Add record   Delete record

DV7056G
1 = Dexmedetomidine
2 = Acetaminophen
3 = Ibuprofen
4 = Acetylsalicylic acid
5 = Alfentanil
6 = Buprenorphine
7 = Butorphanol
8 = Clonidine
9 = Codeine
10 = Dextromethorphan
11 = Hydromorphone
12 = Ketorolac
13 = Meperidine
14 = Methadone
15 = Nalbuphine
16 = Oxymorphone
17 = Remifentanil
18 = Tramadol
98 = Other, specify

Study Exit
Unique ID = SubjectID

SubjectID #

DV7057G
1 = Day 1
2 = Day 2
3 = Day 3
4 = Day 4
5 = Day 5
6 = Day 6
7 = Day 7
8 = Day 8
9 = Day 9
10 = Day 10
11 = Day 11
12 = Day 12
13 = Day 13
14 = Day 14

Study Exit

Study Day	StudyDay #
Reason for exiting study	ExitReason #
Date of exit from study	ExitDay #
Time of exit from study	ExitTime $5
Was the patient on lorazepam at the time of PICU discharge	DCcLoraz #
Was the patient on methadone at the time of PICU discharge	DCcMetho #
Was the patient on buprenorphine at the time of PICU discharge	DCcBurren #
Was the patient on clonidine (for prevention or treatment of opioid withdrawal) at the time of PICU discharge	DCcClond #

DV6032G
1 = Yes
2 = No

DV7059G
1 = Reached end of study - Day 14
2 = Opioid therapy was discontinued
3 = Patient died
4 = Patient discharged from PICU
5 = Patient was started on ECMO
6 = Patient was started on PCA