University of Utah
Central Data Management Coordinating Center

ANNOTATED eCRF FOR PUBLIC USE DATASETS

The CRISIS Prevention Trial

The Critical Illness Stress-Induced Immune Suppression Prevention Trial

CPCCRN Protocol Number 003

Primary Investigator:
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Children's Hospital of Pittsburgh

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Annotations key:

Table name

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

Format (name)
Code list

Calculated / Derived variable

Value not provided

Notes:

All dates have been recoded to reflect the number of calendar days from randomization.

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

studyForm Format:

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0	Demographics
1	Randomization
2	Baseline and Pre-dosing
2.1	Physical Examination
2.2	PRISM III
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5	Study Day 3
6	Study Day 4
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Demographics

Unique ID = subjectID

subjectID #

studyForm #

***DOB (MM/DD/YYYY)**	08 ageInYears #
***Sex**	F sex #
***Race**	Ar race # ve
Ethnicity	H HISPANIC_ETHNICITY #

SEX
1 = Female
2 = Male

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

*Combined with 7 = Other, for RACE format

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

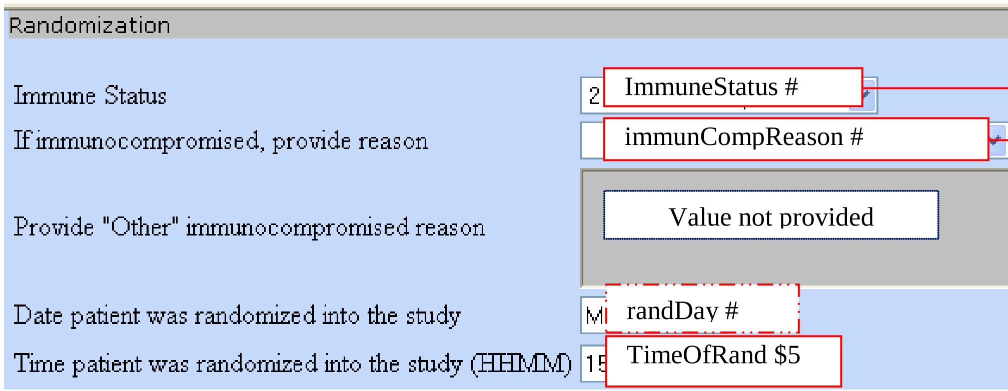
RANDOMIZATION (1 of 1)

Randomization

Unique ID = subjectID

subjectID #

studyForm #



DV6618G
1 = Immune Competent
2 = Immune Compromised

370 (ImmunCompChoices)
1 = Bone Marrow Transplant Recipient
2 = Other Organ Transplant Recipient
3 = Cancer Patient *
4 = Human Immunodeficiency Virus *
5 = Other

*Combined with 5 = Other, for IMMUNCOMPCHOICES format in PUD

Variables from analysis dataset included in the RANDOMIZATION dataset:

Variable	Format	Type	Label	Algorithm / Notes
itt	YESNO.	#	Intent-to-treat Population	=1 if randomized, =0 if not randomized
safe	YESNO.	#	Safety Population	=1 if patient received any study drug, =0 otherwise
trtRand	TRT.	#	Randomized Treatment Group	Treatment assigned by randomization
trtRec	TRT.	#	Treatment Received	Actual treatment received by patient

YESNO
0 = No
1 = Yes

TRT
1 = WHEY
2 = ZSGM

BASELINE (1 of 2)

Baseline and Pre-Dosing
Unique ID = subjectID

subjectID # | studyForm #

Admission Information

Field	Variable
Date of hospital admission	hospAdmitDay #
Time of hospital admission	HospAdmitTime $5
Date of PICU admission	PICUAdmitDay #
Time of PICU admission	PICUAdmitTime $5
Height (cm)	HeightCM #
Weight (kg)	WeightKG #
Chronic Ventilator Support	ChronicVentSupp #
Operative Status	OperativeStatus #
Postoperative type	PostOpType2 #
Other Surgery please describe	Value not provided
Endotracheal tube present at randomization?	EndoTubeAtRand #
Central venous catheter at randomization?	CVCathAtRand #
Urinary catheter at randomization?	UrinCatAtRand #

DV6032G
1 = Yes
2 = No

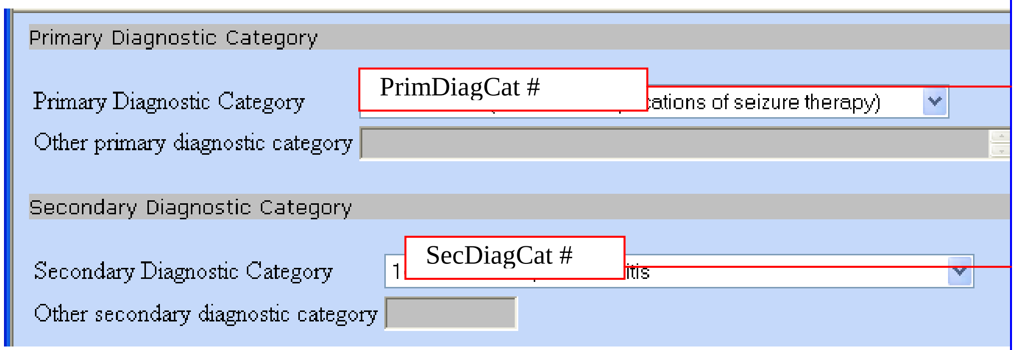
DV6478G
0 = Not postoperative
1 = Postoperative

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

*Combined with 5 = Other, for OPERATIVE_STATUS format in PUD

DV1532G
1 = Not Present
2 = Present

BASELINE (2 of 2)



DV6624G
1 = Asthma (reactive airway disease)
2 = Cancer**
3 = Cardiac arrest w/in 24 hours (closed heart compressions)
4 = Chromosomal abnormality (not hereditary)
5 = Diabetes**
6 = Drug overdose (e.g. ingestion, toxicity)*, **
7 = Gastroesophageal reflux **
8 = Cardiovascular disease – acquired**
9 = Cardiovascular disease – congenital
10 = HIV infection*
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
18 = Suicide attempt (includes intentional drug overdose)
19 = Transplant*, **
20 = Trauma**
21 = None
22 = Other

*Combined with 22 = Other, for PRIDIAGNOSTICCAT format in PUD

** Combined with 22 = Other, for SECDIAGNOSTICCAT format in PUD

Variables from analysis dataset included in the BASELINE dataset:

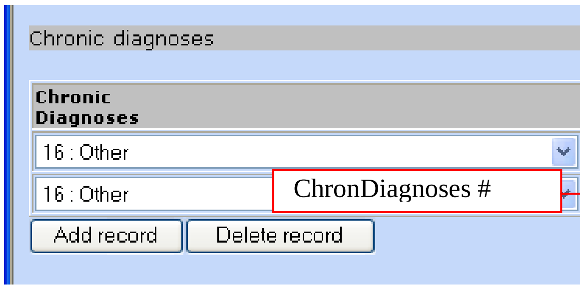
Variable	Format	Type	Label	Algorithm / Notes
PRISMIIICalcS	11.	#	Baseline PRISM III Total Score	Based on the first 12 hours of PICU admission

BASELINE_CHRONICDIAG (1 of 1)

Baseline – Chronic Diagnoses

Unique ID = subjectID, Repeat_instance

subjectID # | studyForm # | Repeat_instance #



ChronDiagnoses #

DV581G
1 = Bronchopulmonary dysplasia (BPD)*
2 = Cancer (oncologic disease)
3 = Cerebral palsy
4 = Chromosomal abnormality (not hereditary conditions)
5 = Congenital heart diseaase
6 = Diabetes*
7 = HIV infection
8 = Hydrocephalus
9 = Intraventricular hemorrhage (from perinatal period)
10 = Mental retardation
11 = Meningomyelocele/spina bifida*
12 = Short gut syndrome*
13 = Static encephalopathy
14 = Transplant
15 = None
16 = Other

*Combined with 16 = Other, for CHRONICDIAGNOSES format in PUD

PHYSICAL_EXAMINATION (1of 1)

Physical Examination

Unique ID = subjectID

subjectID #

studyForm #

Physical Examination

Date of Physical Exam PhysExamDay #

Body System	Select Normal, Abnormal or Not Assessed	Comment
HEENT	HEENTPE #	
Cardiovascular	CardioPE #	
Lungs	LungsPE #	
Abdomen/GI	AbdGIPE #	
Extremities	ExtremitiesPE #	
Neurological	NeurologicalPE #	
Skin	SkinPE #	
Lymph Nodes/Hematology	LymphHemPE #	

DV428G
1 = Normal
2 = Abnormal
3 = Not Assessed

DAILYDATA (1of 3)

Daily Data / Follow Up

Unique ID = subjectID, studyForm

subjectID #

studyForm #

Study Date

Study Date: dayFromRandomization #

Daily Infection Status

Question	Value	Variable
Does the patient exhibit any signs or symptoms of clinical infection?	1 : Yes	InfcnPresence #
Does investigator believe this is a continuing event from the previous day?	1 : Yes	InfcnCont #
Were any diagnostic test ordered?	Value not provided	

DV6032G
1 = Yes
2 = No

Daily Sepsis Status

Question	Value	Variable
Does the patient exhibit any signs or symptoms of sepsis?	1 : Yes	SepsisPresence #
Does investigator believe this is a continuing event from previous day?	1 : Yes	SepsisCont #
Were any new antibiotics ordered?	Value not provided	

DV6032G
1 = Yes
2 = No

Daily Patient Review

Question	Value	Variable
Endotracheal Tube	4 : Removed during this day	EndoTube #
Central Venous Catheter	3 : Inserted/re-inserted during this day	CVCath #
Urinary Catheter	4 : Removed during this day	UrinCath #
Ventilator Support	2 : No	VentSupport #
Additional invasive therapies or catheters present during study day	1 : Yes	AddlTherOrCath #

DV1378G
1 = Not present during this day
2 = Present during this day (continuous)
3 = Inserted/re-inserted during this day
4 = Removed during this day

DV6032G
1 = Yes
2 = No

DAILYDATA (2 of 3)

Additional therapies or catheters

Type of additional therapies or catheters present	Other (please describe)
4:O	
4:O	

Daily Data - Additional Therapies on page 15

Add record | Delete record

Daily medication questions

Steroids	SteroidsGiven #	DV6032G
Dopamine	DopamineGiven #	1 = Yes
Calcineurin Inhibitors	CalcInhibGiven #	2 = No
Intravenous gamma globulin (IVIG)	IVIGGiven #	
Granulocyte colony-stimulating factor (G-CSF)	GCSFGiven #	
Granulocyte-monocyte colony-stimulating factor (GM-CSF)	GMCSFGiven #	
Other Immunosuppressant Therapy	OthImmunTherapy #	
Non-study related Metoclopramide given	MetoclopGiven #	
Supplemental zinc	SuppZnGiven #	
Supplemental selenium	SuppSeGiven #	
Supplemental Glutamine	SuppGlutGiven #	

DAILYDATA (3 of 3)

Daily Nutritional Supplements

Total Parenteral Nutrition	TPNGiven #	DV6032G 1 = Yes 2 = No
TPN contains zinc	TPNHasZn #	
TPN contains selenium	TPNHasSe #	
TPN contains glutamine	TPNHasGlut #	
Enteral feeding	EnteralFeeding #	

DAILYDATA_ADDITIONALTHERAPIES (1 of 1)

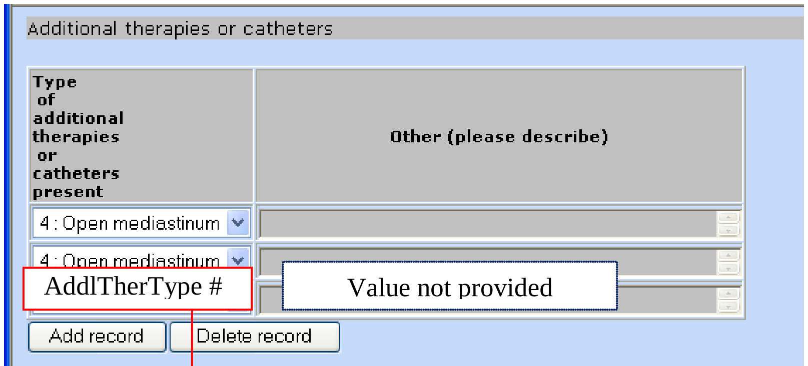
Daily Data – Additional Therapies

Unique ID = subjectID, studyForm, Repeat_instance

subjectID #

studyForm #

Repeat_instance #



AddlTherType #

Value not provided

DV661G
1 = Arterial catheter
2 = Tracheostomy
3 = Chest tube
4 = Open mediastinum
5 = ECMO
6 = Hemodialysis
7 = Peritoneal dialysis
8 = LVAD or BIVAD
9 = ICP monitor
10 = Epidural catheter
11 = None
12 = Other

PELOD (1 of 1)

Pediatric Logistic Organ Dysfunction (PELOD) Score
Unique ID = subjectID, studyForm

subjectID # studyForm #

Note: Sites were instructed to collect PELOD scores on study day 1, 7, 14, 21 and 28 of PICU admission

PELOD

Recompute

Date of Assessment PELODDay #

Total Score

PELOD Total Score PELOD #

OFI (1 of 1)

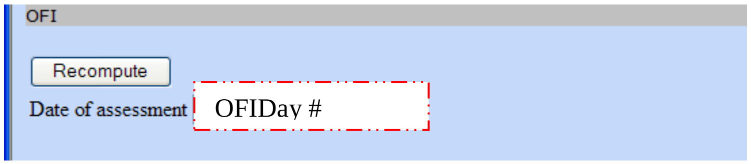
Organ Failure Index (OFI)

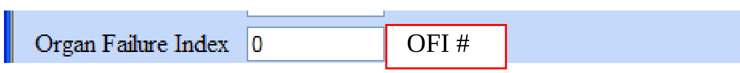
Unique ID = subjectID, studyForm

subjectID #

studyForm #

Note: Sites were instructed to collect OFI scores on study day 1, 7, 14, 21 and 28 of PICU admission

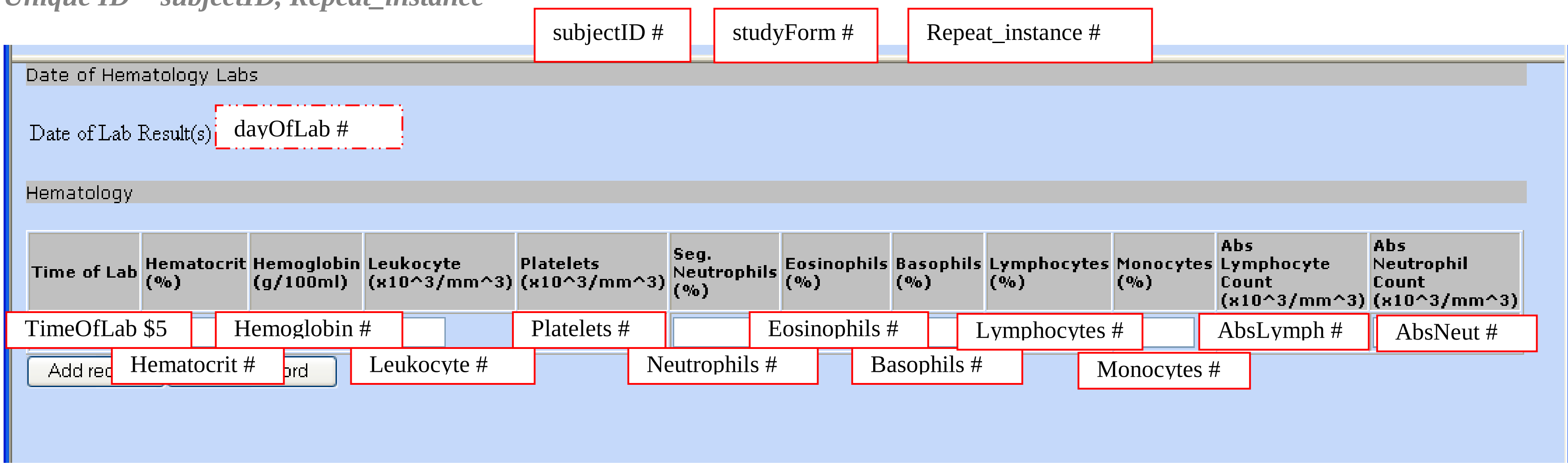




HEMATOLOGY (1of 1)

Daily Hematology Results

Unique ID = subjectID, Repeat_instance



subjectID # studyForm # Repeat_instance #

Date of Hematology Labs

Date of Lab Result(s) dayOfLab #

Hematology

Time of Lab	Hematocrit (%)	Hemoglobin (g/100ml)	Leukocyte (x10^3/mm^3)	Platelets (x10^3/mm^3)	Seg. Neutrophils (%)	Eosinophils (%)	Basophils (%)	Lymphocytes (%)	Monocytes (%)	Abs Lymphocyte Count (x10^3/mm^3)	Abs Neutrophil Count (x10^3/mm^3)
TimeOfLab $5	Hematocrit #	Hemoglobin #	Leukocyte #	Platelets #	Neutrophils #	Eosinophils #	Basophils #	Lymphocytes #	Monocytes #	AbsLymph #	AbsNeut #

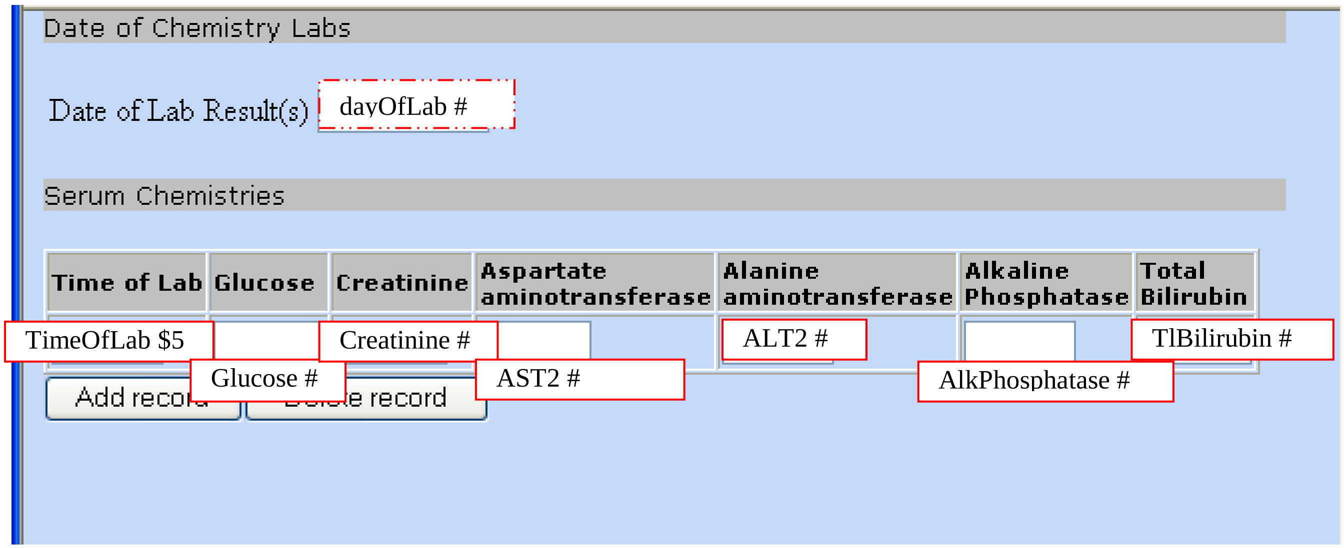
Add record

SERUMCHEM (1of 1)

Daily Serum Chemistry Results

Unique ID = subjectID, Repeat_instance

subjectID # studyForm # Repeat_instance #


Date of Chemistry Labs

Date of Lab Result(s) dayOfLab #

Serum Chemistries

Time of Lab	Glucose	Creatinine	Aspartate aminotransferase	Alanine aminotransferase	Alkaline Phosphatase	Total Bilirubin
TimeOfLab $5	Glucose #	Creatinine #	AST2 #	ALT2 #	AlkPhosphatase #	TlBilirubin #

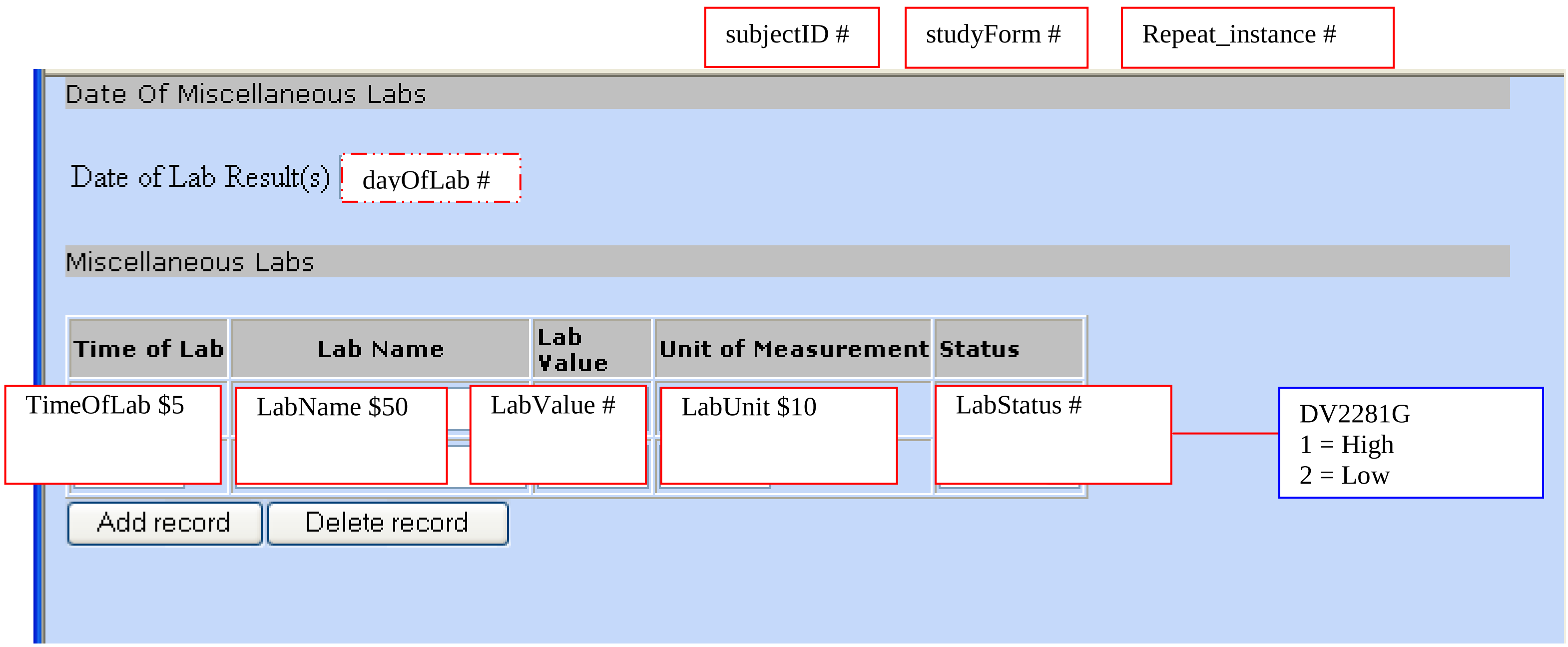
Add record Delete record

MISCLABS (1of 1)

Miscellaneous Laboratory Values

Unique ID = subjectID, Repeat_instance

Note: Sites were instructed to enter all other non-study required laboratory values where the investigator had determined the abnormal value was clinically significant.



FINALSTATUS (1 of 2)

Final Status (includes Day 28 mortality information)

Unique ID = subjectID

subjectID #

studyForm #

Study Summary

Date patient was last evaluated	finalContactDay #	
Were any study medication(s) permanently discontinued prior to Day 28?	StudyMedDiscont #	DV6942G 1 = Yes 2 = No 3 = Patient never received any study drugs

Provide the final status of the patient on the day of last evaluation

Patient Status	PatientStatus #	DV623G 1 = Alive 2 = Dead 3 = Could not determine
If yes, please provide the primary cause of death	PriCauseDeath $255	

Variables from analysis dataset included in the FINALSTATUS dataset:

Variable	Format	Type	Label	Algorithm / Notes
PICUDCTime	$5.	$	Time of PICU discharge (HHMM)	PICU discharge time for the current PICU admission OR death time if PICU discharge time was not provided
HospDCTime	$5.	$	Hospital discharge time (HHMM)	PICU discharge time for the current PICU admission OR death time if PICU discharge time was not provided
studyDay28Death	YESNOUK.	#	Dead on Study Day 28	= 1 if death date is on or before Study Day 28 = 0 if (death date is after Study Day 28) OR (patient is confirmed alive as of Study Day 28 AND NO death date is provided) = -1 if patient is NOT confirmed alive as of Study Day 28 AND patient withdrew from data collection prior to Study Day 28
PICUDCDay		#	Day of PICU discharge (relative to randomization)	(PICU discharge date for the current PICU admission OR death date if PICU discharge date was not provided) – randomization date
hospDCDay		#	Day of hospital discharge (relative to randomization)	(Hospital discharge date for the current hospital admission OR death date if hospital discharge date was not provided) – randomization date
studyDay28		#	Day of Study Day 28 (relative to randomization)	studyDay28: = (Date of Study Day 1 + 27) – randomization date
deathDay		#	Day of death (relative to randomization)	= (date of death, as of the final status evaluation OR Study Day 28 follow up) – randomization date
deathTime	$5.	$5	Time of Death (HHMM)	= time of death, as of the final status evaluation OR Study Day 28 follow up

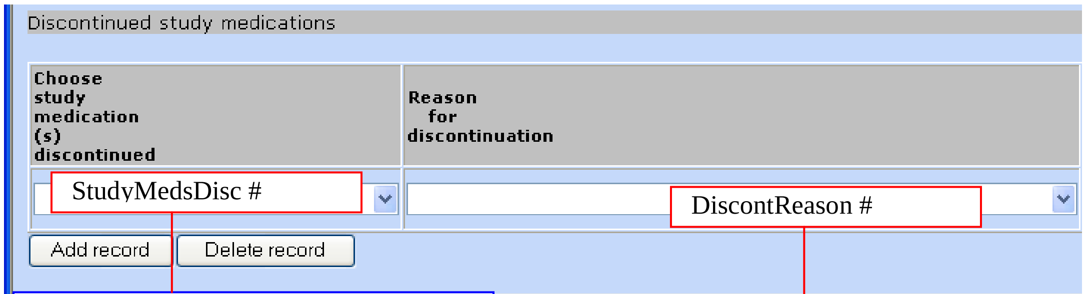
YESNOUK
-1 = Unknown
0 = No
1 = Yes

FINALSTATUS_STUDYMEDDISC (1of 1)

Final Status – Discontinued Study Medications

Unique ID = subjectID, Repeat_instance

subjectID #   studyForm #   Repeat_instance #



DV6627G
1 = Metoclopramide/Placebo
2 = Zinc/Placebo
3 = Selenium/Placebo
4 = Glutamine/Placebo
5 = All study medications discontinued

DV998G
1 = Adverse Event
2 = Failure to tolerate study medication
3 = Development of exclusion criteria
4 = Removal of enteral feeding tube
5 = No IV available
6 = Discharged from PICU
7 = Patient died
8 = Parent withdrew permission for patient to continue on study medication
9 = Other

WITHDRAWALOFCONSENT (1 of 1)

Withdrawal of Consent

Unique ID = subjectID

subjectID #

studyForm #

Withdrawal of Consent

What elements of consent were withdrawn	WDType #
Date consent was withdrawn	WDCDay #
Time consent was withdrawn	WDCTime $5

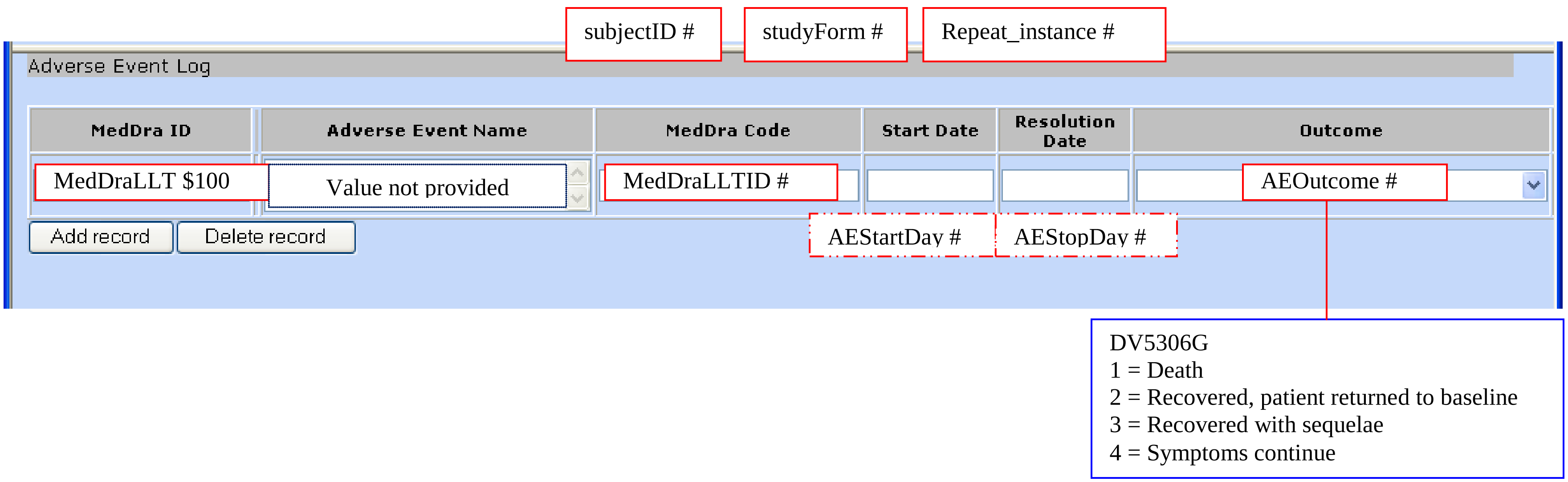
DV6943G
1 = Parent withdrew permission to continue on study medication, data collection can continue
2 = Parent withdrew permission for study medication and data collection to continue, except AEs and 28 Day follow-up
3 = Parent withdrew permission for study medication, data collection and any contact or follow-up

ADVERSEEVENTLOG (1 of 2)

Adverse Events Log

Unique ID = subjectID, Repeat_instance

Note: Adverse events were coded to the lower level term (LLT) in MedDRA version 13.0. The lower level code (MedDRALLTID) and LLT (MEDRALLT) are included in this dataset. We are including sepsis and infection events in the dataset even though these event types were excluded from the summary of AEs provided for the primary manuscript since they overlap with the outcome reporting for this study.



ADVERSEEVENTLOG (2 of 2)

Intensity	Study Drug Action Taken	Study Drug Relationship	Treatment or Action Taken for this AE	Other AE Treatment
AEIntensity #	StDrugAction #	Value not provided	AETreatment1 #	AETreatOther $1024

DV1904G
1 = Mild
2 = Moderate
3 = Severe

DV13G
1 = None
2 = Dose reduced
3 = Study drug interrupted/restarted
4 = Study drug discontinued

DV6311G
1 = None
2 = Intervention: Surgery or Procedure
3 = Medication initiation, change or discontinuation
4 = Other Treatment

DV4348G
1 = Not Serious
2 = Moderately Serious
3 = Serious

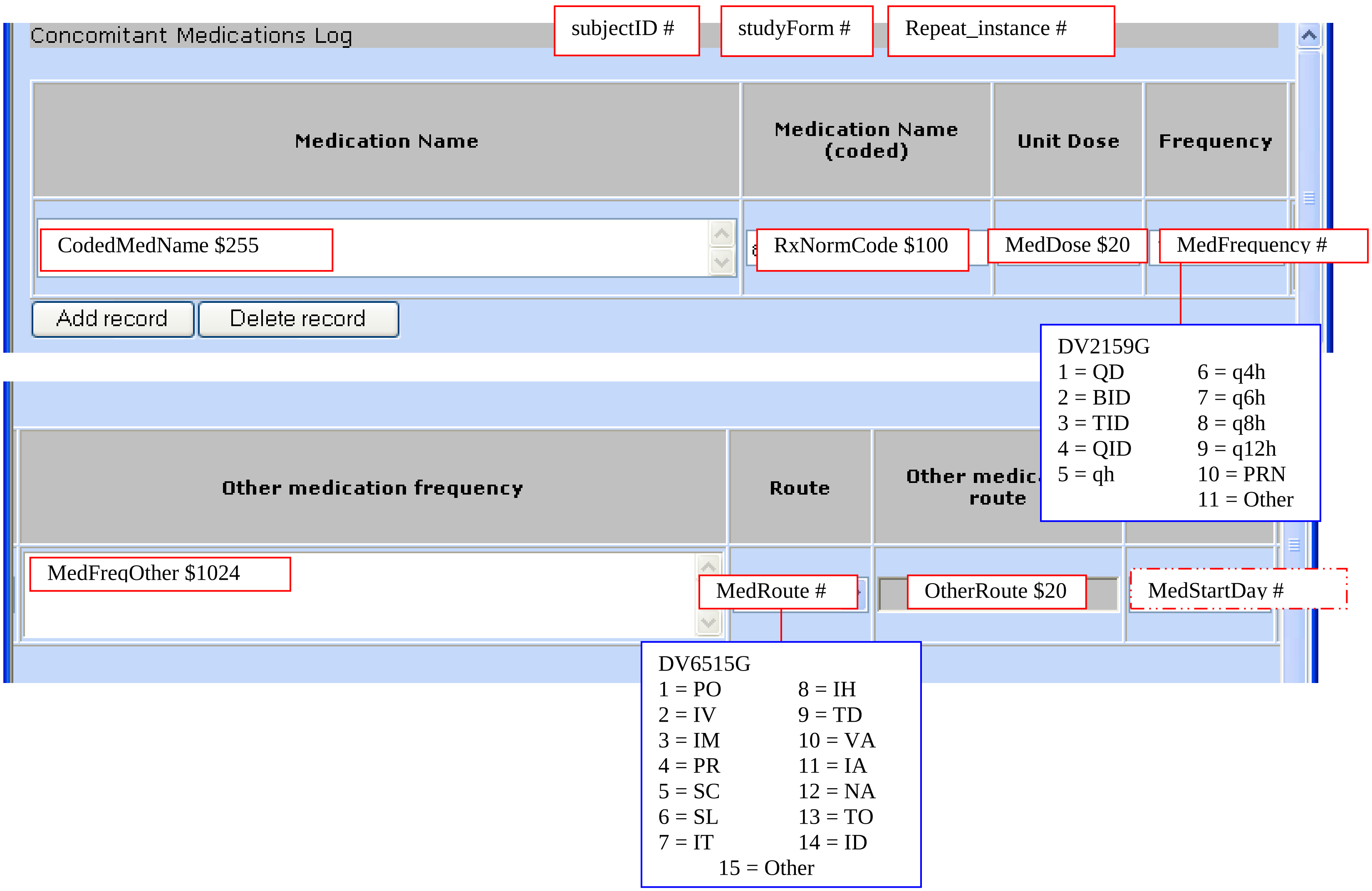
Adverse Event Severity
AESeverity #

CMEDLOG (1 of 2)

Concomitant Medications Log

Unique ID = subjectID, Repeat_instance

Note: Medications were coded in RxNorm version 2010.2.1, and the code (RxNormCode) and medication name (CodedMedName) are included in this dataset. 107 records have been removed from the dataset because they could not be coded.



CMEDLOG (2 of 2)

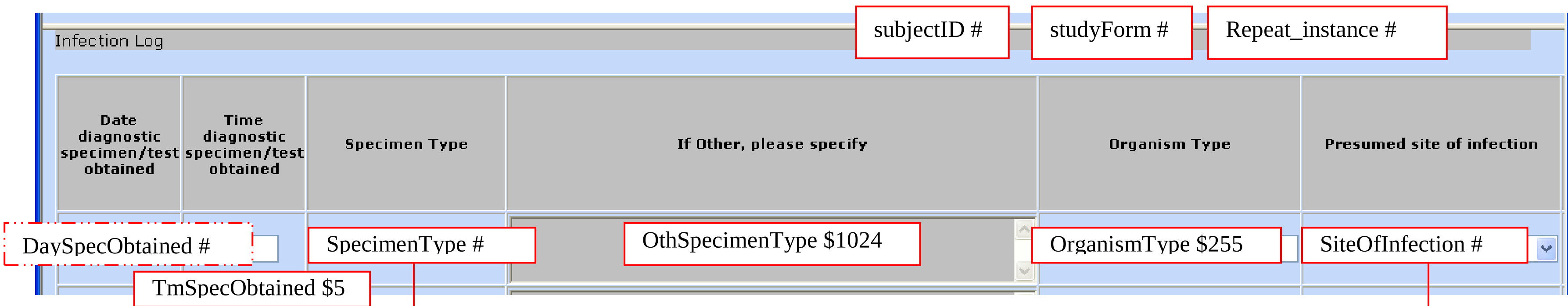
Medication continuing	Stop Date
MedContinuing #	MedStopDay #

DV6190G
1 = Yes
2 = No

INFECTIONLOG (1 of 1)

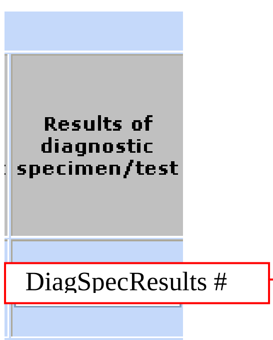
Diagnostic Testing for Infections Log
Unique ID = subjectID, Repeat_instance

Note: Sites were instructed to enter all information regarding bacterial culture, antigen, PCR or antibody testing for an infection occurring within 48 hours prior to PICU admission through the last day the patient participated in the study.



DV4106G
1 = Urine
2 = Feces
3 = Cerebrospinal fluid
4 = Sputum
5 = Blood
6 = Skin
7 = Tissues
8 = Other

DV159G
1 = Urinary tract
2 = Surgical wound
3 = Pneumonia
4 = LRTI other than pneumonia
5 = Bloodstream (primary)
6 = Bone or joint
7 = CNS
8 = Cardiovascular
9 = ENT
10 = GI tract
11 = Reproductive tract
12 = Skin or soft tissue
13 = Systemic
14 = Unknown



DV6401G
1 = Positive
2 = Negative
3 = Pending

PARENTERALADMIN (1 of 1)

Parenteral Study Drug Administration

Unique ID = subjectID

subjectID # studyForm #

Calculated recommended dose

Metoclopramide or Placebo Study Drug Administration

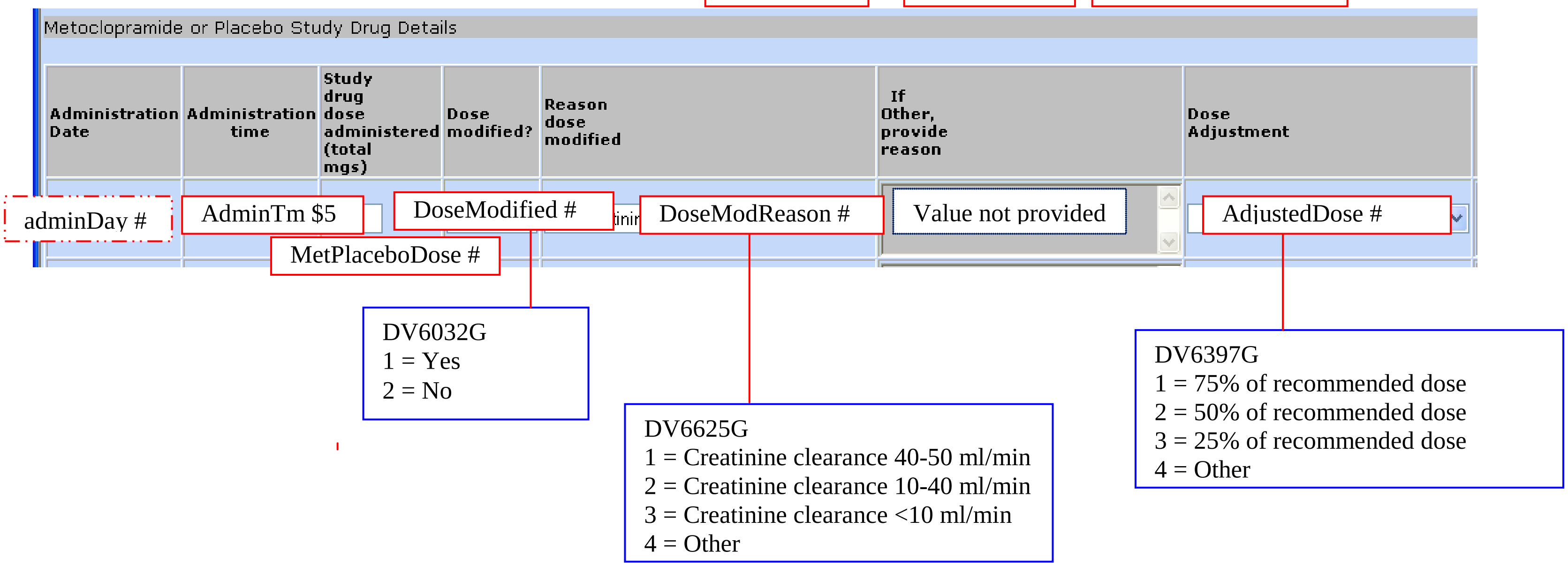
Calculated dose (tl. mgs) - based on patients weight at admission CalcDose #

PARENTERALADMIN_METOCLOPRAMIDE (1 of 1)

Metoclopramide or Placebo Study Drug Administration Log

Unique ID = subjectID, Repeat_instance

subjectID # | studyForm # | Repeat_instance #



ENTERALADMIN (1 of 1)

Enteral Study Drug Administration

Unique ID = subjectID

subjectID # studyForm #

Calculated recommended dose

Zinc or Placebo Study Drug Administration

Calculated dose (tl. mgs) - based on patients age at admission CalcDose2 #

Calculated recommended dose

Selenium or Placebo study Drug Administration

Calculated dose (tl. mcgs) - based on patients age at admission CalcDose3 #

Calculated recommended dose

Glutamine or Placebo Study Drug Administration

Calculated dose (tl. gms) - based on patients weight at admission CalcDose4 #

ENTERALADMIN_ZINC (1 of 1)

Zinc or Placebo Study Drug Administration Log

Unique ID = subjectID, Repeat_instance

subjectID # studyForm # Repeat_instance #

Zinc Or Placebo Details

Administration Date	Administration time	Study Drug dose administered (total mg/day)	Study Drug or Placebo Route
adminDay #	AdminTm2 $5	DrugDose2 #	StudyDrugRoute2 #

Add record Delete record

DV180G
1 = NG
2 = ND
3 = NJ
4 = GT

ENTERALADMIN_SELENIUM (1 of 1)

Selenium or Placebo Study Drug Administration Log

Unique ID = subjectID, Repeat_instance

subjectID # | studyForm # | Repeat_instance #

Selenium or Placebo Details

Administration Date	Administration time	Study Drug dose administered (total mcg/day)	Study Drug or Placebo Route
adminDay #	AdminTm3 $5	DrugDose3 #	StudyDrugRoute3 #

Add record | Delete record

DV180G
1 = NG
2 = ND
3 = NJ
4 = GT

ENTERALADMIN_GLUTAMINE (1 of 1)

Glutamine or Placebo Study Drug Administration Log

Unique ID = subjectID, Repeat_instance

subjectID # | studyForm # | Repeat_instance #

Glutamine or Placebo Details

Administration Date	Administration time	Study Drug dose administered (total gms/day)	Study Drug or Placebo Route
adminDay #	AdminTm4 $5	DrugDose4 #	StudyDrugRoute4 #

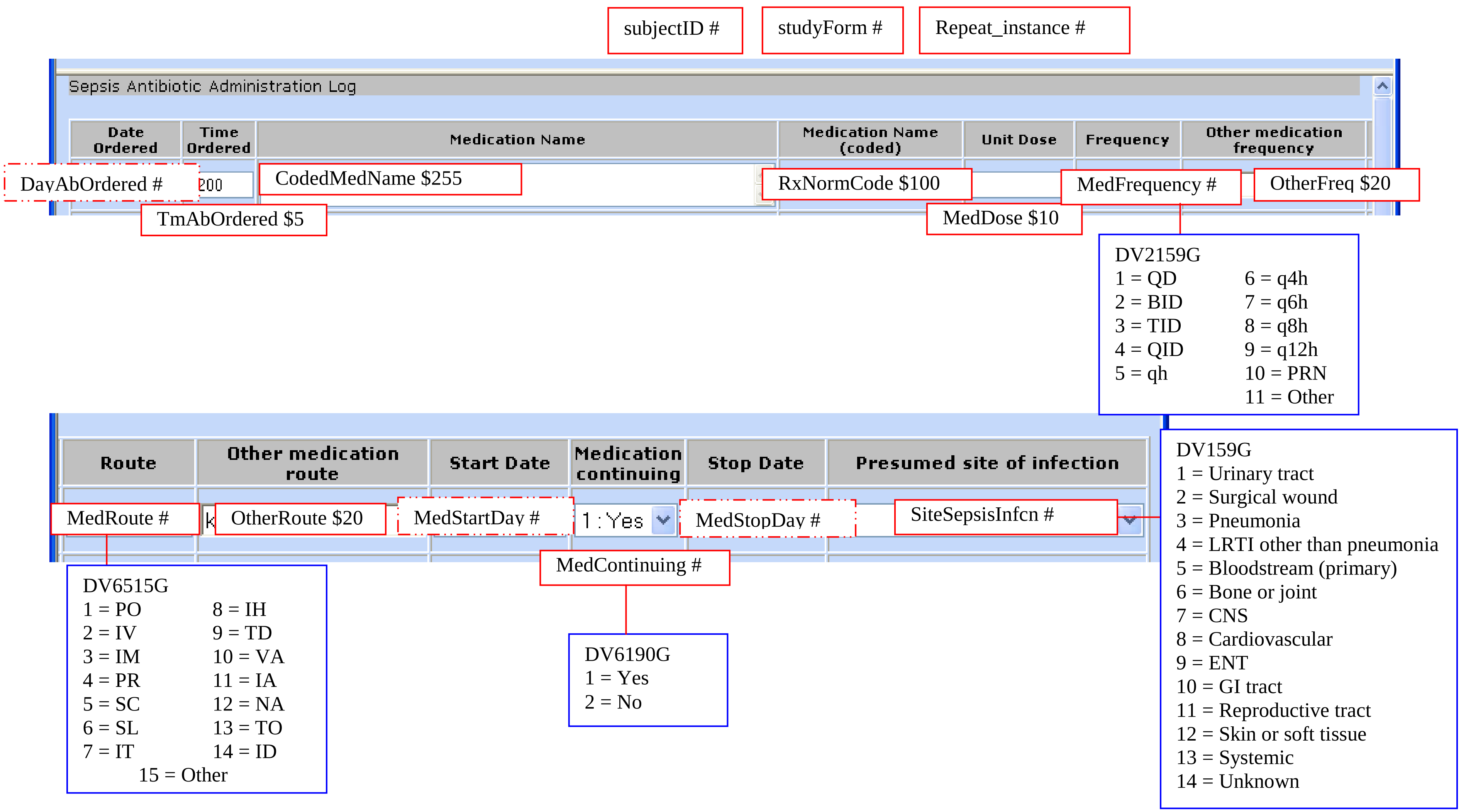
Add record | Delete record

DV180G
1 = NG
2 = ND
3 = NJ
4 = GT

Antibiotic Log

Unique ID = subjectID, Repeat_instance

Note: Medications were coded in RxNorm version 2010.2.1, and the code (RxNormCode) and medication name (CodedMedName) are included in this dataset. One record has been removed from the dataset because it could not be coded.



ENDPTSUM (1 of 3)

Endpoint Summary

Unique ID = subjectID

subjectID #

studyForm #

Endpoint Status

Field	Variable	Codes
Existing Sepsis	ExistSepEpSum #	DV6032G 1 = Yes 2 = No
Existing Infection	ExistInfcnEpSum #	DV6032G 1 = Yes 2 = No
Nosocomial Clinical Sepsis	NosoClinSep #	DV6032G 1 = Yes 2 = No
Number of Sepsis Events	NumSepEvents #	

Date of Nosocomial Clinical Sepsis	Time of Nosocomial Clinical Sepsis

Endpoint Summary – Nosocomial Sepsis Events Log on page 41

Field	Variable	Codes
Nosocomial Clinical Infection	NosoClinInfcn #	DV6032G 1 = Yes 2 = No
Number of Infection Events	NumInfcnEvents #	

Date of Nosocomial Clinical Infection	Time of Nosocomial Clinical Infection

Endpoint Summary – Nosocomial Infection Events Log on page 40

Incidence of Lymphopenia

Field	Variable	Codes
Did this patient have moderate lymphopenia (absolute lymphocyte count <= 1,000 cells/µL for >= 3 days)	ModLym #	DV6190G 1 = Yes 2 = No
Did this patient have prolonged lymphopenia (absolute lymphocyte count <= 1,000 cells/µL for >= 7 days)	ProLym #	DV6190G 1 = Yes 2 = No

Variables from analysis dataset include in the ENDPTSUM dataset:

Variable	Format	Type	Label	Algorithm / Notes
Time1stHrs		#	Time to first nosocomial infection/sepsis event/censor time (hours)	• If patient had any nosocomial sepsis/infection events then = Ceiling of [(date/time of earliest event – PICU admission date/time) / (60*60)] • Else if patient had no nosocomial sepsis/infection events AND did NOT withdraw from data collection then = Ceiling of {[minimum of (hospital discharge date/time, death date/time, 23:59 and 59 seconds on the day patient was last evaluated) – PICU admission date/time] / (60*60)} • Else if patient had no nosocomial sepsis/infection events AND withdrew from data collection then = Ceiling of [(date/time of withdrawal from data collection – PICU admission date/time) / (60*60)]
censor	YESNO.	#	Censored for survival analysis of time to first nosocomial infection/sepsis event	=1 if patient had any nosocomial sepsis/infection events =0 if patient had no any nosocomial sepsis/infection events
NumEvent		#	Number of nosocomial events (infection or sepsis)	=Number of nosocomial clinical sepsis events + number of nosocomial clinical infection events
AntiFreeDay		#	Antibiotic free days in PICU	= Number of days from PICU admission to earliest of PICU discharge, death, final study evaluation Note: for continuing antibiotics with missing antibiotic stop days, assume the antibiotic stop date is the earliest date of (PICU discharge, death, final study evaluation)
pctantifreeDAY		#	Proportion of antibiotic free days in PICU	antiFreeDay / PICUDay
PICUDAY		#	Days in PICU	=earliest of (PICU discharge date, death date, date patient was last evaluated) – PICU admission date + 1
studydayMOD		#	Time from PICU admission to final study evaluation (days)	• If patient did NOT withdraw from data collection then =Ceiling of {[minimum of (hospital discharge date/time, death date/time, 23:59 and 59 seconds on the day patient was last evaluated) – PICU admission date/time] / (60*60*24)} • Else if withdrew from data collection then =Ceiling of [(date/time of withdrawal from data collection – PICU admission date/time) / (60*60*24)]

ENDPTSUM (3 of 3)

EXISTINFSEPSG	SEPINF.	#	Existing Infection or Sepsis Subgroup	=0 if Existing Sepsis=No AND Existing Infection=No =1 if Existing Sepsis=Yes AND Existing Infection=No =2 if Existing Sepsis=No AND Existing Infection=Yes

SEPINF
0 = No Pre-existing Sepsis/Infection
1 = Pre-existing Sepsis
2 = Pre-existing Infection
3 = Not Adjudicated

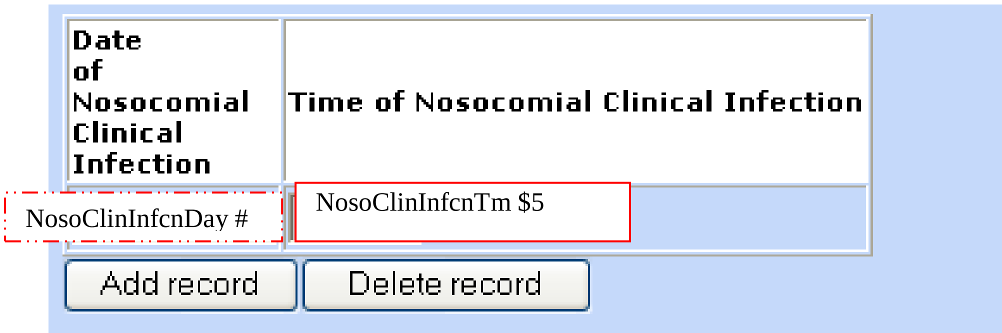
YESNO
0 = No
1 = Yes

Endpoint Summary – Nosocomial Infection Events Log

Unique ID = subjectID, Repeat_instance, organismID

Note: It is possible to have multiple organisms per infection; each organism is on a separate row.

subjectID # studyForm # Repeat_instance #



Variables from analysis dataset include in the ENDPTSUM_NOSOCLININFC dataset:

Variable	Format	Type	Label	Algorithm / Notes
organism		$96		Abstracted from the lab report
organism_category		$22		Categorized organism
specimen_location		$50		Abstracted from the lab report
specimen_type		$96		Categorized specimen location
organismID		#	Organism identifier (per infection)	

ENDPTSUM_NOSOCLINSEP (1 of 1)

Endpoint Summary – Nosocomial Sepsis Events Log

Unique ID = subjectID, Repeat_instance

subjectID # studyForm # Repeat_instance #

Date of Nosocomial Clinical Sepsis	Time of Nosocomial Clinical Sepsis
NosoClinSepDay #	NosoClinSepTm $5

Add record Delete record

MAYOLABS (1 of 1)

Mayo Laboratory Data
Unique ID = subjectID, studyForm, lab

Note: Sites were instructed to collected samples for Mayo Laboratory on Study Day 1 and Study Day 7/Early Exit.

subjectID #

studyForm #

Variables from Mayo laboratory dataset and Daily Data forms:

Variable	Format	Type	Label	Algorithm / Notes
lab	MAYOLABF.	#	Analyte	Provided by Mayo laboratory
labvc	$50.	$50	Lab Value	Provided by Mayo laboratory CANCELLED indicates specimen was hemolyzed, quantity not sufficient, specimen received at ambient temp, or interfering substance present in sample. Lab was unable to process.
LabDay		#	Lab Day (relative to randomization)	Sample date – randomization date
labtm	TIME5.	$5	Lab Time	Sample time

MAYOLABF
1 = Prolactin (ng/mL)
2 = Selenium (ng/mL)
3 = Zinc (mcg/mL)