Data Set Name: analysis.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	GROUP	Num	8		Sedation protocol group
4	AGEYRS	Num	8		Age at PICU admission, y
5	AGEYRSLOG1	Num	8		Age at PICU admission (log-transformed)
6	AGECAT	Num	8		Age at PICU admission category
7	FEMALE	Num	8		Female
8	WHITE	Num	8		Non-Hispanic white
9	BASEPCPCNORM	Num	8		Baseline PCPC score = 1
10	BASEPOPCNORM	Num	8		Baseline POPC score = 1
11	VERBAL	Num	8		Able to verbally communicate pain at baseline
12	PRISMSCORE	Num	8		PRISM III-12 score
13	PRISMSCORELOG1	Num	8		PRISM III-12 score (log-transformed)
14	RISKMORT	Num	8		Risk of mortality based on PRISM III-12 score, %
15	RISKMORTLOG1	Num	8		Risk of mortality based on PRISM III-12 score (log-transformed)
16	PRIMARYCAT	Num	8		Primary diagnosis category
17	PARDSDAY1	Num	8		PARDS based on day 1 OI or OSI
18	NMBDAY02	Num	8		Neuromuscular blockade for entire duration of days 0-2
19	PREMATURE	Num	8		Medical history: Prematurity
20	ASTHMA	Num	8		Medical history: Asthma
21	SEIZURES	Num	8		Medical history: Seizure disorder
22	ASPIRATION	Num	8		Medical history: Neurologic/neuromuscular disorder placing patient at risk of aspiration
23	CANCEREVER	Num	8		Medical history: Cancer (Current or previous diagnosis)
24	CHROMABN	Num	8		Medical history: Known chromosomal abnormality
25	CHRONTRACH	Num	8		Admitted with tracheostomy
26	TRANSFER	Num	8		Intubated at other hospital and transferred to participating PICU
27	DURMV28	Num	8		Duration of mechanical ventilation through day 28, d
28	CENS	Num	8		Not successfully extubated by day 28
29	CENSCAT	Num	8		Not successfully extubated by day 28 category
30	DURRECOVER	Num	8		Time to recovery from acute respiratory failure, d
31	RECCENS	Num	8		Censor variable for time to recovery from acute respiratory failure
32	DURWEANMV	Num	8		Duration of weaning from mechanical ventilation, d
33	WEANCENS	Num	8		Censor variable for duration of weaning from mechanical ventilation
34	DURASSTBR28	Num	8		Duration of assisted breathing through day 28, d
35	ASSTBRCENS	Num	8		Censor variable for duration of assisted breathing
36	NEUROTEST	Num	8		Neurological testing

Num	Variable	Type	Len	Format	Label
37	PICULOS	Num	8		PICU length of stay, d
38	PICUCENS	Num	8		Censor variable for PICU length of stay
39	HOSPLOS	Num	8		Hospital length of stay, d
40	HOSPCENS	Num	8		Censor variable of hospital length of stay
41	DEATH28	Num	8		In-hospital mortality at day 28
42	DEATH90	Num	8		In-hospital mortality at day 90
43	IPM	Num	8		Inadequate pain management
44	ISM	Num	8		Inadequate sedation management
45	CSIW	Num	8		Clinically significant iatrogenic withdrawal
46	EXTUBFAIL	Num	8		Extubation failure
47	STRIDOR	Num	8		Postextubation stridor
48	NUMUNPLEXTUB	Num	8		No. unplanned endotracheal tube extubation
49	VENTDAYS	Num	8		No. ventilator days
50	LNVENTDAYS	Num	8		Natural log of no. ventilator days
51	NUMUNPLTUBE	Num	8		No. unplanned removal of any invasive tube
52	DEVICEDAYS	Num	8		No. device days
53	LNDEVICEDAYS	Num	8		Natural log of no. device days
54	NUMVAP	Num	8		No. ventilator-associated pneumonia
55	NUMCABSI	Num	8		No. catheter-associated bloodstream infection
56	CVLINEDAYS	Num	8		No. central line days
57	LNCVLINEDAYS	Num	8		Natural log of no. central line days
58	ULCER	Num	8		Immobility-related stage >=2 pressure ulcers
59	NEWTRACH	Num	8		New tracheostomy
60	PRIMNARC	Num	8		Primary opioid agent
61	MOREQWTMEAN	Num	8		Mean daily opioid dose, mg/kg
62	MOREQWTMEANLOG1	Num	8		Mean daily opioid dose (log-transformed)
63	MOREQWTMAX	Num	8		Peak daily opioid dose, mg/kg
64	MOREQWTMAXLOG1	Num	8		Peak daily opioid dose (log-transformed)
65	MOREQWTTOT	Num	8		Cumulative opioid dose, mg/kg
66	MOREQWTTOTLOG1	Num	8		Cumulative opioid dose (log-transformed)
67	NARCEXP	Num	8		No. opioid exposure days
68	NARCCENS	Num	8		Censor variable for no. opioid exposure days
69	PRIMBENZ	Num	8		Primary benzodiazepine agent
70	MIDEQWTMEAN	Num	8		Mean daily benzodiazepine dose, mg/kg
71	MIDEQWTMEANLOG1	Num	8		Mean daily benzodiazepine dose (log-transformed)
72	MIDEQWTMAX	Num	8		Peak daily benzodiazepine dose, mg/kg
73	MIDEQWTMAXLOG1	Num	8		Peak daily benzodiazepine dose (log-transformed)
74	MIDEQWTTOT	Num	8		Cumulative benzodiazepine dose, mg/kg
75	MIDEQWTTOTLOG1	Num	8		Cumulative benzodiazepine dose (log-transformed)

Num	Variable	Type	Len	Format	Label
76	DEX	Num	8		Dexmedetomidine
77	PROP	Num	8		Propofol
78	BARB	Num	8		Barbiturates
79	KET	Num	8		Ketamine
80	CLON	Num	8		Clonidine
81	METH	Num	8		Methadone
82	CH	Num	8		Chloral hydrate
83	NUMSEDCLASS	Num	8		No. different sedative classes received
84	NUMSEDCLASSLOG1	Num	8		No. different sedative classes received (log-transformed)
85	SLEEPMED	Num	8		Hypnotic medications
86	DELMED	Num	8		Antidelirium medications
87	NMBAGIT	Num	8		Neuromuscular blockade to manage agitation
88	PCTDAYSAWAKE	Num	8		Study days awake and calm, %
89	TIMETOAWAKE	Num	8		Days to first awake/calm state
90	AWAKECENS	Num	8		Censor variable for days to first awake/calm state
91	PCTDAYSNOPAIN	Num	8		Study days with modal pain score <4, %
92	PCTDAYSPAINEP	Num	8		Study days with an episode of pain, %
93	PCTDAYSAGITEP	Num	8		Study days with an episode of agitation, %
94	IWS	Num	8		Iatrogenic withdrawal syndrome
95	PEAKWAT	Num	8		Peak WAT-1 score
96	PEAKWATLOG1	Num	8		Peak WAT-1 score (log-transformed)
97	PCTDAYSWATGE3	Num	8		Study days with WAT-1 score >=3, %
98	AGEYRS_OLD	Num	8		Age at PICU admission, y (old)
99	AGEYRSLOG1_OLD	Num	8		Age at PICU admission (log-transformed) (old)
100	AGECAT_OLD	Num	8		Age at PICU admission category (old)
101	VERBAL_OLD	Num	8		Able to verbally communicate pain at baseline (old)
102	PRISMSCORE_OLD	Num	8		PRISM III-12 score (old)
103	PRISMSCORELOG1_OLD	Num	8		PRISM III-12 score (log-transformed) (old)
104	RISKMORT_OLD	Num	8		Risk of mortality based on PRISM III-12 score, % (old)
105	RISKMORTLOG1_OLD	Num	8		Risk of mortality based on PRISM III-12 score (log-transformed) (old)
106	PARDSDAY1_OLD	Num	8		PARDS based on day 1 OI or OSI (old)
107	DURMV28_OLD	Num	8		Duration of mechanical ventilation through day 28, d (old)
108	CENS_OLD	Num	8		Not successfully extubated by day 28 (old)
109	CENSCAT_OLD	Num	8		Not successfully extubated by day 28 category (old)
110	DURRECOVER_OLD	Num	8		Time to recovery from acute respiratory failure, d (old)
111	DURWEANMV_OLD	Num	8		Duration of weaning from mechanical ventilation, d (old)
112	WEANCENS_OLD	Num	8		Censor variable for duration of weaning from mechanical ventilation (old)
113	DURASSTBR28_OLD	Num	8		Duration of assisted breathing through day 28, d (old)
114	ASSTBRCENS_OLD	Num	8		Censor variable for duration of assisted breathing (old)

Num	Variable	Type	Len	Format	Label
115	NUMUNPLEXTUB_OLD	Num	8		No. unplanned endotracheal tube extubation (old)
116	VENTDAYS_OLD	Num	8		No. ventilator days (old)
117	LNVENTDAYS_OLD	Num	8		Natural log of no. ventilator days (old)
118	NUMUNPLTUBE_OLD	Num	8		No. unplanned removal of any invasive tube (old)
119	DEVICEDAYS_OLD	Num	8		No. device days (old)
120	LNDEVICEDAYS_OLD	Num	8		Natural log of no. device days (old)
121	MOREQWTMEAN_OLD	Num	8		Mean daily opioid dose, mg/kg (old)
122	MOREQWTMEANLOG1_OLD	Num	8		Mean daily opioid dose (log-tranformed) (old)
123	MOREQWTMAX_OLD	Num	8		Peak daily opioid dose, mg/kg (old)
124	MOREQWTMAXLOG1_OLD	Num	8		Peak daily opioid dose (log-transformed) (old)
125	MOREQWTTOT_OLD	Num	8		Cumulative opioid dose, mg/kg (old)
126	MOREQWTTOTLOG1_OLD	Num	8		Cumulative opioid dose (log-transformed) (old)
127	MIDEQWTMEAN_OLD	Num	8		Mean daily benzodiazepine dose, mg/kg (old)
128	MIDEQWTMEANLOG1_OLD	Num	8		Mean daily benzodiazepine dose (log-tranformed) (old)
129	MIDEQWTMAX_OLD	Num	8		Peak daily benzodiazepine dose, mg/kg (old)
130	MIDEQWTMAXLOG1_OLD	Num	8		Peak daily benzodiazepine dose (log-transformed) (old)
131	MIDEQWTTOT_OLD	Num	8		Cumulative benzodiazepine dose, mg/kg (old)
132	MIDEQWTTOTLOG1_OLD	Num	8		Cumulative benzodiazepine dose (log-transformed) (old)
133	IWS_OLD	Num	8		Iatrogenic withdrawal syndrome (old)
134	PEAKWAT_OLD	Num	8		Peak WAT-1 score (old)
135	PEAKWATLOG1_OLD	Num	8		Peak WAT-1 score (log-transformed) (old)
136	PCTDAYSWATGE3_OLD	Num	8		Study days with WAT-1 score >=3, % (old)
137	ANYFU	Num	8		Any follow-up
138	DEATHFU	Num	8		Death post-discharge
139	SCHCAT	Num	8		Parent education category
140	INCOMECAT	Num	8		Median household income of zip code of residence category
141	BASEFSNORM	Num	8		Normal functional status at baseline
142	INTDONE	Num	8		Follow-up interview done
143	POSTDISLOC	Num	8		Post-discharge location
144	READMIT	Num	8		Readmitted to a hospital overnight post-discharge
145	PAIDHELP	Num	8		Received paid medical help at home
146	FUPCPC	Num	8		PCPC at follow-up
147	FUPOPC	Num	8		POPC at follow-up
148	ANYDECLINE	Num	8		Decline in PCPC and/or POPC from baseline to follow-up
149	PCPCDECLINE	Num	8		Decline in PCPC from baseline to follow-up
150	POPCDECLINE	Num	8		Decline in POPC from baseline to follow-up
151	ITQOLDONE	Num	8		ITQOL done
152	AGECATITQOL	Num	8		Age at ITQOL category
153	OVERHEALTH	Num	8		ITQOL: Overall health

Num	Variable	Type	Len	Format	Label
154	PHYSABIL	Num	8		ITQOL: Physical abilities
155	GROWTHDEV	Num	8		ITQOL: Growth and development
156	GDRISK	Num	8		At-risk based on ITQOL growth and development score
157	PAINDIS	Num	8		ITQOL: Bodily pain and discomfort
158	TEMPMOOD	Num	8		ITQOL: Temperament and moods
159	GENBEHAV	Num	8		ITQOL: General behavior
160	GLOBBEHAV	Num	8		ITQOL: Global behavior
161	GETALONG	Num	8		ITQOL: Getting along with others
162	GENHEALTH	Num	8		ITQOL: General health perceptions
163	CHANGEINHEALTH	Num	8		ITQOL: Change in health compared to 1 y ago
164	PARENTEMO	Num	8		ITQOL: Parental impact-emotional score
165	PARENTTIME	Num	8		ITQOL: Parental impact-time score
166	FAMILYCO	Num	8		ITQOL: Family cohesion
167	PEDSDONE	Num	8		Parent-report PedsQL done
168	AGECATPEDS	Num	8		Age at parent-report PedsQL category
169	AGECATPEDS_OLD	Num	8		Age at parent-report PedsQL category (old)
170	PEDSTOT	Num	8		Parent-report PedsQL: Total score
171	PEDSTOTRISK	Num	8		At-risk based on parent-report PedsQL total score
172	PEDSPHYS	Num	8		Parent-report PedsQL: Physical health summary
173	PHYSRISK	Num	8		At-risk based on parent-report PedsQL physical health summary score
174	PEDSPS	Num	8		Parent-report PedsQL: Psychosocial health summary
175	PSRISK	Num	8		At-risk based on parent-report PedsQL psychosocial health summary score
176	PEDSEMO	Num	8		Parent-report PedsQL: Emotional functioning
177	EMORISK	Num	8		At-risk based on parent-report PedsQL emotional functioning score
178	PEDSSOC	Num	8		Parent-report PedsQL: Social functioning
179	SOCRISK	Num	8		At-risk based on parent-report PedsQL social functioning score
180	PEDSSCHOOL	Num	8		Parent-report PedsQL: School functioning
181	SCHOOLRISK	Num	8		At-risk based on parent-report PedsQL school functioning score
182	PEDSSELFDONE	Num	8		Self-report PedsQL done
183	AGECATPEDSSELF	Num	8		Age at self-report PedsQL category
184	PEDSSELFTOT	Num	8		Self-report PedsQL: Total score
185	SELFTOTRISK	Num	8		At-risk based on self-report PedsQL total score
186	PEDSSELFPHYS	Num	8		Self-report PedsQL: Physical health summary
187	SELFPHYSRISK	Num	8		At-risk based on self-report PedsQL physical health summary score
188	PEDSSELFPS	Num	8		Self-report PedsQL: Psychosocial health summary
189	SELFPSRISK	Num	8		At-risk based on self-report PedsQL psychosocial health summary score
190	PEDSSELFEMO	Num	8		Self-report PedsQL: Emotional functioning
191	SELFEMORISK	Num	8		At-risk based on self-report PedsQL emotional functioning score

Num	Variable	Type	Len	Format	Label
192	PEDSSELFSOC	Num	8		Self-report PedsQL: Social functioning
193	SELFSOCRISK	Num	8		At-risk based on self-report PedsQL social functioning score
194	PEDSSELFSCHOOL	Num	8		Self-report PedsQL: School functioning
195	SELFSCHOOLRISK	Num	8		At-risk based on self-report PedsQL school functioning score
196	CPSSDONE	Num	8		CPSS done
197	AGECATCPSS	Num	8		Age at CPSS category
198	REEXP	Num	8		CPSS: Re-experiencing subscale
199	AVOID	Num	8		CPSS: Avoidance subscale
200	AROUSAL	Num	8		CPSS: Hyperarousal subscale
201	CPSSTOT	Num	8		CPSS: Total score
202	PTSD	Num	8		Screened positive for PTSD based on CPSS total score
203	CPSSSEV	Num	8		CPSS: Severity-of-impairment score

Data Set Name: fm01_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	SCRN_DAYSSINCEDAY0	Num	8		Screening date (days since study day 0)
4	AGE2WK	Num	8		>=2 weeks of age & >=42 weeks postmenstrual age
5	AGE18YR	Num	8		<18 years of age
6	MECHVENT	Num	8		Intubated and mechanically ventilated
7	ACUTELUNG	Num	8		Acute lung disease - primary reason for intubation presumed to be airways and/or parenchymal lung disease
8	EXTUB24	Num	8		Expected to be extubated in next 24 hours
9	CYANOTIC	Num	8		Cyanotic heart disease with unrepaired or palliated right to left intracardiac shunt
10	SINGLEVENT	Num	8		History of single ventricle at any stage of repair
11	HERNIA	Num	8		Congenital diaphragmatic hernia or congenital/acquired diaphragm paralysis
12	PPH	Num	8		Primary pulmonary hypertension
13	CRITAIR	Num	8		Critical airway
14	OBSTRUCT	Num	8		Anatomical obstruction of lower airway
15	VENTDEPT	Num	8		Ventilator dependent (including noninvasive) at baseline
16	NEUROMUS	Num	8		Neuromuscular respiratory failure
17	SPINAL	Num	8		Spinal cord injury above lumbar region
18	PCA	Num	8		Pain managed by patient controlled analgesia or epidural catheter
19	PREVSED	Num	8		Transferred from outside ICU where sedatives already administered for >24 hours
20	DNR	Num	8		Family/medical team not providing full support
21	RESTORE	Num	8		Enrolled previously in RESTORE
22	TRIAL	Num	8		Enrolled in any other critical care interventional clinical trial concurrently or within the last 30 days
23	ALLERGY	Num	8		Known allergy to any study medications (morphine and midazolam)
24	PREGNANT	Num	8		Pregnant
25	ELIGIBLE	Num	8		Eligible
26	CONSENT	Num	8		Parent/guardian provided consent
27	CONSENT_DAYSSINCEDAY0	Num	8		Date/time of consent (days since study day 0)

Data Set Name: *fm02_biolincc.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	FEMALE	Num	8		Female
4	RACE	Num	8		Race
5	ETHNIC	Num	8		Ethnicity
6	BASEPCPC	Num	8		Baseline PCPC
7	BASEPOPC	Num	8		Baseline POPC
8	VERBAL	Num	8		Able to verbally communicate pain at baseline
9	HOSPADM_DAYSSINCEDAY0	Num	8		Date of hospital admission (days since study day 0)
10	PICUADM_DAYSSINCEDAY0	Num	8		Date/time of PICU admission (days since study day 0)
11	WT	Num	8		Weight at PICU admission
12	HT	Num	8		Height at PICU admission
13	BMI	Num	8		Body mass index at PICU admission
14	INTUB_DAYSSINCEDAY0	Num	8		Date/time of intubation (days since study day 0)
15	TRANSFER	Num	8		Transfer patient
16	CHRONTRACH	Num	8		Chronic tracheostomy
17	ASTBRST_DAYSSINCEDAY0	Num	8		Date/time of initiation of assisted breathing (days since study day 0)
18	STUDYDAY0	Num	8		Date/time of study day 0 (days since study day 0)
19	PRIMARY	Num	8		Primary reason for intubation and mechanical ventilation
20	INTUBXRAY	Num	8		Chest x-ray on day of intubation
21	INTUBBILAT	Num	8		Acute onset bilateral infiltrates/opacities on x-ray
22	INTUBARTBLOOD	Num	8		Arterial blood gas on study day 0
23	INTUBPFPAO2	Num	8		Lowest PF ratio: PaO2
24	INTUBPFFIO2	Num	8		Lowest PF ratio: FiO2
25	INTUBPFMAP	Num	8		Mean airway pressure at lowest PF ratio
26	INTUBSFSPO2	Num	8		Lowest SF ratio: SpO2
27	INTUBSFFIO2	Num	8		Lowest SF ratio: FiO2
28	INTUBSFMAP	Num	8		Mean airway pressure at lowest SF ratio
29	INTUBLAHT	Num	8		Evidence of left atrial hypertension
30	PASTMHX_PREMATURE	Num	8		Prematurity
31	PASTMHX_ASTHMA	Num	8		Asthma
32	PASTMHX_BPD	Num	8		Bronchopulmonary dysplasia
33	PASTMHX_CF	Num	8		Cystic fibrosis
34	PASTMHX_IMMUNODEF	Num	8		Immunodeficiency
35	PASTMHX_ASPIRATION	Num	8		Neurologic/neuromuscular disorder which places patient at risk for aspiration
36	PASTMHX_SEIZURES	Num	8		Seizure disorder

Num	Variable	Type	Len	Format	Label
37	PASTMHX_BMTCHEMO	Num	8		Post bone marrow transplant or active chemotherapy
38	PASTMHX_SICKLECELL	Num	8		Sickle cell disease
39	PASTMHX_NOMHX	Num	8		No past medical history

Data Set Name: fm03_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	TEMPLO	Num	8		Lowest temp, C
4	TEMPHI	Num	8		Highest temp, C
5	HRLO	Num	8		Lowest HR, bpm
6	HRHI	Num	8		Highest HR, bpm
7	SBPLO	Num	8		Lowest SBP, mmHg
8	SBPHI	Num	8		Highest SBP, mmHg
9	PRISMPUP	Num	8		Worst pupillary response
10	PRISMEYE	Num	8		Worst GCS: Eye opening
11	PRISMVERBAL	Num	8		Worst GCS: Verbal
12	PRISMMOTOR	Num	8		Worst GCS: Motor response
13	PRISMCONSC	Num	8		Worst level of consciousness
14	PHLO	Num	8		Lowest pH
15	PHHI	Num	8		Highest pH
16	PH1	Num	8		pH one draw only
17	PHND	Num	8		pH not done
18	PCO2LO	Num	8		Lowest PCO2, mmHg
19	PCO2HI	Num	8		Highest PCO2, mmHg
20	PCO21	Num	8		PCO2 one draw only
21	PCO2ND	Num	8		PCO2 not done
22	PAO2LO	Num	8		Lowest PaO2, mmHg
23	PAO2ND	Num	8		PaO2 not done
24	KLO	Num	8		Lowest potassium, mmol/L
25	KHI	Num	8		Highest potassium, mmol/L
26	K1	Num	8		Potassium one draw only
27	KND	Num	8		Potassium not done
28	CO2LO	Num	8		Lowest total CO2, mmol/L
29	CO2HI	Num	8		Highest total CO2, mmol/L
30	CO21	Num	8		Total CO2 one draw only
31	CO2ND	Num	8		Total CO2 not done
32	GLUCLO	Num	8		Lowest glucose, mg/dL
33	GLUCHI	Num	8		Highest glucose, mg/dL
34	GLUC1	Num	8		Glucose one draw only
35	GLUCND	Num	8		Glucose not done
36	BUNHI	Num	8		Highest BUN, mg/dL

Num	Variable	Type	Len	Format	Label
37	BUNND	Num	8		BUN not done
38	CREATHI	Num	8		Highest creatinine, mg/dL
39	CREATND	Num	8		Creatinine not done
40	WBCLO	Num	8		Lowest WBC count, K/uL
41	WBCHI	Num	8		Highest WBC count, K/uL
42	WBC1	Num	8		WBC count one draw only
43	WBCND	Num	8		WBC count not done
44	PLATELO	Num	8		Lowest platelet count, K/uL
45	PLATEHI	Num	8		Highest platelet count, K/uL
46	PLATE1	Num	8		Platelet one draw only
47	PLATEND	Num	8		Platelet not done
48	PTHI	Num	8		Highest PT, sec
49	PTND	Num	8		PT not done
50	PTTHI	Num	8		Highest PTT, sec
51	PTTND	Num	8		PTT not done
52	ASTHI	Num	8		Highest AST, U/L
53	ASTND	Num	8		AST not done
54	INPATIENT	Num	8		Admitted to PICU from inpatient location
55	POSTOP	Num	8		Admitted to PICU for post-op care within 24 hrs of surgery
56	PREVADM	Num	8		Previous PICU admissions during this hospitalization
57	DIABETES	Num	8		Acute diagnosis of diabetes primary reason for PICU admission
58	CANCER	Num	8		Admitted with acute or chronic diagnosis of cancer
59	NONOP	Num	8		Admitted with acute diagnosis of non-operative cardiovascular disease
60	CPR	Num	8		Pre-ICU CPR that required cardiac massage during this hospitalization
61	CHROMABN	Num	8		Known chromosomal abnormality

Data Set Name: fm04a_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	INTUBCOMF	Num	8		Intubated/mechanically ventilated
5	NMB	Num	8		Receive neuromuscular blocking agent
6	NMBOFTEN	Num	8		How often did patient receive neuromuscular blocking agent
7	AGITHR	Num	8		No. hours assessed for agitation
8	AAPHR	Num	8		No. hours assumed agitation present (AAP)
9	PAINHR	Num	8		No. hours assessed for pain
10	APPHR	Num	8		No. hours assumed pain present (APP)
11	NMBENTIRE	Num	8		Receive neuromuscular blocking agent for entire study day
12	SBS8	Num	8		SBS score closest to 08:00
13	SBSLO	Num	8		Lowest SBS score
14	SBSHI	Num	8		Highest SBS score
15	NMBAGIT	Num	8		Neuromuscular blocking agent used to manage agitation
16	SBSMOD	Num	8		Modal SBS score
17	SBSDOC	Num	8		SBS scores documented per RESTORE
18	PAINTOOL	Num	8		Pain assessment tool used closest to 08:00
19	PAINTOOLOTH	Char	128	$128.	Other pain assessment tool
20	PAIN8	Num	8		Pain score closest to 08:00
21	PAINLO	Num	8		Lowest pain score
22	PAINHI	Num	8		Highest pain score
23	PAINMOD	Num	8		Modal pain score
24	PAINDOC	Num	8		Pain scores documented per RESTORE
25	NARC	Num	8		Receive narcotics
26	NARCCONT	Num	8		Continuous infusions of narcotics administered
27	NARCDISCON	Num	8		Continuous infusions of narcotics discontinued
28	NARCDISDUR	Num	8		How long were narcotics discontinued (min)
29	NARCINT	Num	8		Scheduled intermittent doses of narcotics administered
30	NARCINTROUTE	Num	8		How were scheduled intermittent narcotics administered
31	NARCBOL	Num	8		PRN bolus or one time doses of narcotics administered
32	NARCBOLNO	Num	8		Total no. of PRN and one time narcotic doses
33	NARCBOLROUTE	Num	8		How were PRN and one time narcotic doses administered
34	MORPHTOT	Num	8		Total morphine this study day, mg/24 hr
35	FENTTOT	Num	8		Total fentanyl this study day, mcg/24 hr
36	METHTOT	Num	8		Total methadone this study day, mg/24 hr

Num	Variable	Type	Len	Format	Label
37	NARCWEAN5	Num	8		Patient weaning from 5 or more days of narcotics
38	BENZ	Num	8		Receive benzodiazepines
39	BENZCONT	Num	8		Continuous infusions of benzodiazepines administered
40	BENZDISCON	Num	8		Continuous infusions of benzodiazepines discontinued
41	BENZDISDUR	Num	8		How long were benzodiazepines discontinued (min)
42	BENZINT	Num	8		Scheduled intermittent doses of benzodiazepines administered
43	BENZINTROUTE	Num	8		How were scheduled intermittent benzodiazepines administered
44	BENZBOL	Num	8		PRN bolus or one time doses of benzodiazepines administered
45	BENZBOLNO	Num	8		Total no. of PRN and one time benzodiazepines
46	BENZBOLROUTE	Num	8		How were PRN and one time benzodiazepines administered
47	MIDAZTOT	Num	8		Total midazolam this study day, mg/24 hr
48	LORAZTOT	Num	8		Total lorazepam this study day, mg/24 hr
49	COMFMED	Num	8		Receive other comfort medications
50	COMFMEDCODE1	Num	8		1st other comfort medication
51	COMFMEDOTH1	Char	128	$128.	1st other comfort medication: Other (not in list)
52	COMFMEDTOT1	Num	8		1st other comfort medication: Total 24-hr dose
53	COMFMEDTOT_UNIT1	Num	8		1st other comfort medication: Dose unit
54	COMFMEDCODE2	Num	8		2nd other comfort medication
55	COMFMEDOTH2	Char	128	$128.	2nd other comfort medication: Other (not in list)
56	COMFMEDTOT2	Num	8		2nd other comfort medication: Total 24-hr dose
57	COMFMEDTOT_UNIT2	Num	8		2nd other comfort medication: Dose unit
58	COMFMEDCODE3	Num	8		3rd other comfort medication
59	COMFMEDOTH3	Char	128	$128.	3rd other comfort medication: Other (not in list)
60	COMFMEDTOT3	Num	8		3rd other comfort medication: Total 24-hr dose
61	COMFMEDTOT_UNIT3	Num	8		3rd other comfort medication: Dose unit
62	COMFMEDCODE4	Num	8		4th other comfort medication
63	COMFMEDTOT4	Num	8		4th other comfort medication: Total 24-hr dose
64	COMFMEDTOT_UNIT4	Num	8		4th other comfort medication: Dose unit
65	COMFMEDCODE5	Num	8		5th other comfort medication
66	COMFMEDTOT5	Num	8		5th other comfort medication: Total 24-hr dose
67	COMFMEDTOT_UNIT5	Num	8		5th other comfort medication: Dose unit
68	COMFMEDCODE6	Num	8		6th other comfort medication
69	COMFMEDTOT6	Num	8		6th other comfort medication: Total 24-hr dose
70	COMFMEDTOT_UNIT6	Num	8		6th other comfort medication: Dose unit
71	COMFMEDCODE7	Num	8		7th other comfort medication
72	COMFMEDTOT7	Num	8		7th other comfort medication: Total 24-hr dose
73	COMFMEDTOT_UNIT7	Num	8		7th other comfort medication: Dose unit
74	SLEEPMED	Num	8		Receive sleep medication
75	SLEEPMEDCODE	Num	8		Sleep medication

Num	Variable	Type	Len	Format	Label
76	SLEEPMEDTOT	Num	8		Total 24-hour dose of sleep agent
77	SLEEPMEDTOT_UNIT	Num	8		Dose unit of sleep agent
78	DELMED	Num	8		Receive delirium medication
79	DELMEDCODE	Num	8		Delirium medication
80	DELMEDOTH	Char	128	$128.	Other (not in list) delirium medication
81	DELMEDTOT	Num	8		Total 24-hour dose of delirium agent
82	DELMEDTOT_UNIT	Num	8		Dose unit of delirium agent
83	MEDOTHER	Num	8		Receive medication for any other reason
84	MEDOTHER_ACETAM	Num	8		Acetaminophen
85	MEDOTHER_TYLCOD	Num	8		Tylenol with codeine
86	MEDOTHER_CH	Num	8		Chloral hydrate
87	MEDOTHER_CLONAZ	Num	8		Clonazepam
88	MEDOTHER_CLON	Num	8		Clonidine
89	MEDOTHER_COD	Num	8		Codeine
90	MEDOTHER_DEX	Num	8		Dexmedetomidine
91	MEDOTHER_DIAZ	Num	8		Diazepam
92	MEDOTHER_DIPHEN	Num	8		Diphenhydramine
93	MEDOTHER_DROP	Num	8		Droperidol
94	MEDOTHER_ETOM	Num	8		Etomidate
95	MEDOTHER_FLUM	Num	8		Flumazenil
96	MEDOTHER_HALO	Num	8		Haloperidol
97	MEDOTHER_HYDROMOR	Num	8		Hydromorphone
98	MEDOTHER_HYDROXYZ	Num	8		Hydroxyzine
99	MEDOTHER_IBU	Num	8		Ibuprofen
100	MEDOTHER_KET	Num	8		Ketamine
101	MEDOTHER_KETORO	Num	8		Ketorolac
102	MEDOTHER_MEL	Num	8		Melatonin
103	MEDOTHER_MEP	Num	8		Meperidine
104	MEDOTHER_NALBU	Num	8		Nalbuphine hydrochloride
105	MEDOTHER_NALOX	Num	8		Naloxone hydrochloride
106	MEDOTHER_OLANZ	Num	8		Olanzapine
107	MEDOTHER_OXYCODIR	Num	8		Oxycodone immediate release
108	MEDOTHER_OXYCODSR	Num	8		Oxycodone sustained release
109	MEDOTHER_PENTO	Num	8		Pentobarbital
110	MEDOTHER_PENTOTHAL	Num	8		Pentothal sodium
111	MEDOTHER_PHENO	Num	8		Phenobarbital
112	MEDOTHER_PROP	Num	8		Propofol
113	MEDOTHER_RISP	Num	8		Risperidone
114	MEDOTHER_SUF	Num	8		Sufentanil

Num	Variable	Type	Len	Format	Label
115	MEDOTHER_SWEETEASE	Num	8		Sweet-Ease
116	MEDOTHER_ZOL	Num	8		Zolpidem
117	MEDOTHER_INHALAN	Num	8		Any inhalation anesthetic
118	MEDOTHER_OTHER	Num	8		Other medication
119	PUP	Num	8		Pupillary response
120	GCSEYE	Num	8		GCS: Eye opening
121	GCSVERBAL	Num	8		GCS: Best verbal response
122	GCSMOTOR	Num	8		GCS: Best motor response
123	CONSC	Num	8		Worst level of consciousness
124	BRAINCT	Num	8		Brain CT
125	BRAINMRI	Num	8		Brain MRI
126	LUMBAR	Num	8		Lumbar puncture
127	ASTBR	Num	8		Assisted breathing
128	NONE	Num	8		Assisted breathing: None
129	NONEHR	Num	8		Assisted breathing: None hr
130	CPAP	Num	8		Assisted breathing: CPAP >=5 cmH2O
131	CPAPHR	Num	8		Assisted breathing: CPAP hr
132	HHFNC	Num	8		Assisted breathing: HHFNC >=5 L/min
133	HHFNCHR	Num	8		Assisted breathing: HHFNC hr
134	BIPAP	Num	8		Assisted breathing: BiPAP
135	BIPAPHR	Num	8		Assisted breathing: BiPAP hr
136	VENT	Num	8		Assisted breathing: Ventilator
137	VENTHR	Num	8		Assisted breathing: Ventilator hr
138	SPONTBR08	Num	8		Vent: Spontaneously breathing at 08:00
139	SPONWORATE	Num	8		Vent: Spontaneous without a set backup rate
140	SPONWORATEHR	Num	8		Vent: Spontaneous without a set backup rate hr
141	SPONWRATE	Num	8		Vent: Spontaneous with a set backup rate
142	SPONWRATEHR	Num	8		Vent: Spontaneous with a set backup rate hr
143	CONTROLMODE	Num	8		Vent: Controlled only
144	CONTROLMODEHR	Num	8		Vent: Controlled only hr
145	HFOV	Num	8		Vent: HFOV
146	HFOVHR	Num	8		Vent: HFOV hr
147	PAO2	Num	8		PaO2, mmHg
148	PAO2NOSPEC	Num	8		PaO2: No arterial specimen
149	PAO2ECMO	Num	8		PaO2: On ECMO
150	MAP	Num	8		Mean airway pressure, cm H2O
151	MAPNOPRES	Num	8		Mean airway pressure: No airway pressure
152	MAPECMO	Num	8		Mean airway pressure: On ECMO
153	FIO2	Num	8		FiO2

Num	Variable	Type	Len	Format	Label
154	FIO2NOTAB	Num	8		FiO2: Not on assisted breathing
155	SPO2	Num	8		SpO2, %
156	RESPXRAY	Num	8		Chest x-ray obtained
157	RESPBILAT	Num	8		Chest x-ray: First day new bilateral infiltrates identified
158	RESPLAHT	Num	8		Evidence of left atrial hypertension
159	INTUB	Num	8		Intubated or remained intubated
160	AIRLEAK	Num	8		ETT air leak
161	EXTUB	Num	8		Extubated
162	EXTUB_HRSSINCEINTUB1	Num	8		1st extubation: Time (hours since intubation)
163	EXTUBTYPE1	Num	8		1st extubation: Type
164	REINTUB1	Num	8		1st extubation: Reintubated
165	REINTUB_HRSSINCEEXTUB1	Num	8		1st extubation: Reintubation date/time (hours since extubation)
166	REINTUBCODE1	Num	8		1st extubation: Reason patient was reintubated
167	REINTUBCODEOTH1	Char	20	$20.	1st extubation: Other reason patient was reintubated
168	EXTUB_HRSSINCEINTUB2	Num	8		2nd extubation: Time (hours since intubation)
169	EXTUBTYPE2	Num	8		2nd extubation: Type
170	REINTUB2	Num	8		2nd extubation: Reintubated
171	REINTUB_HRSSINCEEXTUB2	Num	8		2nd extubation: Reintubation date/time (hours since extubation)
172	REINTUBCODE2	Num	8		2nd extubation: Reason patient was reintubated
173	EXTUB_HRSSINCEINTUB3	Num	8		3rd extubation: Time (hours since intubation)
174	EXTUBTYPE3	Num	8		3rd extubation: Type
175	REINTUB3	Num	8		3rd extubation: Reintubated
176	REINTUB_HRSSINCEEXTUB3	Num	8		3rd extubation: Reintubation date/time (hours since extubation)
177	REINTUBCODE3	Num	8		3rd extubation: Reason patient was reintubated
178	BUN	Num	8		BUN, mg/dL
179	BUNNDLABS	Num	8		BUN: Not done
180	CREAT	Num	8		Creatinine, mg/dL
181	CREATNDLABS	Num	8		Creatinine: Not done
182	ALT	Num	8		ALT, U/L
183	ALTNDLABS	Num	8		ALT: Not done
184	BILITOT	Num	8		Total bilirubin, mg/dL
185	BILITOTNDLABS	Num	8		Total bilirubin: Not done
186	BILIDIRECT	Num	8		Direct bilirubin, mg/dL
187	BILIDIRNDLABS	Num	8		Direct bilirubin: Not done
188	PT	Num	8		Prothrombin Time (PT), sec
189	PTNDLABS	Num	8		PT: Not done
190	ALB	Num	8		Albumin, g/dL
191	ALBNDLABS	Num	8		Albumin: Not done
192	TOTPROT	Num	8		Total protein, g/dL

Num	Variable	Type	Len	Format	Label
193	TOTPROTNDLABS	Num	8		Total protein: Not done
194	WBC	Num	8		White Blood Cell (WBC) count, K/uL
195	WBCNDLABS	Num	8		WBC count: Not done
196	PLATE	Num	8		Platelet count, K/uL
197	PLATENDLABS	Num	8		Platelet count: Not done
198	VASOACTIVE	Num	8		Any vasoactive medications
199	DIALYSIS	Num	8		Any dialysis technique
200	SUPPLO2	Num	8		Any supplemental oxygen
201	ICUINT	Num	8		ICU-only interventions
202	OUTICUINT	Num	8		Patient escorted outside the ICU for any intervention
203	ART	Num	8		Devices: Arterial line
204	CVL	Num	8		Devices: Central venous line
205	PVL	Num	8		Devices: Peripheral IV
206	NGTUBE	Num	8		Devices: Nasogastric drainage tube
207	BLADCATH	Num	8		Devices: Bladder catheter
208	CHESTTUBE	Num	8		Devices: Chest tube
209	WOUNDDRAIN	Num	8		Devices: Surgical wound drain
210	EVENTLOG_IPM	Num	8		AE: Inadequate pain management
211	EVENTLOG_ISM	Num	8		AE: Inadequate sedation management
212	EVENTLOG_CSIW	Num	8		AE: Clinically significant iatrogenic withdrawal
213	EVENTLOG_SELFEXTUB	Num	8		AE: Unplanned ETT extubation
214	EVENTLOG_STRIDOR	Num	8		AE: Postextubation stridor
215	EVENTLOG_EXTUBFAIL	Num	8		AE: Extubation failure
216	EVENTLOG_ART	Num	8		AE: Unplanned removal of arterial access
217	EVENTLOG_CVL	Num	8		AE: Unplanned removal of central venous access
218	EVENTLOG_PVL	Num	8		AE: Unplanned removal of peripheral venous access
219	EVENTLOG_NGTUBE	Num	8		AE: Unplanned removal of nasogastric drainage tube
220	EVENTLOG_OTHTUBE	Num	8		AE: Unplanned removal of other tube
221	EVENTLOG_VAP	Num	8		AE: Ventilator-associated pneumonia
222	EVENTLOG_CABSI	Num	8		AE: Catheter-associated bloodstream infection
223	EVENTLOG_ULCER	Num	8		AE: Stage 2+ pressure ulcers
224	EVENTLOG_TRACH	Num	8		AE: New tracheostomy
225	EVENTLOG_OTHEVENT	Num	8		AE: Other
226	EVENTLOG_NOEVENT	Num	8		AE: None
227	WAT	Num	8		WAT-1 performed
228	STUDYDIS	Num	8		Discharged from RESTORE study
229	STUDYDISREAS	Num	8		Study discharge reason

Data Set Name: fm04b_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	TRAJECTIDEN	Num	8		Trajectory of illness identified
5	TRAJECTILL	Num	8		Trajectory of illness
6	ACDRIPINC	Num	8		Acute phase: Drips increased for >=3 non-procedural boluses Q8H
7	ACDRIPINCHYPO	Num	8		Acute phase: Drips not increased due to hypotension
8	TIAA	Num	8		Titration phase: If morning SBS -3, arousal assessment
9	TIAAAWAKE	Num	8		Titration phase: If AA, achieved awake state
10	TIAAMIN	Num	8		Titration phase: If AA, total time sedatives turned off (min)
11	TIAAENDPT	Num	8		Titration phase: If AA, endpoint
12	TIMODAA	Num	8		Titration phase: If morning SBS -2, modified arousal assessment
13	TIMODAAAWAKE	Num	8		Titration phase: If modified AA, achieved awake state
14	TIMODAAMIN	Num	8		Titration phase: If modified AA, total time sedative reduced by 50% (min)
15	TIMODAAENDPT	Num	8		Titration phase: If modified AA, endpoint
16	TIDRIPINC	Num	8		Titration phase: Drips increased for >=3 non-procedural boluses Q8H
17	TIDRIPDEC	Num	8		Titration phase: Drips decreased for <=2 non-procedural boluses Q8H
18	WEANAA	Num	8		Weaning phase: If morning SBS -3, arousal assessment
19	WEANAAAWAKE	Num	8		Weaning phase: If AA, achieved awake state
20	WEANAAMIN	Num	8		Weaning phase: If AA, total time sedatives turned off (min)
21	WEANAAENDPT	Num	8		Weaning phase: If AA, endpoint
22	WEANMODAA	Num	8		Weaning phase: If morning SBS -2, modified arousal assessment
23	WEANMODAAAWAKE	Num	8		Weaning phase: If modified AA, achieved awake state
24	WEANMODAAMIN	Num	8		Weaning phase: If modified AA, total time sedative reduced by 50% (min)
25	WEANMODAAENDPT	Num	8		Weaning phase: If modified AA, endpoint
26	WEAN5DAYS	Num	8		Weaning phase: Receive >= 5 days of comfort medications
27	WEANDRIPDISCON	Num	8		Weaning phase, <5 days: Sedatives discontinued per protocol
28	WEANNARC	Num	8		Weaning phase, >=5 days: Narcotics weaned per protocol
29	WEANBENZ	Num	8		Weaning phase, >=5 days: Benzodiazepines weaned per protocol
30	WEANSAME	Num	8		Weaning phase, >=5 days: Narcotics and benzodiazepines weaned at same time
31	WEANMAXWAT1	Num	8		Weaning phase, >=5 days: Maximum WAT-1 score identified
32	MAXWAT1	Num	8		Weaning phase, >=5 days: Maximum (target) WAT-1 score
33	WEANHIGHWAT	Num	8		Weaning phase, >=5 days: Scored higher than maximum WAT-1 score
34	WEANCLONIDINE	Num	8		Weaning phase, >=5 days: Clonidine

Num	Variable	Type	Len	Format	Label
35	WEANMETHADONE	Num	8		Weaning phase, >=5 days: Methadone
36	WEANWATDOC12	Num	8		Weaning phase, >=5 days: WAT-1 documented every 12 hours
37	INTUBCOMF	Num	8		Intubated/mechanically ventilated
38	NMB	Num	8		Receive neuromuscular blocking agent
39	NMBOFTEN	Num	8		How often did patient receive neuromuscular blocking agent
40	AGITHR	Num	8		No. hours assessed for agitation
41	AAPHR	Num	8		No. hours assumed agitation present (AAP)
42	PAINHR	Num	8		No. hours assessed for pain
43	APPHR	Num	8		No. hours assumed pain present (APP)
44	NMBENTIRE	Num	8		Receive neuromuscular blocking agent for entire study day
45	SBSTA	Num	8		First prescribed target SBS score
46	SBSTADUR	Num	8		No. hours within first prescribed target
47	SBSTA2	Num	8		Second prescribed target SBS score
48	SBSTA2DUR	Num	8		No. hours within second prescribed target
49	SBS8	Num	8		SBS score closest to 08:00
50	SBSLO	Num	8		Lowest SBS score
51	SBSHI	Num	8		Highest SBS score
52	NMBAGIT	Num	8		Neuromuscular blocking agent used to manage agitation
53	SBSMOD	Num	8		Modal SBS score
54	SBSDOC	Num	8		SBS scores documented per RESTORE
55	PAINTOOL	Num	8		Pain assessment tool used closest to 08:00
56	PAINTOOLOTH	Char	128	$128.	Other pain assessment tool
57	PAIN8	Num	8		Pain score closest to 08:00
58	PAINLO	Num	8		Lowest pain score
59	PAINHI	Num	8		Highest pain score
60	PAINMOD	Num	8		Modal pain score
61	PAINDOC	Num	8		Pain scores documented per RESTORE
62	NARC	Num	8		Receive narcotics
63	NARCCONT	Num	8		Continuous infusions of narcotics administered
64	NARCINT	Num	8		Scheduled intermittent doses of narcotics administered
65	NARCINTROUTE	Num	8		How were scheduled intermittent narcotics administered
66	NARCBOL	Num	8		PRN bolus or one time doses of narcotics administered
67	NARCBOLNO	Num	8		Total no. of PRN and one time narcotic doses
68	NARCBOLROUTE	Num	8		How were PRN and one time narcotic doses administered
69	MORPHTOT	Num	8		Total morphine this study day, mg/24 hr
70	FENTTOT	Num	8		Total fentanyl this study day, mcg/24 hr
71	METHTOT	Num	8		Total methadone this study day, mg/24 hr
72	NARCWEAN5	Num	8		Patient weaning from 5 or more days of narcotics
73	BENZ	Num	8		Receive benzodiazepines

Num	Variable	Type	Len	Format	Label
74	BENZCONT	Num	8		Continuous infusions of benzodiazepines administered
75	BENZINT	Num	8		Scheduled intermittent doses of benzodiazepines administered
76	BENZINTROUTE	Num	8		How were scheduled intermittent benzodiazepines administered
77	BENZBOL	Num	8		PRN bolus or one time doses of benzodiazepines administered
78	BENZBOLNO	Num	8		Total no. of PRN and one time benzodiazepines
79	BENZBOLROUTE	Num	8		How were PRN and one time benzodiazepines administered
80	MIDAZTOT	Num	8		Total midazolam this study day, mg/24 hr
81	LORAZTOT	Num	8		Total lorazepam this study day, mg/24 hr
82	COMFMED	Num	8		Receive other comfort medications
83	COMFMEDCODE1	Num	8		1st other comfort medication
84	COMFMEDOTH1	Char	128	$128.	1st other comfort medication: Other (not in list)
85	COMFMEDTOT1	Num	8		1st other comfort medication: Total 24-hr dose
86	COMFMEDTOT_UNIT1	Num	8		1st other comfort medication: Dose unit
87	COMFMEDCODE2	Num	8		2nd other comfort medication
88	COMFMEDOTH2	Char	128	$128.	2nd other comfort medication: Other (not in list)
89	COMFMEDTOT2	Num	8		2nd other comfort medication: Total 24-hr dose
90	COMFMEDTOT_UNIT2	Num	8		2nd other comfort medication: Dose unit
91	COMFMEDCODE3	Num	8		3rd other comfort medication
92	COMFMEDOTH3	Char	128	$128.	3rd other comfort medication: Other (not in list)
93	COMFMEDTOT3	Num	8		3rd other comfort medication: Total 24-hr dose
94	COMFMEDTOT_UNIT3	Num	8		3rd other comfort medication: Dose unit
95	COMFMEDCODE4	Num	8		4th other comfort medication
96	COMFMEDOTH4	Char	128	$128.	4th other comfort medication: Other (not in list)
97	COMFMEDTOT4	Num	8		4th other comfort medication: Total 24-hr dose
98	COMFMEDTOT_UNIT4	Num	8		4th other comfort medication: Dose unit
99	COMFMEDCODE5	Num	8		5th other comfort medication
100	COMFMEDOTH5	Char	128	$128.	5th other comfort medication: Other (not in list)
101	COMFMEDTOT5	Num	8		5th other comfort medication: Total 24-hr dose
102	COMFMEDTOT_UNIT5	Num	8		5th other comfort medication: Dose unit
103	COMFMEDCODE6	Num	8		6th other comfort medication
104	COMFMEDOTH6	Char	128	$128.	6th other comfort medication: Other (not in list)
105	COMFMEDTOT6	Num	8		6th other comfort medication: Total 24-hr dose
106	COMFMEDTOT_UNIT6	Num	8		6th other comfort medication: Dose unit
107	COMFMEDCODE7	Num	8		7th other comfort medication
108	COMFMEDTOT7	Num	8		7th other comfort medication: Total 24-hr dose
109	COMFMEDTOT_UNIT7	Num	8		7th other comfort medication: Dose unit
110	SLEEPMED	Num	8		Receive sleep medication
111	SLEEPMEDCODE	Num	8		Sleep medication
112	SLEEPMEDOTH	Char	128	$128.	Other (not in list) sleep medication

Num	Variable	Type	Len	Format	Label
113	SLEEPMEDTOT	Num	8		Total 24-hour dose of sleep agent
114	SLEEPMEDTOT_UNIT	Num	8		Dose unit of sleep agent
115	DELMED	Num	8		Receive delirium medication
116	DELMEDCODE	Num	8		Delirium medication
117	DELMEDOTH	Char	128	$128.	Other (not in list) delirium medication
118	DELMEDTOT	Num	8		Total 24-hour dose of delirium agent
119	DELMEDTOT_UNIT	Num	8		Dose unit of delirium agent
120	MEDOTHER	Num	8		Receive medication for any other reason
121	MEDOTHER_ACETAM	Num	8		Acetaminophen
122	MEDOTHER_TYLCOD	Num	8		Tylenol with codeine
123	MEDOTHER_CH	Num	8		Chloral hydrate
124	MEDOTHER_CLONAZ	Num	8		Clonazepam
125	MEDOTHER_CLON	Num	8		Clonidine
126	MEDOTHER_COD	Num	8		Codeine
127	MEDOTHER_DEX	Num	8		Dexmedetomidine
128	MEDOTHER_DIAZ	Num	8		Diazepam
129	MEDOTHER_DIPHEN	Num	8		Diphenhydramine
130	MEDOTHER_DROP	Num	8		Droperidol
131	MEDOTHER_ETOM	Num	8		Etomidate
132	MEDOTHER_FLUM	Num	8		Flumazenil
133	MEDOTHER_HALO	Num	8		Haloperidol
134	MEDOTHER_HYDROMOR	Num	8		Hydromorphone
135	MEDOTHER_HYDROXYZ	Num	8		Hydroxyzine
136	MEDOTHER_IBU	Num	8		Ibuprofen
137	MEDOTHER_KET	Num	8		Ketamine
138	MEDOTHER_KETORO	Num	8		Ketorolac
139	MEDOTHER_MEL	Num	8		Melatonin
140	MEDOTHER_MEP	Num	8		Meperidine
141	MEDOTHER_NALBU	Num	8		Nalbuphine hydrochloride
142	MEDOTHER_NALOX	Num	8		Naloxone hydrochloride
143	MEDOTHER_OLANZ	Num	8		Olanzapine
144	MEDOTHER_OXYCODIR	Num	8		Oxycodone immediate release
145	MEDOTHER_OXYCODSR	Num	8		Oxycodone sustained release
146	MEDOTHER_PENTO	Num	8		Pentobarbital
147	MEDOTHER_PENTOTHAL	Num	8		Pentothal sodium
148	MEDOTHER_PHENO	Num	8		Phenobarbital
149	MEDOTHER_PROP	Num	8		Propofol
150	MEDOTHER_RISP	Num	8		Risperidone
151	MEDOTHER_SUF	Num	8		Sufentanil

Num	Variable	Type	Len	Format	Label
152	MEDOTHER_SWEETEASE	Num	8		Sweet-Ease
153	MEDOTHER_ZOL	Num	8		Zolpidem
154	MEDOTHER_INHALAN	Num	8		Any inhalation anesthetic
155	MEDOTHER_OTHER	Num	8		Other medication
156	PUP	Num	8		Pupillary response
157	GCSEYE	Num	8		GCS: Eye opening
158	GCSVERBAL	Num	8		GCS: Best verbal response
159	GCSMOTOR	Num	8		GCS: Best motor response
160	CONSC	Num	8		Worst level of consciousness
161	BRAINCT	Num	8		Brain CT
162	BRAINMRI	Num	8		Brain MRI
163	LUMBAR	Num	8		Lumbar puncture
164	ASTBR	Num	8		Assisted breathing
165	NONE	Num	8		Assisted breathing: None
166	NONEHR	Num	8		Assisted breathing: None hr
167	CPAP	Num	8		Assisted breathing: CPAP >=5 cmH2O
168	CPAPHR	Num	8		Assisted breathing: CPAP hr
169	HHFNC	Num	8		Assisted breathing: HHFNC >=5 L/min
170	HHFNCHR	Num	8		Assisted breathing: HHFNC hr
171	BIPAP	Num	8		Assisted breathing: BiPAP
172	BIPAPHR	Num	8		Assisted breathing: BiPAP hr
173	VENT	Num	8		Assisted breathing: Ventilator
174	VENTHR	Num	8		Assisted breathing: Ventilator hr
175	SPONTBR08	Num	8		Vent: Spontaneously breathing at 08:00
176	SPONWORATE	Num	8		Vent: Spontaneous without a set backup rate
177	SPONWORATEHR	Num	8		Vent: Spontaneous without a set backup rate hr
178	SPONWRATE	Num	8		Vent: Spontaneous with a set backup rate
179	SPONWRATEHR	Num	8		Vent: Spontaneous with a set backup rate hr
180	CONTROLMODE	Num	8		Vent: Controlled only
181	CONTROLMODEHR	Num	8		Vent: Controlled only hr
182	HFOV	Num	8		Vent: HFOV
183	HFOVHR	Num	8		Vent: HFOV hr
184	PAO2	Num	8		PaO2, mmHg
185	PAO2NOSPEC	Num	8		PaO2: No arterial specimen
186	PAO2ECMO	Num	8		PaO2: On ECMO
187	MAP	Num	8		Mean airway pressure, cm H2O
188	MAPNOPRES	Num	8		Mean airway pressure: No airway pressure
189	MAPECMO	Num	8		Mean airway pressure: On ECMO
190	FIO2	Num	8		FiO2

Num	Variable	Type	Len	Format	Label
191	FIO2NOTAB	Num	8		FiO2: Not on assisted breathing
192	SPO2	Num	8		SpO2, %
193	RESPXRAY	Num	8		Chest x-ray obtained
194	RESPBILAT	Num	8		Chest x-ray: First day new bilateral infiltrates identified
195	RESPLAHT	Num	8		Evidence of left atrial hypertension
196	INTUB	Num	8		Intubated or remained intubated
197	AIRLEAK	Num	8		ETT air leak
198	ERTDONE	Num	8		Extubation readiness test (ERT) done
199	ERTNO	Num	8		No. ERTs performed
200	EXTUB	Num	8		Extubated
201	EXTUB_HRSSINCEINTUB1	Num	8		1st extubation: Time (hours since intubation)
202	EXTUBTYPE1	Num	8		1st extubation: Type
203	UNPLEXTUBAA1	Num	8		1st extubation: If unplanned extubation, occur during arousal assessment
204	REINTUB1	Num	8		1st extubation: Reintubated
205	REINTUB_HRSSINCEEXTUB1	Num	8		1st extubation: Reintubation date/time (hours since extubation)
206	REINTUBCODE1	Num	8		1st extubation: Reason patient was reintubated
207	REINTUBCODEOTH1	Char	20	$20.	1st extubation: Other reason patient was reintubated
208	EXTUB_HRSSINCEINTUB2	Num	8		2nd extubation: Time (hours since intubation)
209	EXTUBTYPE2	Num	8		2nd extubation: Type
210	UNPLEXTUBAA2	Num	8		2nd extubation: If unplanned extubation, occur during arousal assessment
211	REINTUB2	Num	8		2nd extubation: Reintubated
212	REINTUB_HRSSINCEEXTUB2	Num	8		2nd extubation: Reintubation date/time (hours since extubation)
213	REINTUBCODE2	Num	8		2nd extubation: Reason patient was reintubated
214	BUN	Num	8		BUN, mg/dL
215	BUNNDLABS	Num	8		BUN: Not done
216	CREAT	Num	8		Creatinine, mg/dL
217	CREATNDLABS	Num	8		Creatinine: Not done
218	ALT	Num	8		ALT, U/L
219	ALTNDLABS	Num	8		ALT: Not done
220	BILITOT	Num	8		Total bilirubin, mg/dL
221	BILITOTNDLABS	Num	8		Total bilirubin: Not done
222	BILIDIRECT	Num	8		Direct bilirubin, mg/dL
223	BILIDIRNDLABS	Num	8		Direct bilirubin: Not done
224	PT	Num	8		Prothrombin Time (PT), sec
225	PTNDLABS	Num	8		PT: Not done
226	ALB	Num	8		Albumin, g/dL
227	ALBNDLABS	Num	8		Albumin: Not done
228	TOTPROT	Num	8		Total protein, g/dL
229	TOTPROTNDLABS	Num	8		Total protein: Not done

Num	Variable	Type	Len	Format	Label
230	WBC	Num	8		White Blood Cell (WBC) count, K/uL
231	WBCNDLABS	Num	8		WBC count: Not done
232	PLATE	Num	8		Platelet count, K/uL
233	PLATENDLABS	Num	8		Platelet count: Not done
234	VASOACTIVE	Num	8		Any vasoactive medications
235	DIALYSIS	Num	8		Any dialysis technique
236	SUPPLO2	Num	8		Any supplemental oxygen
237	ICUINT	Num	8		ICU-only interventions
238	OUTICUINT	Num	8		Patient escorted outside the ICU for any intervention
239	ART	Num	8		Devices: Arterial line
240	CVL	Num	8		Devices: Central venous line
241	PVL	Num	8		Devices: Peripheral IV
242	NGTUBE	Num	8		Devices: Nasogastric drainage tube
243	BLADCATH	Num	8		Devices: Bladder catheter
244	CHESTTUBE	Num	8		Devices: Chest tube
245	WOUNDDRAIN	Num	8		Devices: Surgical wound drain
246	EVENTLOG_IPM	Num	8		AE: Inadequate pain management
247	EVENTLOG_ISM	Num	8		AE: Inadequate sedation management
248	EVENTLOG_CSIW	Num	8		AE: Clinically significant iatrogenic withdrawal
249	EVENTLOG_SELFEXTUB	Num	8		AE: Unplanned ETT extubation
250	EVENTLOG_STRIDOR	Num	8		AE: Postextubation stridor
251	EVENTLOG_EXTUBFAIL	Num	8		AE: Extubation failure
252	EVENTLOG_ART	Num	8		AE: Unplanned removal of arterial access
253	EVENTLOG_CVL	Num	8		AE: Unplanned removal of central venous access
254	EVENTLOG_PVL	Num	8		AE: Unplanned removal of peripheral venous access
255	EVENTLOG_NGTUBE	Num	8		AE: Unplanned removal of nasogastric drainage tube
256	EVENTLOG_OTHTUBE	Num	8		AE: Unplanned removal of other tube
257	EVENTLOG_VAP	Num	8		AE: Ventilator-associated pneumonia
258	EVENTLOG_CABSI	Num	8		AE: Catheter-associated bloodstream infection
259	EVENTLOG_ULCER	Num	8		AE: Stage 2+ pressure ulcers
260	EVENTLOG_TRACH	Num	8		AE: New tracheostomy
261	EVENTLOG_OTHEVENT	Num	8		AE: Other
262	EVENTLOG_NOEVENT	Num	8		AE: None
263	WAT	Num	8		WAT-1 performed
264	STUDYDIS	Num	8		Discharged from RESTORE study
265	STUDYDISREAS	Num	8		Study discharge reason

Data Set Name: *fm05a_biolincc.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	PAINTOOL	Num	8		Pain assessment tool used closest to 08:00
5	PAINTOOLOTH	Char	128	$128.	Other pain assessment tool
6	PAIN8	Num	8		Pain score closest to 08:00
7	NARC	Num	8		Receive narcotics
8	MORPHTOT	Num	8		Total morphine this study day, mg/24 hr
9	FENTTOT	Num	8		Total fentanyl this study day, mcg/24 hr
10	METHTOT	Num	8		Total methadone this study day, mg/24 hr
11	BENZ	Num	8		Receive benzodiazepines
12	MIDAZTOT	Num	8		Total midazolam this study day, mg/24 hr
13	LORAZTOT	Num	8		Total lorazepam this study day, mg/24 hr
14	COMFMED	Num	8		Receive other comfort medications
15	COMFMEDCODE1	Num	8		1st other comfort medication
16	COMFMEDOTH1	Char	128	$128.	1st other comfort medication: Other (not in list)
17	COMFMEDTOT1	Num	8		1st other comfort medication: Total 24-hr dose
18	COMFMEDTOT_UNIT1	Num	8		1st other comfort medication: Dose unit
19	COMFMEDCODE2	Num	8		2nd other comfort medication
20	COMFMEDOTH2	Char	128	$128.	2nd other comfort medication: Other (not in list)
21	COMFMEDTOT2	Num	8		2nd other comfort medication: Total 24-hr dose
22	COMFMEDTOT_UNIT2	Num	8		2nd other comfort medication: Dose unit
23	COMFMEDCODE3	Num	8		3rd other comfort medication
24	COMFMEDOTH3	Char	128	$128.	3rd other comfort medication: Other (not in list)
25	COMFMEDTOT3	Num	8		3rd other comfort medication: Total 24-hr dose
26	COMFMEDTOT_UNIT3	Num	8		3rd other comfort medication: Dose unit
27	COMFMEDCODE4	Num	8		4th other comfort medication
28	COMFMEDOTH4	Char	128	$128.	4th other comfort medication: Other (not in list)
29	COMFMEDTOT4	Num	8		4th other comfort medication: Total 24-hr dose
30	COMFMEDTOT_UNIT4	Num	8		4th other comfort medication: Dose unit
31	SLEEPMED	Num	8		Receive sleep medication
32	SLEEPMEDCODE	Num	8		Sleep medication
33	SLEEPMEDTOT	Num	8		Total 24-hour dose of sleep agent
34	SLEEPMEDTOT_UNIT	Num	8		Dose unit of sleep agent
35	DELMED	Num	8		Receive delirium medication
36	DELMEDCODE	Num	8		Delirium medication

Num	Variable	Type	Len	Format	Label
37	DELMEDTOT	Num	8		Total 24-hour dose of delirium agent
38	DELMEDTOT_UNIT	Num	8		Dose unit of delirium agent
39	MEDOTHER	Num	8		Receive medication for any other reason
40	MEDOTHER_ACETAM	Num	8		Acetaminophen
41	MEDOTHER_TYLCOD	Num	8		Tylenol with codeine
42	MEDOTHER_CH	Num	8		Chloral hydrate
43	MEDOTHER_CLONAZ	Num	8		Clonazepam
44	MEDOTHER_CLON	Num	8		Clonidine
45	MEDOTHER_COD	Num	8		Codeine
46	MEDOTHER_DEX	Num	8		Dexmedetomidine
47	MEDOTHER_DIAZ	Num	8		Diazepam
48	MEDOTHER_DIPHEN	Num	8		Diphenhydramine
49	MEDOTHER_DROP	Num	8		Droperidol
50	MEDOTHER_ETOM	Num	8		Etomidate
51	MEDOTHER_FLUM	Num	8		Flumazenil
52	MEDOTHER_HALO	Num	8		Haloperidol
53	MEDOTHER_HYDROMOR	Num	8		Hydromorphone
54	MEDOTHER_HYDROXYZ	Num	8		Hydroxyzine
55	MEDOTHER_IBU	Num	8		Ibuprofen
56	MEDOTHER_KET	Num	8		Ketamine
57	MEDOTHER_KETORO	Num	8		Ketorolac
58	MEDOTHER_MEL	Num	8		Melatonin
59	MEDOTHER_MEP	Num	8		Meperidine
60	MEDOTHER_NALBU	Num	8		Nalbuphine hydrochloride
61	MEDOTHER_NALOX	Num	8		Naloxone hydrochloride
62	MEDOTHER_OLANZ	Num	8		Olanzapine
63	MEDOTHER_OXYCODIR	Num	8		Oxycodone immediate release
64	MEDOTHER_OXYCODSR	Num	8		Oxycodone sustained release
65	MEDOTHER_PENTO	Num	8		Pentobarbital
66	MEDOTHER_PENTOTHAL	Num	8		Pentothal sodium
67	MEDOTHER_PHENO	Num	8		Phenobarbital
68	MEDOTHER_PROP	Num	8		Propofol
69	MEDOTHER_RISP	Num	8		Risperidone
70	MEDOTHER_SUF	Num	8		Sufentanil
71	MEDOTHER_SWEETEASE	Num	8		Sweet-Ease
72	MEDOTHER_ZOL	Num	8		Zolpidem
73	MEDOTHER_INHALAN	Num	8		Any inhalation anesthetic
74	MEDOTHER_OTHER	Num	8		Other medication
75	PUP	Num	8		Pupillary response

Num	Variable	Type	Len	Format	Label
76	CONSC	Num	8		Worst level of consciousness
77	WAT	Num	8		WAT-1 performed
78	BOUNCEBACK	Num	8		Patient transferred back to PICU
79	BOUNCEBACKREAS	Num	8		Transfer required for continued management of the same clinical problem and/or related to the use weaning of sedation
80	BOUNCEBACKREAS2	Num	8		Same problem and/or related to use/weaning of sedation
81	STUDYDIS	Num	8		Discharged from RESTORE study
82	STUDYDISREAS	Num	8		Study discharge reason

Data Set Name: fm05b_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	WEANPLAN	Num	8		Weaning plan followed
5	WEANNARC	Num	8		Narcotics weaned per protocol
6	WEANBENZ	Num	8		Benzodiazepines weaned per protocol
7	WEANSAME	Num	8		Narcotics and benzodiazepines weaned at same time
8	WEANMAXWAT1	Num	8		Maximum WAT-1 score identified
9	MAXWAT1	Num	8		Maximum (target) WAT-1 score
10	WEANHIGHWAT	Num	8		Scored higher than maximum WAT-1 score
11	WEANCLONIDINE	Num	8		Clonidine
12	WEANMETHADONE	Num	8		Methadone
13	PAINTOOL	Num	8		Pain assessment tool used closest to 08:00
14	PAINTOOLOTH	Char	128	$128.	Other pain assessment tool
15	PAIN8	Num	8		Pain score closest to 08:00
16	NARC	Num	8		Receive narcotics
17	MORPHTOT	Num	8		Total morphine this study day, mg/24 hr
18	FENTTOT	Num	8		Total fentanyl this study day, mcg/24 hr
19	METHTOT	Num	8		Total methadone this study day, mg/24 hr
20	BENZ	Num	8		Receive benzodiazepines
21	MIDAZTOT	Num	8		Total midazolam this study day, mg/24 hr
22	LORAZTOT	Num	8		Total lorazepam this study day, mg/24 hr
23	COMFMED	Num	8		Receive other comfort medications
24	COMFMEDCODE1	Num	8		1st other comfort medication
25	COMFMEDOTH1	Char	128	$128.	1st other comfort medication: Other (not in list)
26	COMFMEDTOT1	Num	8		1st other comfort medication: Total 24-hr dose
27	COMFMEDTOT_UNIT1	Num	8		1st other comfort medication: Dose unit
28	COMFMEDCODE2	Num	8		2nd other comfort medication
29	COMFMEDOTH2	Char	128	$128.	2nd other comfort medication: Other (not in list)
30	COMFMEDTOT2	Num	8		2nd other comfort medication: Total 24-hr dose
31	COMFMEDTOT_UNIT2	Num	8		2nd other comfort medication: Dose unit
32	COMFMEDCODE3	Num	8		3rd other comfort medication
33	COMFMEDOTH3	Char	128	$128.	3rd other comfort medication: Other (not in list)
34	COMFMEDTOT3	Num	8		3rd other comfort medication: Total 24-hr dose
35	COMFMEDTOT_UNIT3	Num	8		3rd other comfort medication: Dose unit
36	COMFMEDCODE4	Num	8		4th other comfort medication

Num	Variable	Type	Len	Format	Label
37	COMFMEDOTH4	Char	128	$128.	4th other comfort medication: Other (not in list)
38	COMFMEDTOT4	Num	8		4th other comfort medication: Total 24-hr dose
39	COMFMEDTOT_UNIT4	Num	8		4th other comfort medication: Dose unit
40	COMFMEDCODE5	Num	8		5th other comfort medication
41	COMFMEDOTH5	Char	128	$128.	5th other comfort medication: Other (not in list)
42	COMFMEDTOT5	Num	8		5th other comfort medication: Total 24-hr dose
43	COMFMEDTOT_UNIT5	Num	8		5th other comfort medication: Dose unit
44	COMFMEDCODE6	Num	8		6th other comfort medication
45	COMFMEDOTH6	Char	128	$128.	6th other comfort medication: Other (not in list)
46	COMFMEDTOT6	Num	8		6th other comfort medication: Total 24-hr dose
47	COMFMEDTOT_UNIT6	Num	8		6th other comfort medication: Dose unit
48	SLEEPMED	Num	8		Receive sleep medication
49	SLEEPMEDCODE	Num	8		Sleep medication
50	SLEEPMEDTOT	Num	8		Total 24-hour dose of sleep agent
51	SLEEPMEDTOT_UNIT	Num	8		Dose unit of sleep agent
52	DELMED	Num	8		Receive delirium medication
53	DELMEDCODE	Num	8		Delirium medication
54	DELMEDTOT	Num	8		Total 24-hour dose of delirium agent
55	DELMEDTOT_UNIT	Num	8		Dose unit of delirium agent
56	MEDOTHER	Num	8		Receive medication for any other reason
57	MEDOTHER_ACETAM	Num	8		Acetaminophen
58	MEDOTHER_TYLCOD	Num	8		Tylenol with codeine
59	MEDOTHER_CH	Num	8		Chloral hydrate
60	MEDOTHER_CLONAZ	Num	8		Clonazepam
61	MEDOTHER_CLON	Num	8		Clonidine
62	MEDOTHER_COD	Num	8		Codeine
63	MEDOTHER_DEX	Num	8		Dexmedetomidine
64	MEDOTHER_DIAZ	Num	8		Diazepam
65	MEDOTHER_DIPHEN	Num	8		Diphenhydramine
66	MEDOTHER_DROP	Num	8		Droperidol
67	MEDOTHER_ETOM	Num	8		Etomidate
68	MEDOTHER_FLUM	Num	8		Flumazenil
69	MEDOTHER_HALO	Num	8		Haloperidol
70	MEDOTHER_HYDROMOR	Num	8		Hydromorphone
71	MEDOTHER_HYDROXYZ	Num	8		Hydroxyzine
72	MEDOTHER_IBU	Num	8		Ibuprofen
73	MEDOTHER_KET	Num	8		Ketamine
74	MEDOTHER_KETORO	Num	8		Ketorolac
75	MEDOTHER_MEL	Num	8		Melatonin

Num	Variable	Type	Len	Format	Label
76	MEDOTHER_MEP	Num	8		Meperidine
77	MEDOTHER_NALBU	Num	8		Nalbuphine hydrochloride
78	MEDOTHER_NALOX	Num	8		Naloxone hydrochloride
79	MEDOTHER_OLANZ	Num	8		Olanzapine
80	MEDOTHER_OXYCODIR	Num	8		Oxycodone immediate release
81	MEDOTHER_OXYCODSR	Num	8		Oxycodone sustained release
82	MEDOTHER_PENTO	Num	8		Pentobarbital
83	MEDOTHER_PENTOTHAL	Num	8		Pentothal sodium
84	MEDOTHER_PHENO	Num	8		Phenobarbital
85	MEDOTHER_PROP	Num	8		Propofol
86	MEDOTHER_RISP	Num	8		Risperidone
87	MEDOTHER_SUF	Num	8		Sufentanil
88	MEDOTHER_SWEETEASE	Num	8		Sweet-Ease
89	MEDOTHER_ZOL	Num	8		Zolpidem
90	MEDOTHER_INHALAN	Num	8		Any inhalation anesthetic
91	MEDOTHER_OTHER	Num	8		Other medication
92	PUP	Num	8		Pupillary response
93	CONSC	Num	8		Worst level of consciousness
94	WAT	Num	8		WAT-1 performed
95	BOUNCEBACK	Num	8		Patient transferred back to PICU
96	BOUNCEBACKREAS	Num	8		Transfer required for continued management of the same clinical problem and/or related to the use weaning of sedation
97	BOUNCEBACKREAS2	Num	8		Same problem and/or related to use/weaning of sedation
98	STUDYDIS	Num	8		Discharged from RESTORE study
99	STUDYDISREAS	Num	8		Study discharge reason

Data Set Name: fm06b_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	ERT_HRSSINCEINTUB	Num	8		Time of ERT (hours since study day 0)
5	RETEST	Num	8		Retest after sedation wean
6	ERTSBSSTART	Num	8		SBS score at start of ERT
7	ERTSBSEND	Num	8		SBS score at end of ERT
8	ERTPASS	Num	8		Pass ERT
9	ERTFAIL_SPO2	Num	8		Failed ERT: SpO2 <95%
10	ERTFAIL_TV	Num	8		Failed ERT: Exhaled tidal volume <5 mL/kg
11	ERTFAIL_RR	Num	8		Failed ERT: Respiratory rate not in range for age
12	EXTUB6ERT	Num	8		Extubated within 6 hours of passing ERT
13	NOTEXTUBREAS_NOLEAK	Num	8		Not extubated: No ETT leak
14	NOTEXTUBREAS_OVERSED	Num	8		Not extubated: Insufficient respiratory effort due to oversedation
15	NOTEXTUBREAS_NEUROLOG	Num	8		Not extubated: Insufficient respiratory effort due to questionable neurological status
16	NOTEXTUBREAS_NEUROMUS	Num	8		Not extubated: Insufficient respiratory effort due to questionable neuromuscular status
17	NOTEXTUBREAS_PROCSED	Num	8		Not extubated: Planned procedure required deep sedation
18	NOTEXTUBREAS_PROCOR	Num	8		Not extubated: Planned surgical procedure in operating room
19	NOTEXTUBREAS_SECRET	Num	8		Not extubated: Excessive secretions
20	NOTEXTUBREAS_OTH	Num	8		Not extubated: Other reason
21	NOTEXTUBOTHREAS	Char	78		Not extubated: Other reason category

Data Set Name: fm07_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	DAY	Num	8		Study day
4	WATNO	Num	8		Number of times WAT-1 completed this day
5	WATHI	Num	8		Highest WAT-1 score this day
6	STOOL	Num	8		Any loose or watery stools
7	VOMIT	Num	8		Any vomiting, wretching, or gagging
8	WATTEMP	Num	8		Temperature often >37.8C
9	STBEHAV	Num	8		State behavior
10	TREMOR	Num	8		Tremor
11	SWEAT	Num	8		Sweating
12	MOVE	Num	8		Uncoordinated/repetitive movements
13	YAWN	Num	8		Yawning/sneezing
14	STARTLE	Num	8		Startle to touch
15	MUSCLE	Num	8		Muscle tone
16	TIMETOCALM	Num	8		Time to gain calm state (SBS <=0)

Data Set Name: *fm08_biolincc.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	WITHDRAW	Num	8		Withdrawn early from study
4	WITHDRAW_DAYSSINCEDAY0	Num	8		Date withdrawn (days since study day 0)
5	WITHDRAWREAS	Num	8		Reason withdrawn
6	WITHDRAWREASOTH	Char	128	$128.	Other reason withdrawn
7	DEVEXCLYN	Num	8		Developed exclusion criterion after enrollment
8	DEVEXCL	Num	8		Exclusion criterion developed
9	DEVEXCL_DAYSSINCEDAY0	Num	8		Date/time exclusion criterion developed (days since study day 0)
10	MEDGOALCHANGE	Num	8		Primary goal of comfort management changed
11	MEDGOALCHANGE_DAYSSINCEDAY0	Num	8		Date goal changed (days since study day 0)
12	MEDGOALCHANGEREAS	Char	36	$36.	Rationale for continued opioid or benzodiazepine use
13	EXTUB_DAYSSINCEDAY0	Num	8		Date/time of successful endotrachaeal extubation (days since study day 0)
14	NAEXTUB_TRACH	Num	8		Not extubated: Discharged with tracheostomy
15	NAEXTUB_TRANSFER	Num	8		Not extubated: Still intubated on transfer to another ICU
16	NAEXTUB_DEATH	Num	8		Not extubated: Died by Study Day 90
17	NAEXTUB_DAY90	Num	8		Not extubated: Still intubated on Study Day 90
18	ASTBREND_DAYSSINCEDAY0	Num	8		Date/time assisted breathing discontinued (days since study day 0)
19	NAASTBREND_DIS	Num	8		Assisted breathing not discontinued: Still on assisted breathing on hospital discharge
20	NAASTBREND_TRANSFER	Num	8		Assisted breathing not discontinued: Still on assisted breathing on transfer to another ICU
21	NAASTBREND_DEATH	Num	8		Assisted breathing not discontinued: Died by Study Day 90
22	NAASTBREND_DAY90	Num	8		Assisted breathing not discontinued: Still on assisted breathing on Study Day 90
23	MEDREADY_DAYSSINCEDAY0	Num	8		Date/time medically ready for off PICU service care (days since study day 0)
24	PICUDIS_DAYSSINCEDAY0	Num	8		Date/time discharged from the PICU (days since study day 0)
25	PICUDISLOC	Num	8		Location of PICU discharge
26	NARCPICUDIS	Num	8		On narcotics at PICU discharge
27	BENZPICUDIS	Num	8		On benzodiazepines at PICU discharge
28	CLONPICUDIS	Num	8		On clonidine at PICU discharge
29	HOSPDIS_DAYSSINCEDAY0	Num	8		Date discharged from hospital (days since study day 0)
30	HOSPDISLOC	Num	8		Location of hospital discharge
31	CONSENTFU	Num	8		Parent/guardian provided consent for follow-up
32	ASSENTFU	Num	8		Subject provided assent/consent for follow-up

Num	Variable	Type	Len	Format	Label
33	ASSENTFUOTH	Char	27	$27.	Other reason subject did not assent for follow-up
34	NARCHOSPDIS	Num	8		On narcotics at hospital discharge
35	BENZHOSPDIS	Num	8		On benzodiazepines at hospital discharge
36	CLONHOSPDIS	Num	8		On clonidine at hospital discharge
37	DISPCPC	Num	8		PCPC at hospital discharge
38	DISPOPC	Num	8		POPC at hospital discharge
39	DEATH	Num	8		Died
40	DEATH_DAYSSINCEDAY0	Num	8		Date of death (days since study day 0)
41	PRIMDEATH	Num	8		Primary cause of death
42	PRIMDEATHBMT	Num	8		Primary cause of death: If cancer, bone marrow transplant
43	SECDEATH	Num	8		Secondary cause of death
44	SECDEATHBMT	Num	8		Secondary cause of death: If cancer, bone marrow transplant
45	DEATHCIRC	Num	8		Death circumstance

Data Set Name: fm09_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	AEST_DAYSSINCEDAY0	Num	8		Start date/time of event (days since study day 0)
4	AESPEC	Num	8		RESTORE Specified Event
5	AE	Num	8		Specified event type
6	AEOTHTUBE	Char	128	$128.	Other invasive tube type
7	AEOTH	Char	50		Other event type
8	AEOTHEXP	Num	8		Other event: Expected
9	AESED	Num	8		Other event: Related to sedation management
10	AESEVERITY	Num	8		AE severity
11	AESEVERE	Num	8		AE severe type
12	AEREL	Num	8		AE relationship to study
13	AEUNEXPSAE	Num	8		If UP/SAE, local IRB notified
14	AECSIWWATPRE	Num	8		Clinically significant iatrogenic withdrawal: WAT-1 score before rescue therapy
15	AECSIWWATPOST	Num	8		Clinically significant iatrogenic withdrawal: WAT-1 score after rescue therapy
16	AESELFEXTUBSBS	Num	8		Unplanned ETT extubation: Last recorded SBS score
17	AESELFEXTUBMIN	Num	8		Unplanned ETT extubation: Minutes from last sedative titration/administration of bolus
18	AESELFEXTUBETT	Num	8		Unplanned ETT extubation: Oral or nasal ETT
19	AESELFEXTUBRATIO	Num	8		Unplanned ETT extubation: Nurse-patient ratio
20	AESELFEXTUBCARE	Num	8		Unplanned ETT extubation: Occurred during nursing care
21	AESELFEXTUBNURSE	Num	8		Unplanned ETT extubation: Occurred with nurse at bedside
22	AESELFEXTUBPARENT	Num	8		Unplanned ETT extubation: Occurred with parent at bedside
23	AESELFEXTUBDEL	Num	8		Unplanned ETT extubation: Subject appears to be in state of delirium
24	AESTRIDORSIZE	Num	8		Postextubation stridor: ETT size
25	AESTRIDORETT	Num	8		Postextubation stridor: Oral or nasal ETT
26	AESTRIDORCUFF	Num	8		Postextubation stridor: Cuffed ETT
27	AESTRIDORSTER	Num	8		Postextubation stridor: Steroid use pre-extubation
28	AESTRIDORBRONCH	Num	8		Postextubation stridor: Bronchosopy for airway evaluation
29	AESTRIDORPARAL	Num	8		Postextubation stridor: Diagnosis of post-extubation vocal cord paralysis
30	AESTRIDORHIST	Num	8		Postextubation stridor: History of difficult/traumatic intubation
31	AESTRIDORINF	Num	8		Postextubation stridor: Current tracheal infection
32	AEEXTUBFAILEPI	Num	8		Extubation failure: Use of racemic epinephrine to prevent reintubation

Num	Variable	Type	Len	Format	Label
33	AEARTSBSPRE	Num	8		Unplanned removal of arterial access: SBS score pre-removal
34	AEARTSBSPOST	Num	8		Unplanned removal of arterial access: SBS score post-removal
35	AECVLSBSPRE	Num	8		Unplanned removal of central venous access: SBS score pre-removal
36	AECVLSBSPOST	Num	8		Unplanned removal of central venous access: SBS score post-removal
37	AEPVLSBSPRE	Num	8		Unplanned removal of peripheral venous access: SBS score pre-removal
38	AEPVLSBSPOST	Num	8		Unplanned removal of peripheral venous access: SBS score post-removal
39	AENGTUBESBSPRE	Num	8		Unplanned removal of nasogastric drainage tube: SBS score pre-removal
40	AENGTUBESBSPOST	Num	8		Unplanned removal of nasogastric drainage tube: SBS score post-removal
41	AEOTHTUBESBSPRE	Num	8		Unplanned removal of other invasive tube: SBS score pre-removal
42	AEOTHTUBESBSPOST	Num	8		Unplanned removal of other invasive tube: SBS score post-removal
43	AEVAPREFLEX	Num	8		VAP: Strong cough/gag reflex
44	AEVAPCPR	Num	8		VAP: Subject received CPR this episode of illness
45	AEVAPXRAY	Num	8		VAP: Chest x-ray reported new or progressive and persistent infiltrate, consolidation, cavitation, pneumatoceles
46	AEVAPTEMP	Num	8		VAP: Temperature alteration (>38C or <36.5C)
47	AEVAPLEUK	Num	8		VAP: Leukopenia or leukocytosis
48	AEVAPSPUTUM	Num	8		VAP: New onset purulent sputum, change in character of sputum, increased respiratory secretions or increased suctioning req.
49	AEVAPCOUGH	Num	8		VAP: New onset or worsening cough, dyspnea, or tachypnea
50	AEVAPRALES	Num	8		VAP: Rales or bronchial breath sounds
51	AEVAPGAS	Num	8		VAP: Worsening gas exchange
52	AEVAPPOS	Num	8		VAP: Positive culture results
53	AEVAPABX	Num	8		VAP: New antibiotics initiated
54	AEVAPADJ	Num	8		VAP: Adjudicated by local infectious disease officer (RN/MD)
55	AECABSIPATH	Num	8		CA-BSI: Pathogen cultured
56	AECABSIREL	Num	8		CA-BSI: Related to infection at another site
57	AECABSISS	Num	8		CA-BSI: Signs or symptoms of infection
58	AECABSISSREL	Num	8		CA-BSI: Signs and symptoms related to infection at another site
59	AECABSICONTAM	Num	8		CA-BSI: Common skin contaminants
60	AECABSIPOS	Num	8		CA-BSI: Other positive culture results
61	AECABSIABX	Num	8		CA-BSI: New antibiotics in response to other culture

Num	Variable	Type	Len	Format	Label
62	AECABSICV	Num	8		CA-BSI: Central access device terminating at or close to heart or great vessel
63	AECABSIADJ	Num	8		CA-BSI: Adjudicated by local infectious disease officer (RN/MD)
64	AEULCERBRADENQ	Num	8		Stage 2+ pressure ulcer: Braden Q
65	AEULCERBRADENQ_DAYSSINCEDAY0	Num	8		Stage 2+ pressure ulcer: Date Braden Q (days since study day 0)
66	AEULCERLOC	Num	8		Stage 2+ pressure ulcer: Location
67	AETRACHRAT	Char	29	$29.	Tracheostomy: Rationale
68	AETRACHSEC	Num	8		Tracheostomy: Tracheostomy secondary to agitation related airway trauma

Data Set Name: fm10_biolincc.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ID	Num	8		Patient ID
2	SITE	Char	3	$3.	Site
3	PD_DAYSSINCEDAY0	Num	8		Date of protocol deviation (days since study day 0)
4	PD	Char	256		Protocol deviation