Public Use Dataset
Annotated eCRF

Bleeding and Thrombosis During ECMO

(BATE)

CPCCRN Protocol Number 048

Collaborative Pediatric Critical Care Research Network

Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)

Protocol Version 1.0

Version Date: September 26, 2012

Annotated eCRF Version 1.0

Version Date: February 16, 2016

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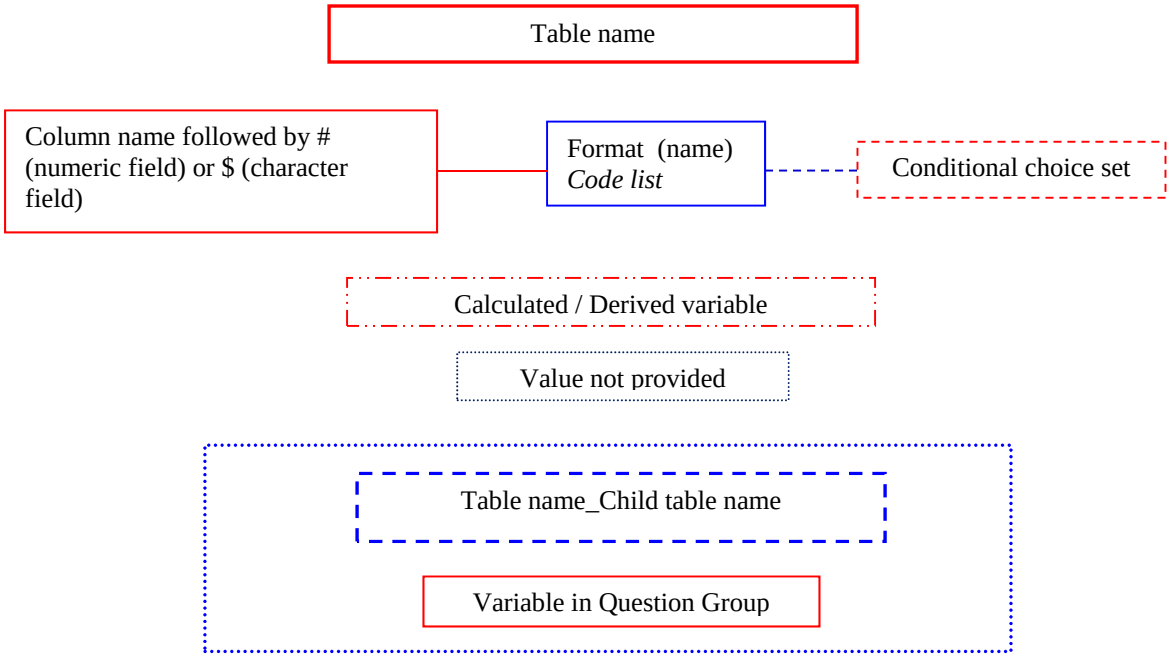
Annotations key



Notes

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

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

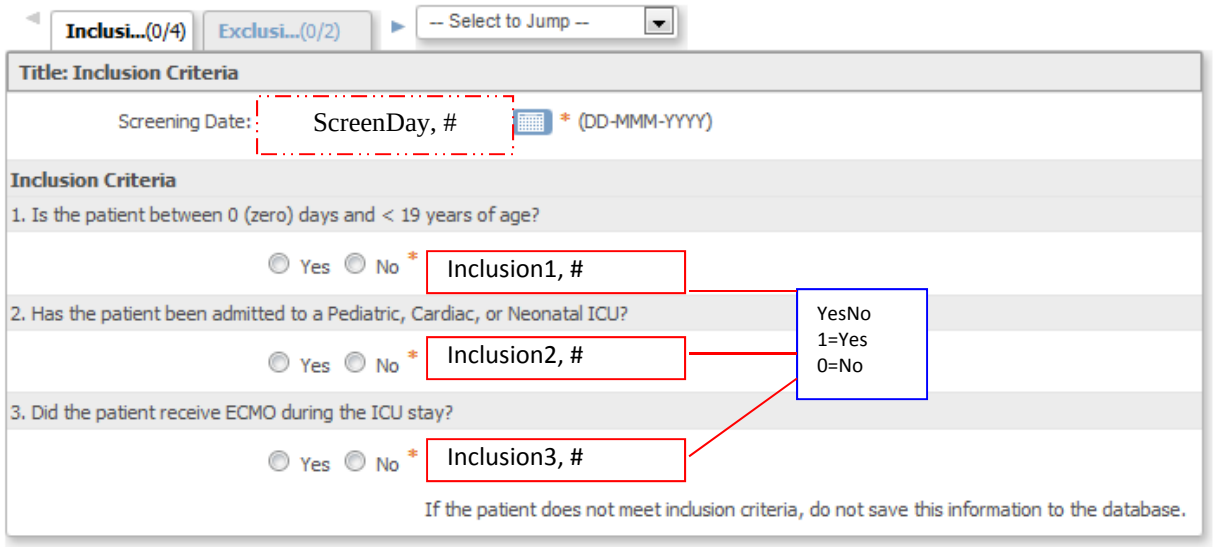
Sensitive and/or identifying information entered in free text fields have been removed from the public use datasets.

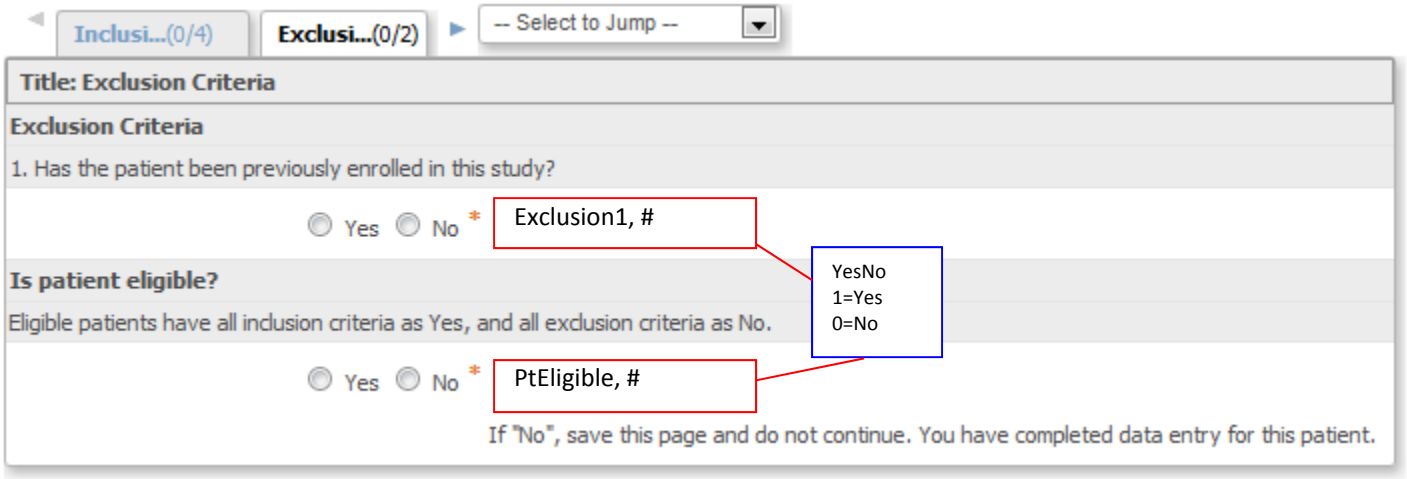
'Date' variables are replaced with 'day' variables. Day variables are populated with the number of days since the reference date, ICU admission date. ICU admission date is coded as 0 (Day 0) and all other dates will be recoded as number of days after Day 0 (if any dates occur before the ICU admission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

Eligibility (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

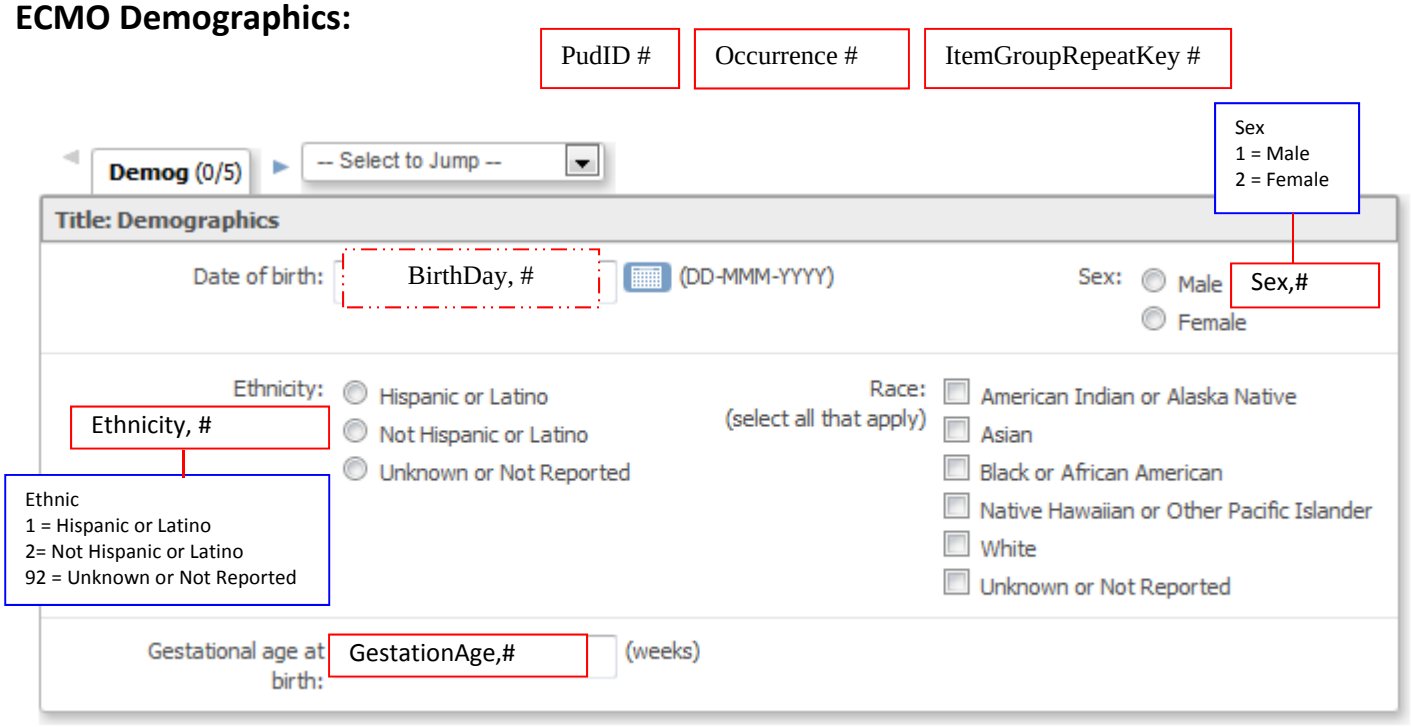
ECMO Eligibility:





Demog (1 of 1)

ECMO Demographics:



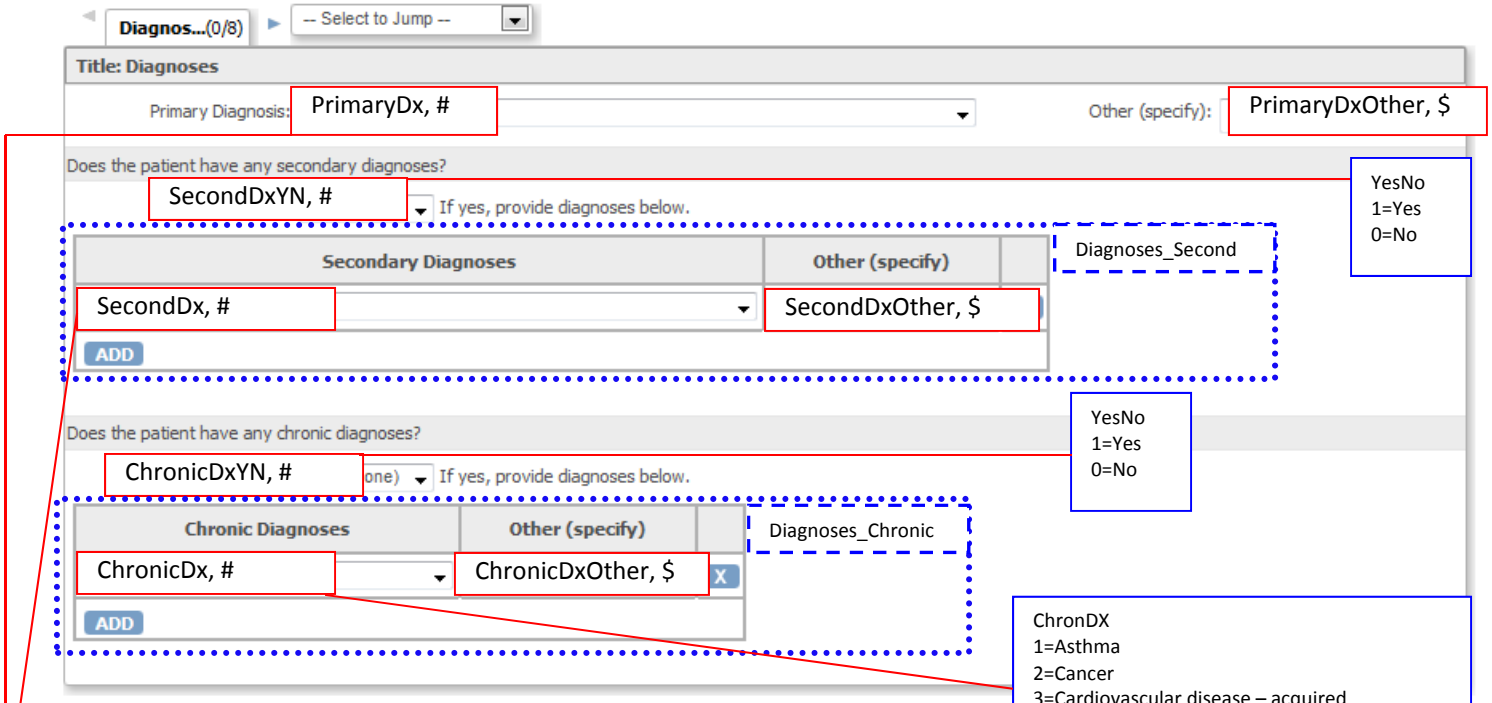
Additional / derived variables included in the DEMOG dataset:

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

Diagnoses (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Diagnoses:



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

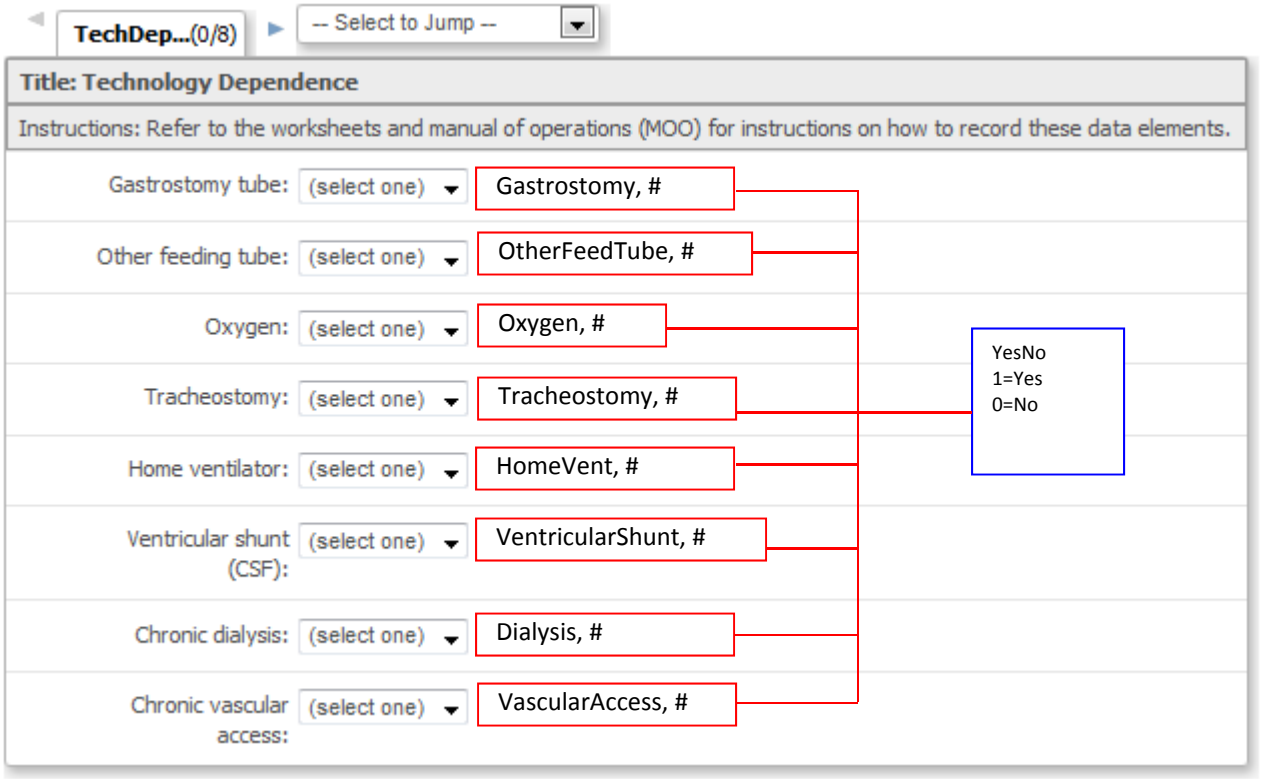
ChronDX
1=Asthma
2=Cancer
3=Cardiovascular disease – acquired
4=Cardiovascular disease – arrhythmia
5=Cardiovascular disease – congenital
6=Chronic renal failure
7=Chronic lung disease (BPD, CF)
8=Congenital anomaly or chromosomal defect
9=Diabetes
10=Musculoskeletal
11=Neurologic - static encephalopathy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

* excluded values: Diagnoses_Second with SecondDx = 15 (HIV), DIAGNOSES_CHRONIC with ChronicDxOther = 'HIV infection'

TechDepend (1 of 1)

PudID #	Occurrence #	ItemGroupRepeatKey #

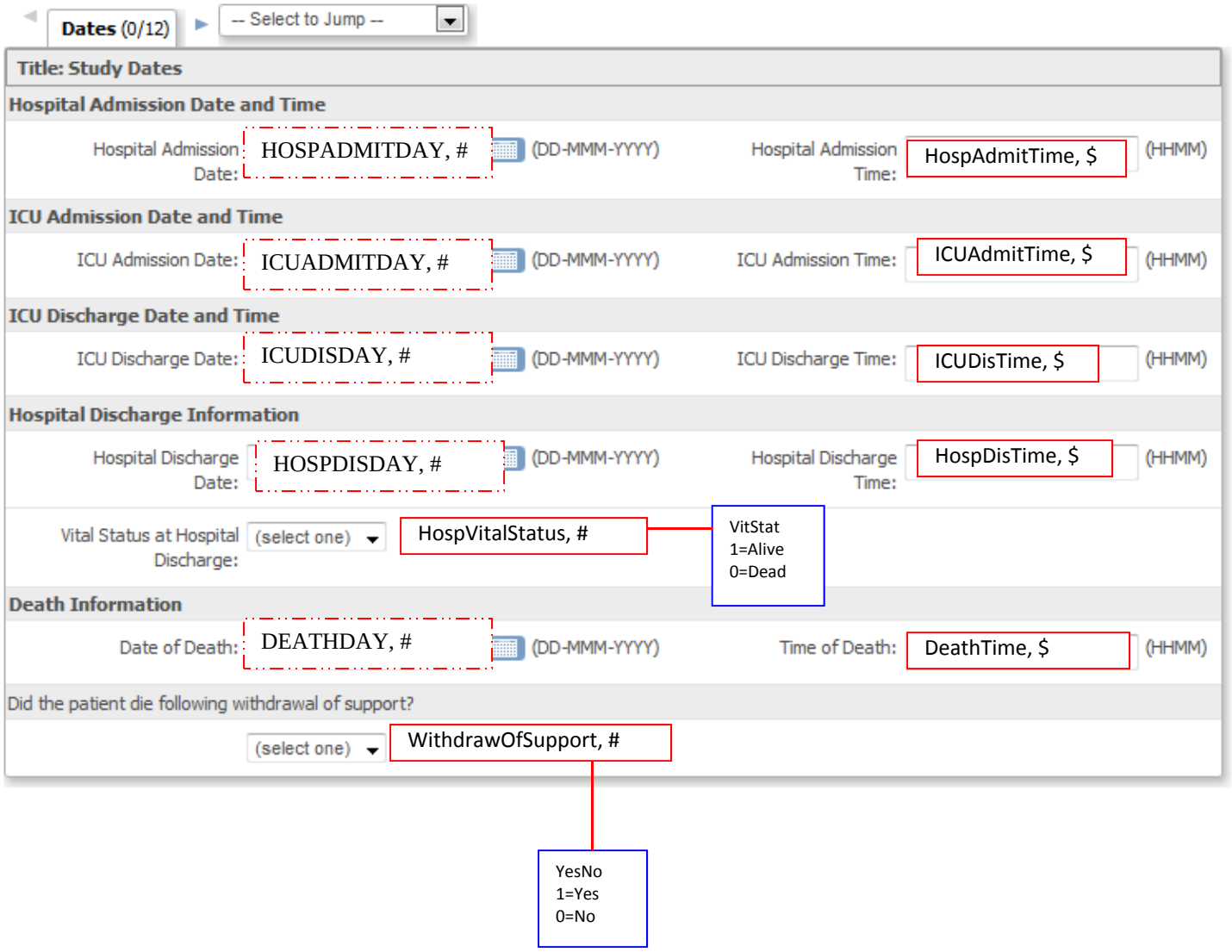
ECMO Technology Dependence:



Dates (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

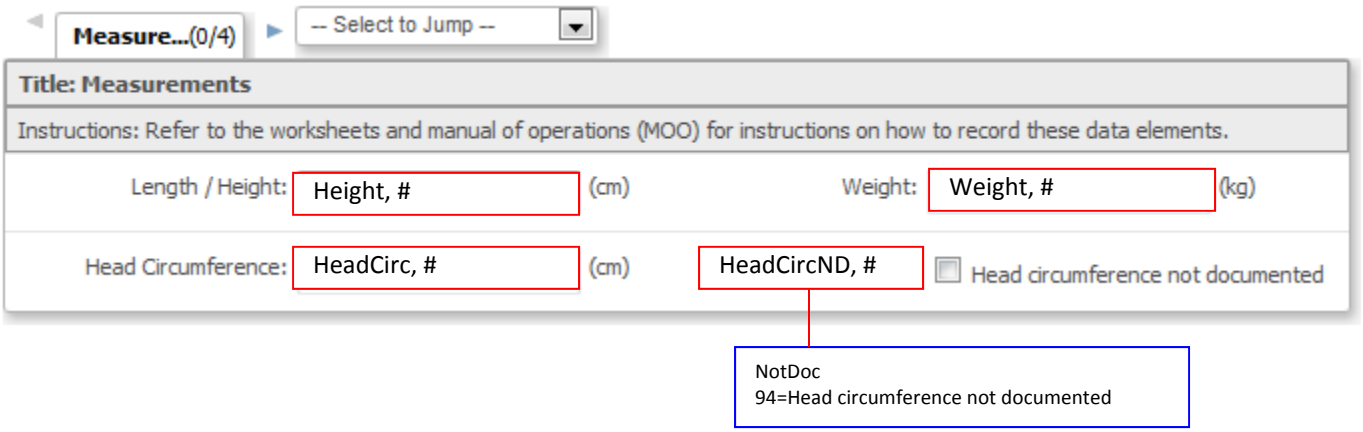
ECMO Hospitalization Dates and Death Information:



PM (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

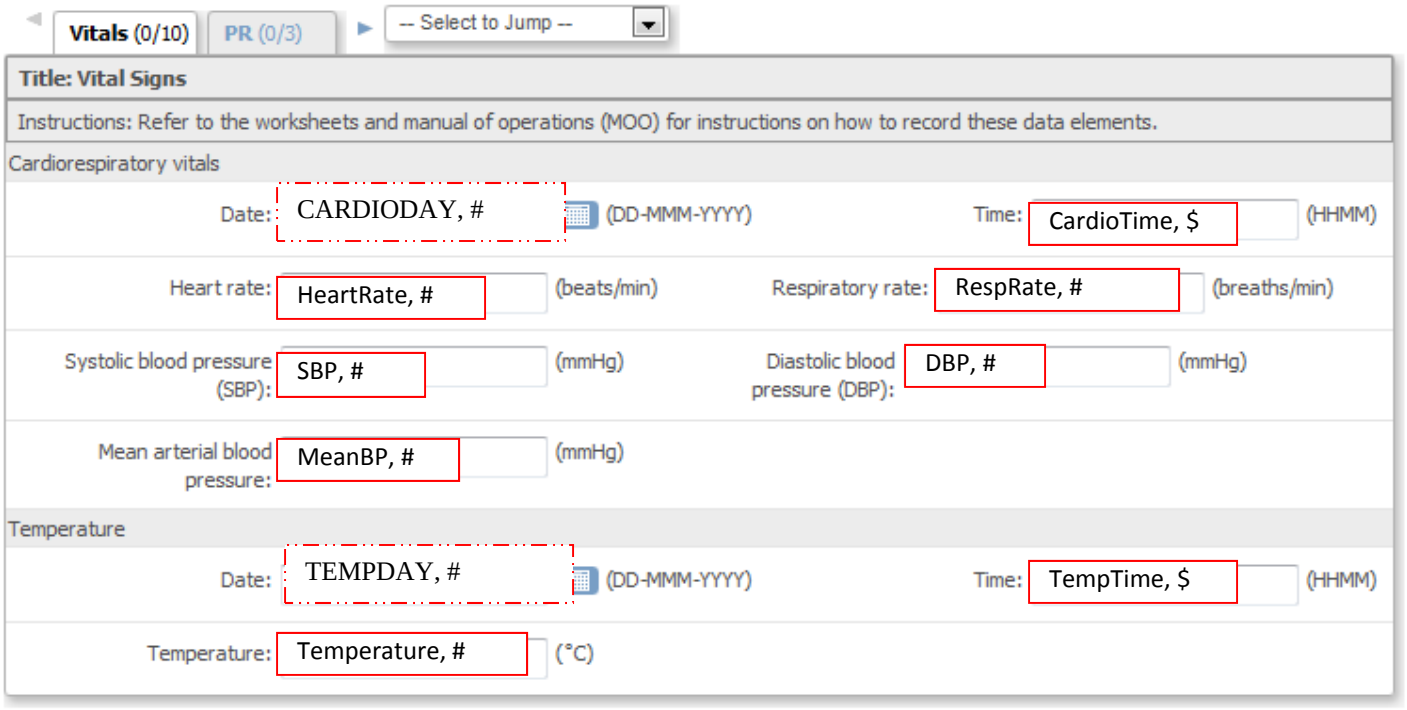
ECMO Physical Measurements:

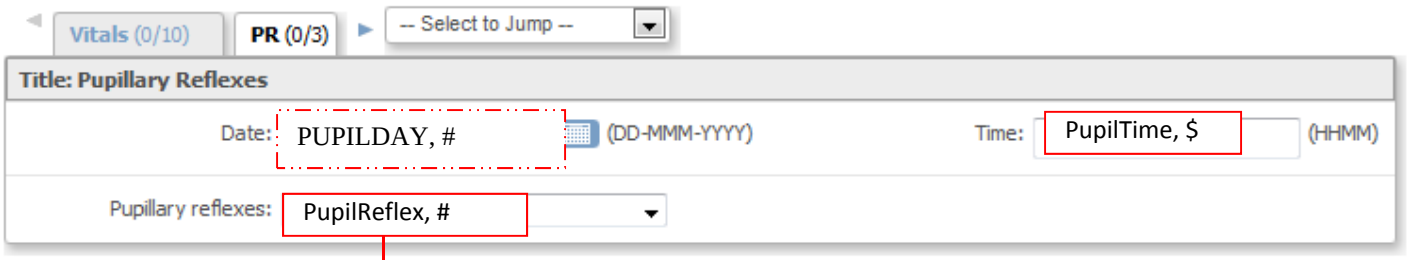


VM (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Vital Measurements:



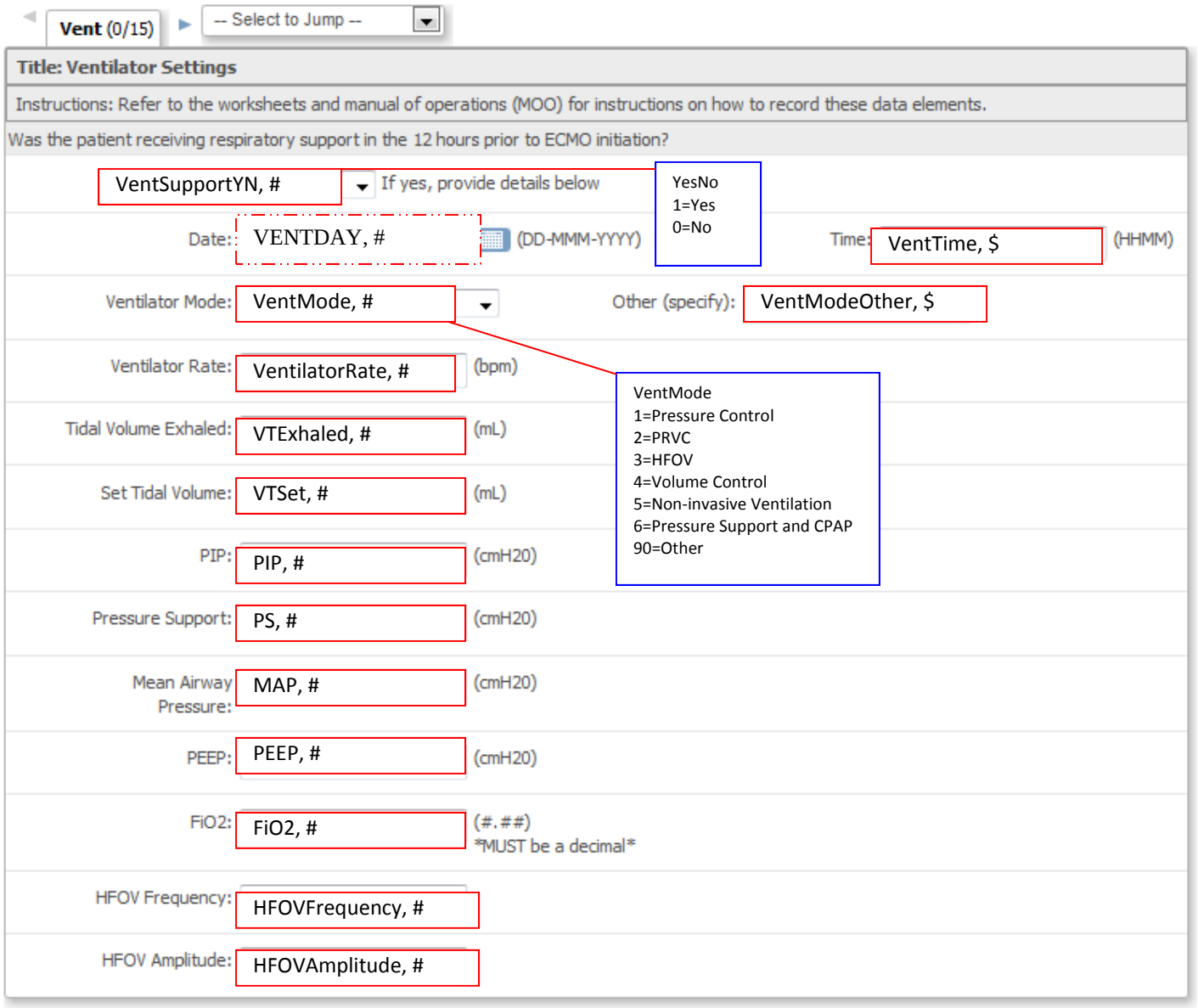


Pupil
1=Both reactive
2=One non-reactive (> 3mm)
3=Both non-reactive (> 3mm)
4=Both pupils < 3mm, cannot be scored

BaseVent (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

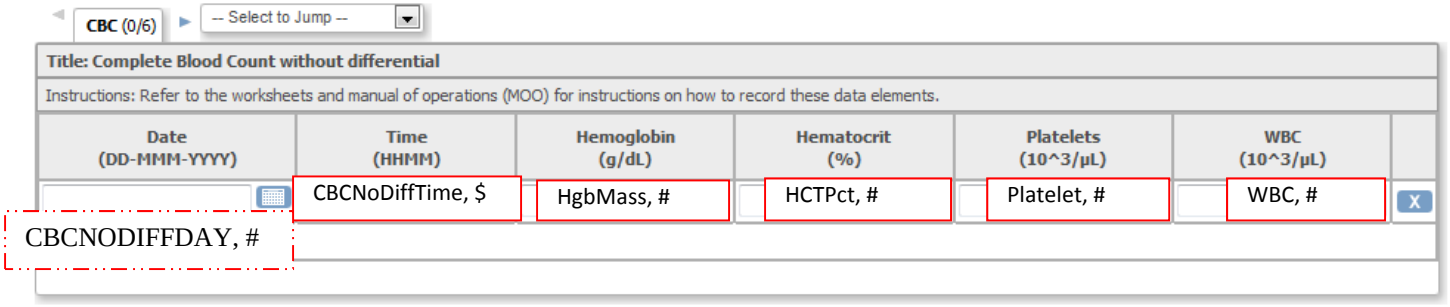
ECMO Baseline Ventilator Settings:



BaseCBC (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

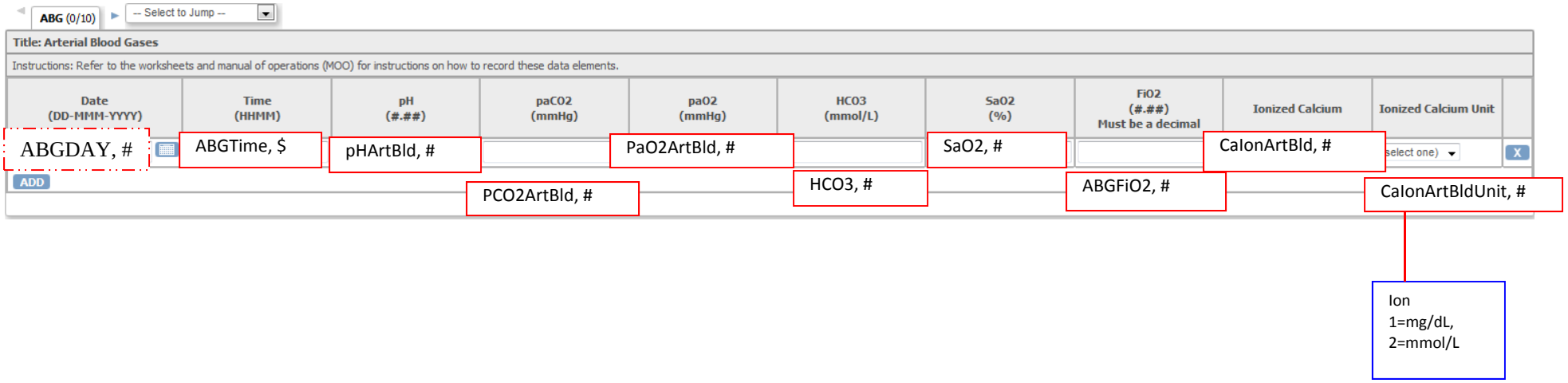
ECMO Baseline Complete Blood Count w/o diff:



BaseABG (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

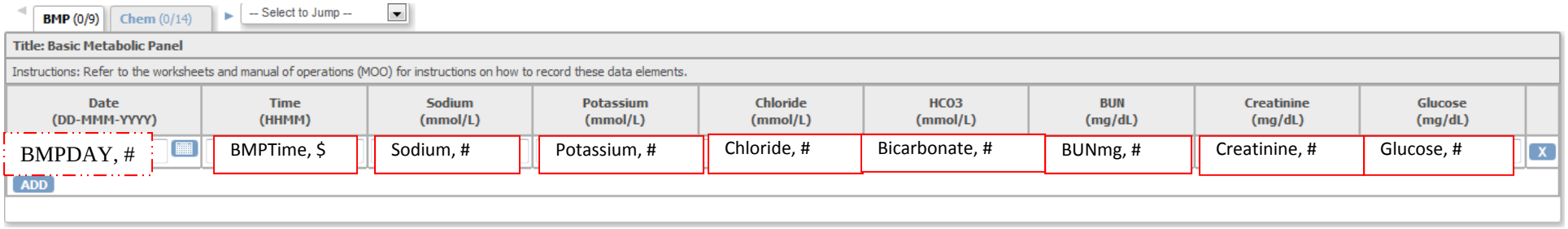
ECMO Baseline Arterial Blood Gases:



BaseBMP (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Baseline Chemistries:

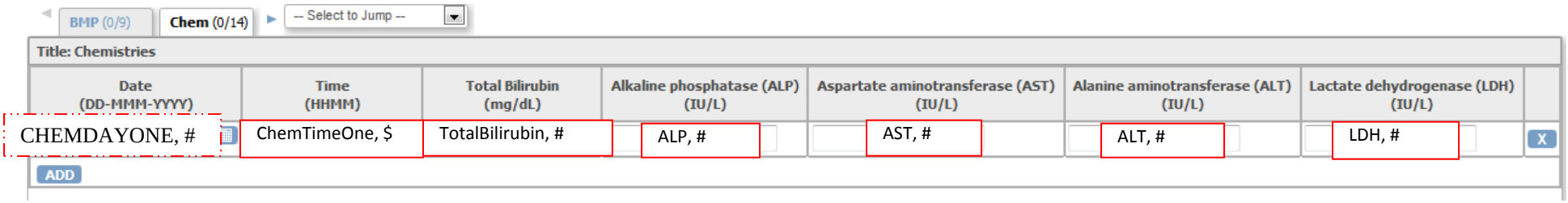


Note: Although the case report form reflects HCO3 as being collected, the lab value being provided in this data field represents total CO2.

BaseChemOne (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Baseline Chemistries:



BaseChemTwo (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Baseline Chemistries:

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

ADD

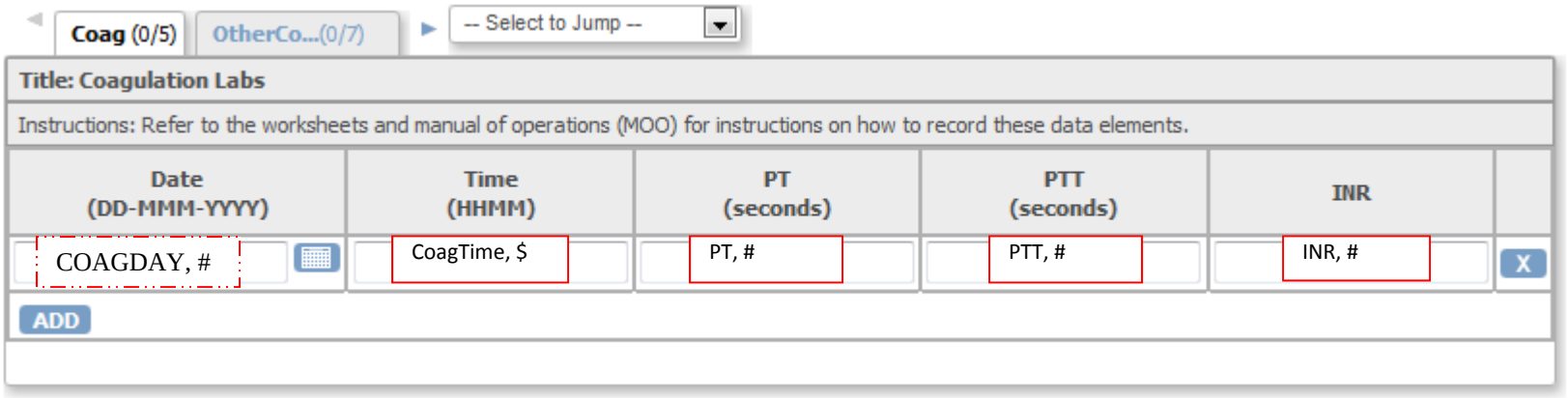
LactateUnit, #

Lactate
1=mg/dL
2=mmol/L

BaseCoag (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

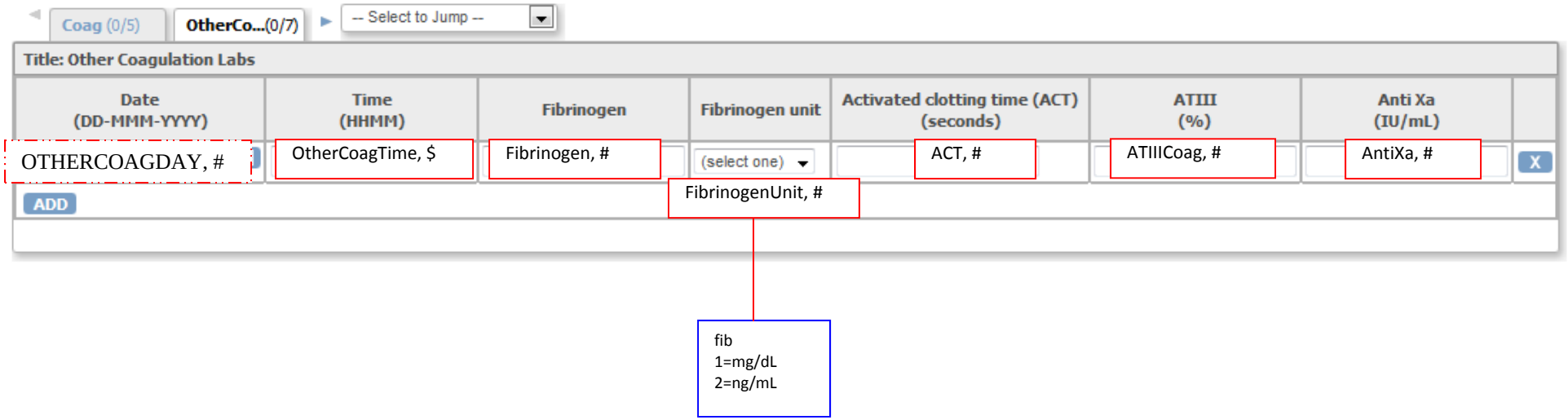
ECMO Baseline Coagulation Labs:



BaseOtherCoag (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

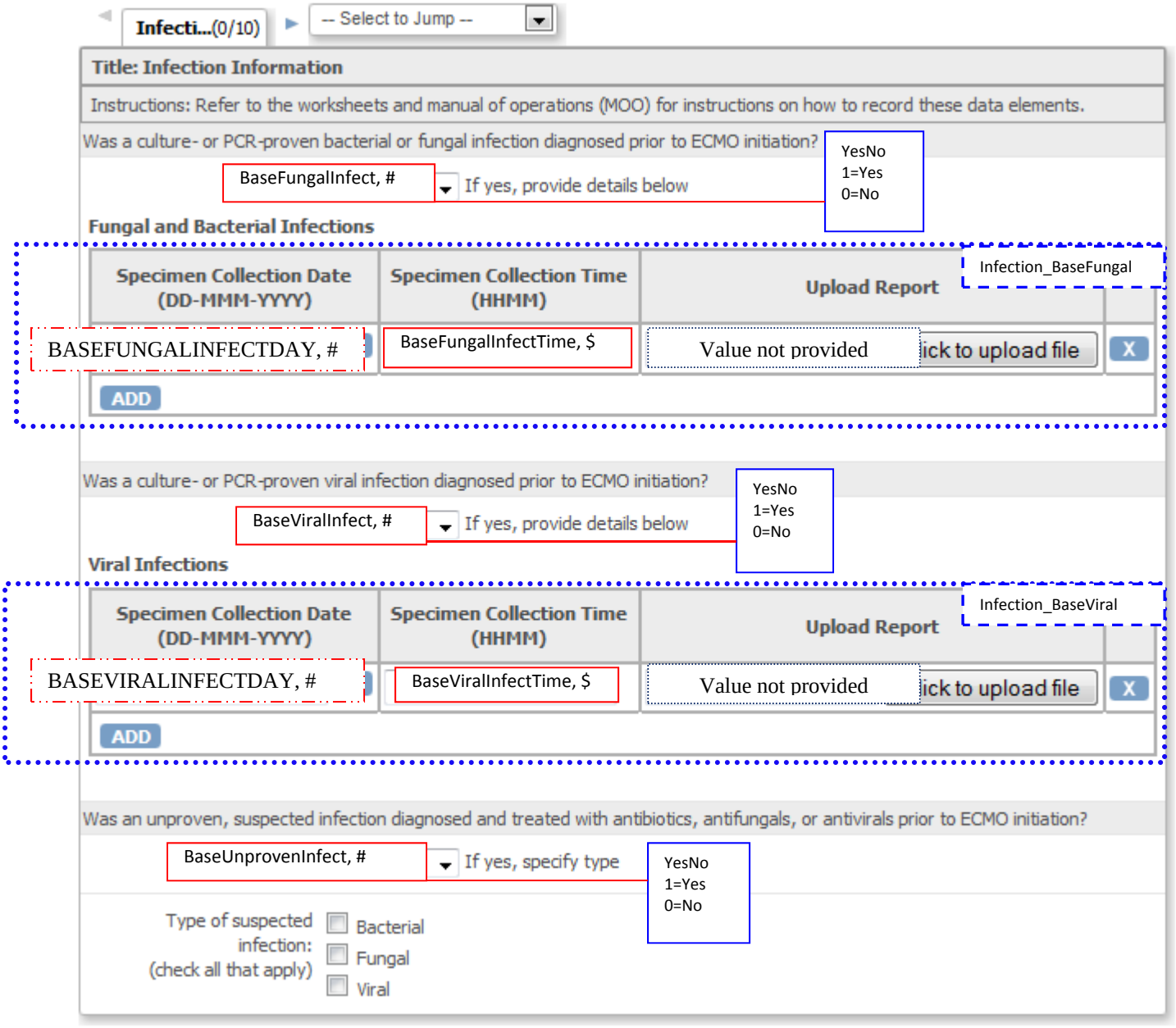
ECMO Baseline Coagulation Labs:



Infection (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Infection Information:



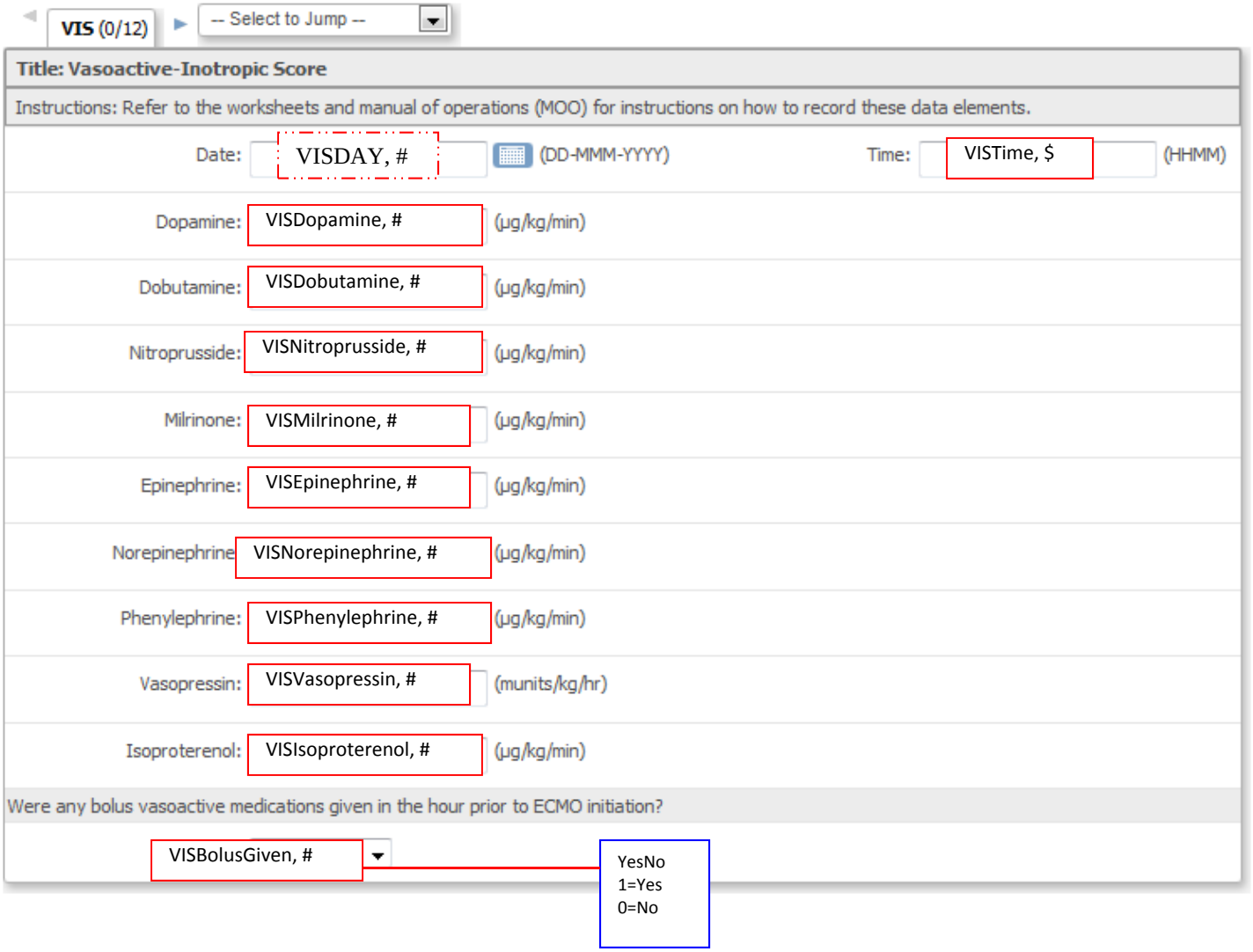
Additional / derived variables included in the INFECTION dataset:

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

VIS (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Vasoactive-Inotropic Score v1.0:

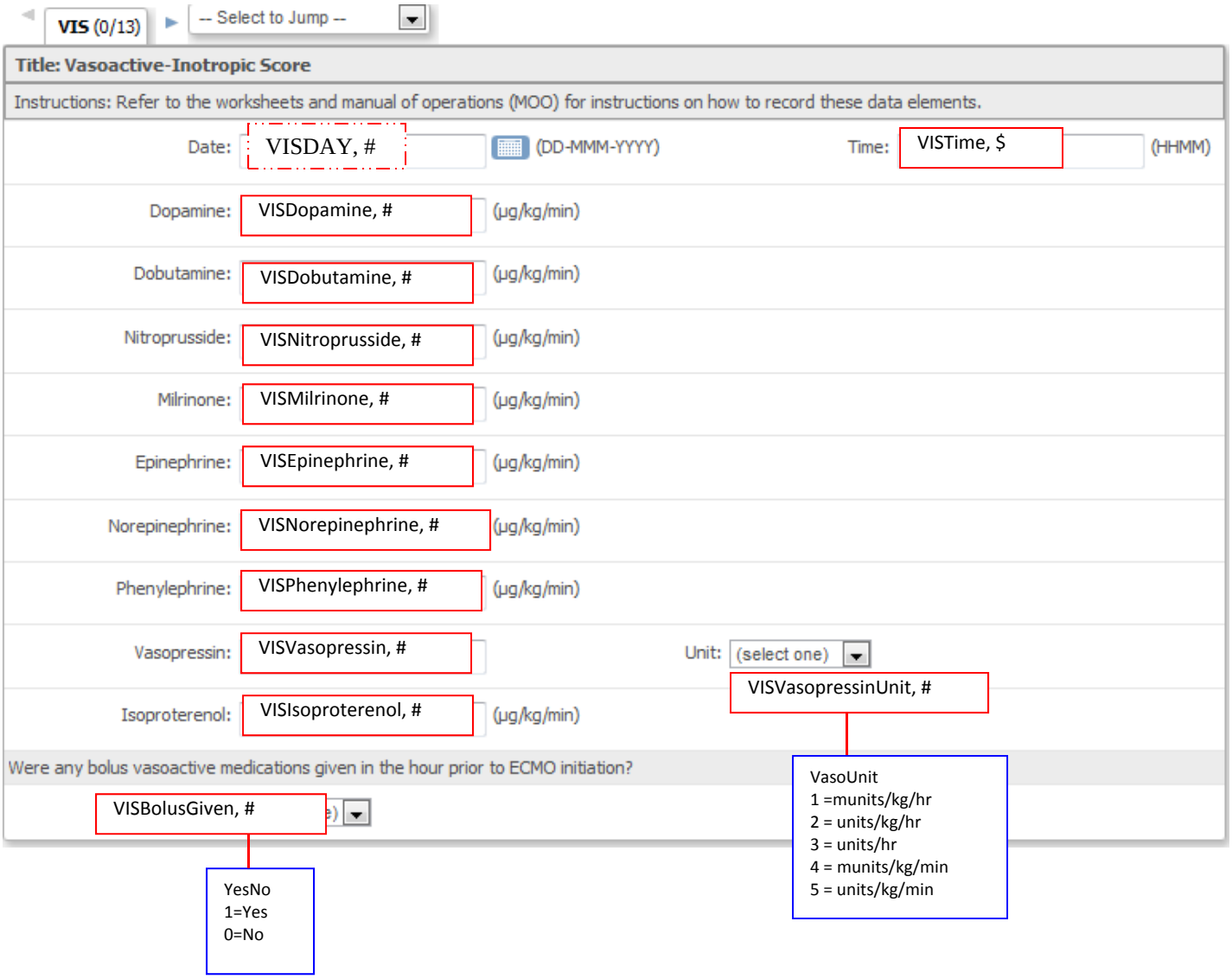


NOTE: Two versions of the Vasoactive-Inotropic Score exist; however, the raw dataset has stacked versions, VIS_ALLVERSIONS.

VIS_v2 (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Vasoactive-Inotropic Score v2.0:



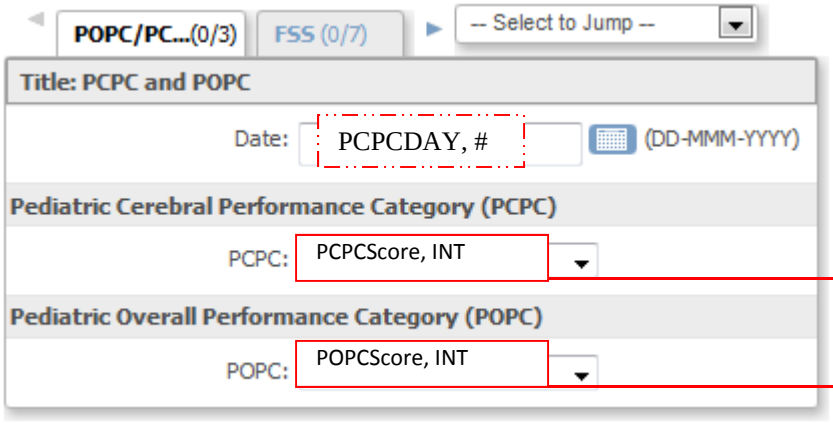
NOTE: Two versions of the Vasoactive-Inotropic Score exist; however, the raw dataset has stacked versions, VIS_ALLVERSIONS.

Severity (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

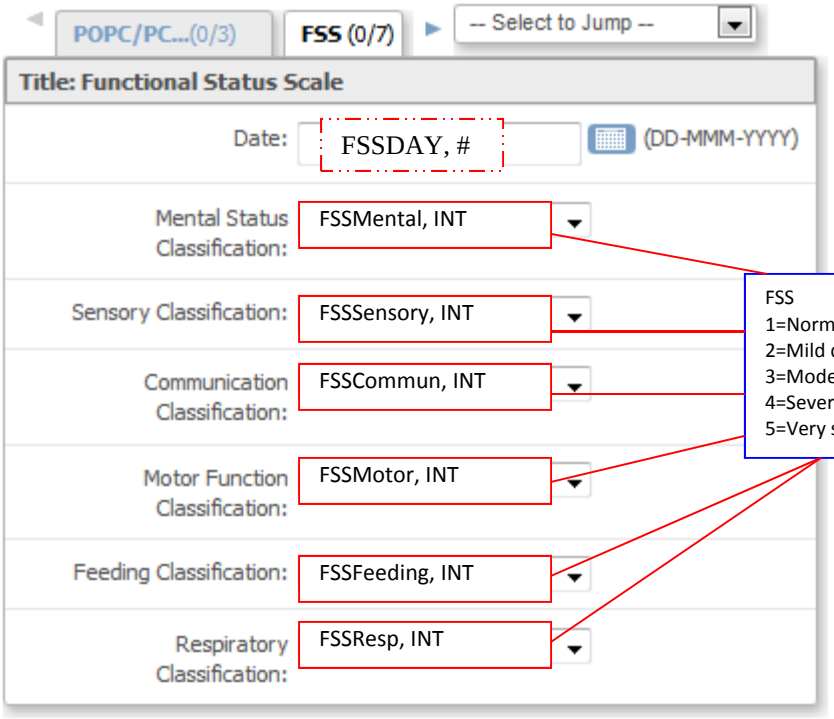
StudyEvent, $

ECMO Functional Status Assessments:



PCPC
1=1 – Normal
2=2 – Mild disability
3=3 – Moderate disability
4=4 – Severe disability
5=5 – Coma/vegetative state
6=6 – Brain Death

POPC
1=1 – Good
2=2 – Mild disability
3=3 – Moderate disability
4=4 – Severe disability
5=5 – Coma/vegetative state
6=6 – Brain Death



FSS
1=Normal
2=Mild dysfunction
3=Moderate dysfunction
4=Severe dysfunction
5=Very severe dysfunction

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

Initiation (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Initiation of ECMO:

ECMO (0/18) -- Select to Jump --

Title: ECMO Information

Initiation date of ECMO: (start of flow): ECMOSTARTDAY, # (DD-MMM-YYYY)

Initiation time of ECMO: ECMOStartTime, $ (HHMM)

Mode of ECMO: ModeECMO, #

Other (specify): ModeECMOOther, $

Mode
1=VA
2=VA + V
3=VA-VV
4=VV
5=VV-VA
6=VVA
7=VVDL
8=VVDL + V
90=Other

Location of ECMO Care: LocationsECMO, # (select one)

ECMOCare
1=PICU
2=NICU
3=CICU

Primary ECMO Indication: IndicationECMO, # (select one)

ECMOInd
1=Respiratory
2=Cardiac
3=ECPR

Does the patient have meconium aspiration syndrome? MAS, # (select one)

Does the patient have congenital diaphragmatic hernia? CDH, # (select one)

Does the patient have congenital cystic adenomatoid malformation? CCAM, # (select one)

Does the patient have persistent pulmonary hypertension of the newborn? PPHTN, # (select one)

Did the patient have any operative procedures in the 24 hours prior to ECMO initiation? OpProcedure, # (select one) If yes, record the date and start time of the most recent procedure

Stop date: OPPROCEDUREDAY, # (DD-MMM-YYYY) Stop time: OpProcedureTime, $ (HHMM)

Was the patient on cardiopulmonary bypass in the 24 hours prior to ECMO initiation? CBP, # (select one) If yes, record the most recent occurrence

Stop date: CPBDAY, # (DD-MMM-YYYY) Stop time: CPBTime, $ (HHMM)

Was the patient placed on ECMO directly from cardiopulmonary bypass? CPBToECMO, # (select one)

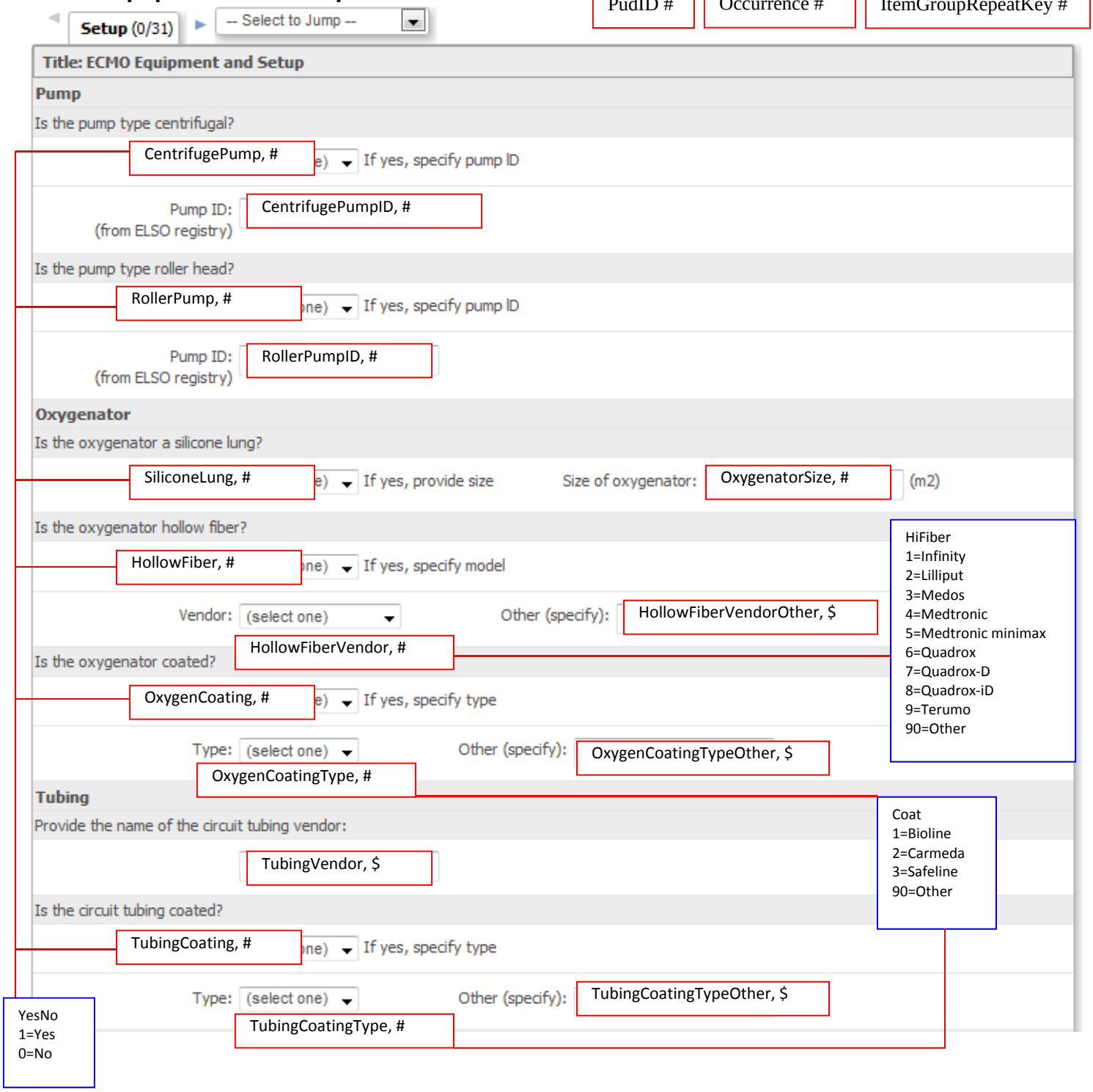
Was the patient placed on ECMO by way of an EXIT procedure? ExitToECMO, # (select one)

YesNo
1=Yes
0=No

Equipment_v2 (1 of 2)

ECMO Equipment and Setup:

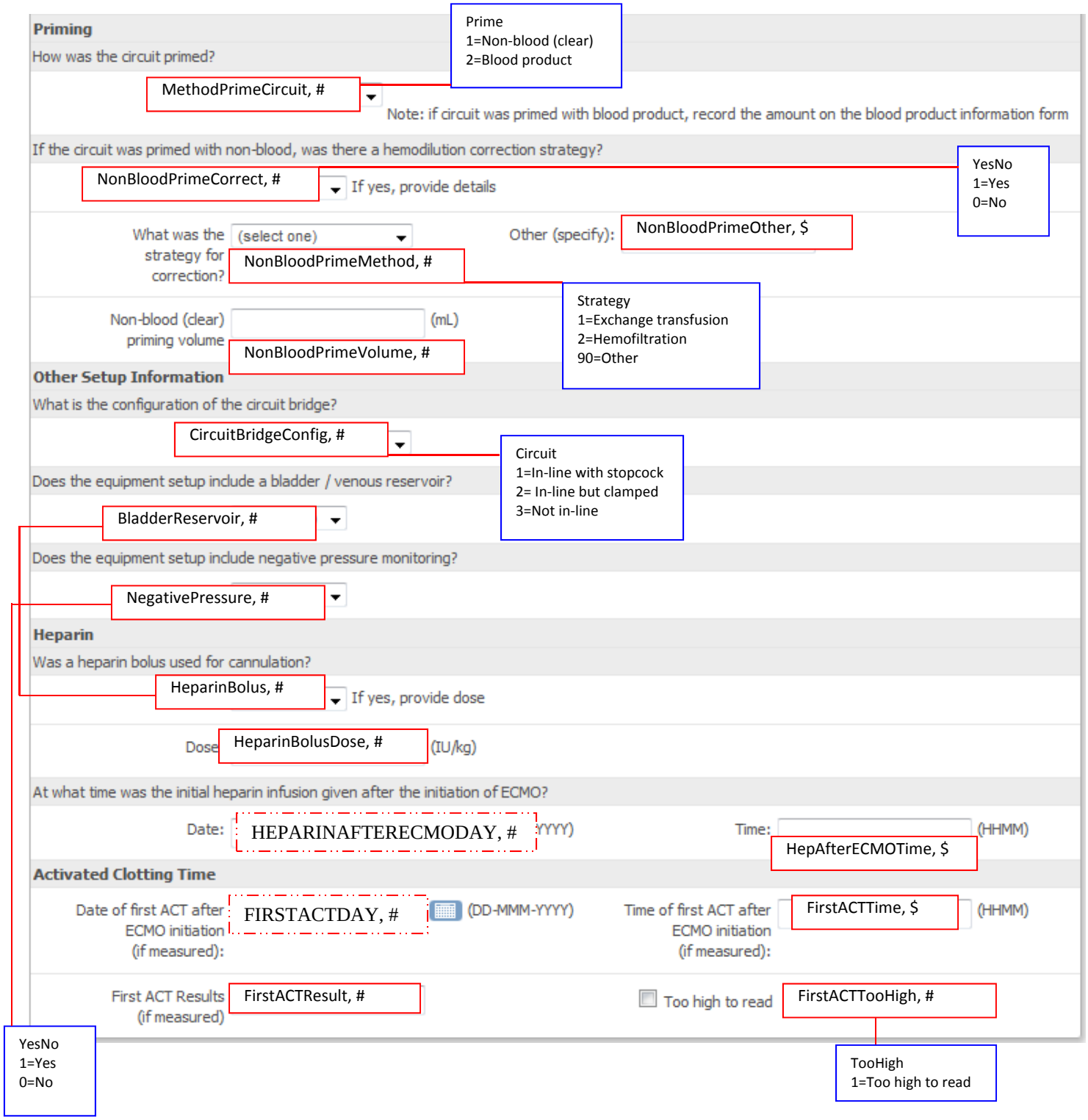
PudID # | Occurrence # | ItemGroupRepeatKey #



Equipment_v2 (2 of 2)

ECMO Equipment and Setup:

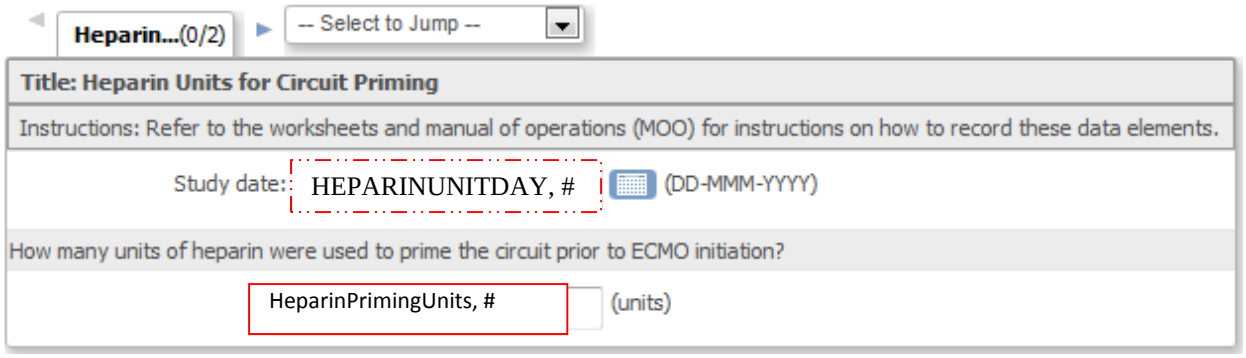
PudID # | Occurrence # | ItemGroupRepeatKey #



HeparinPrime (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

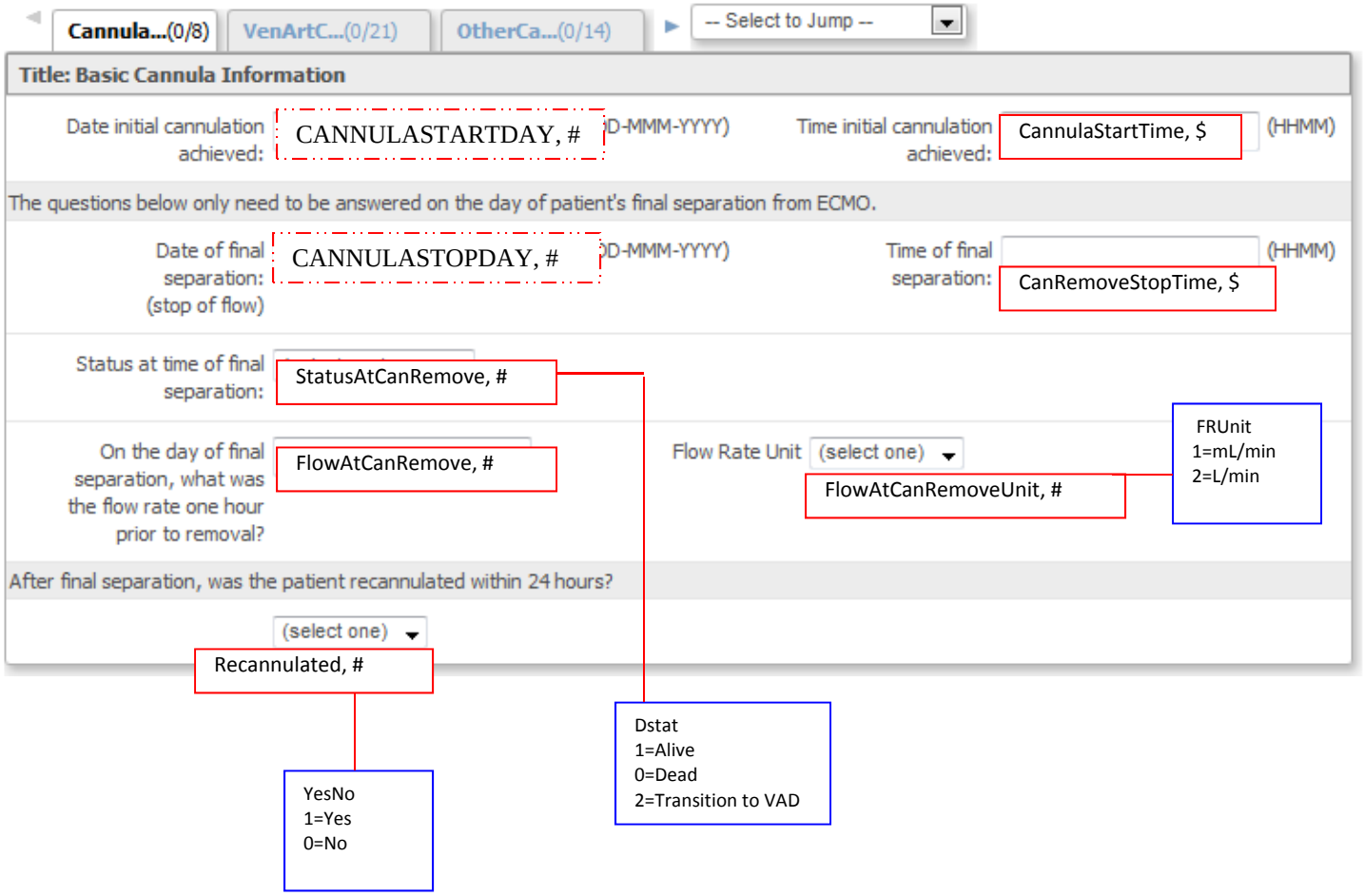
ECMO Heparin Units for Circuit Priming:



Cannulation_v2 (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

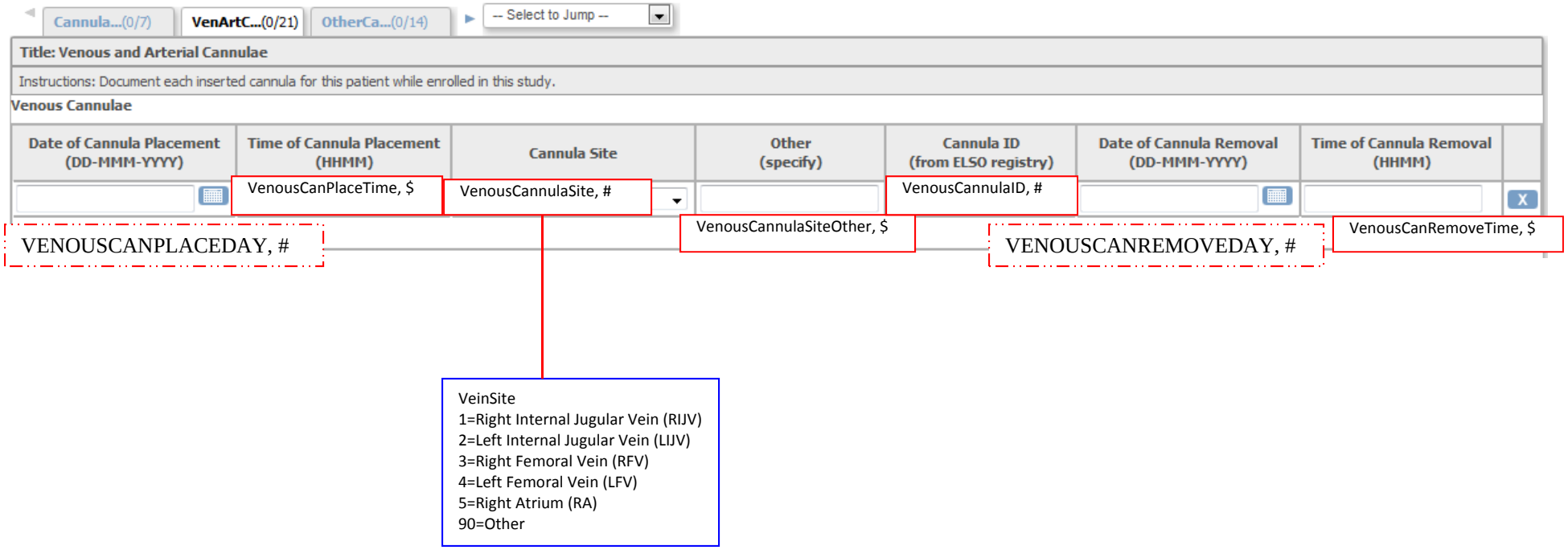
ECMO Cannulation Characteristics:



Cannulation_Venous_v2 (1 of 1)

ECMO Cannulation Characteristics :

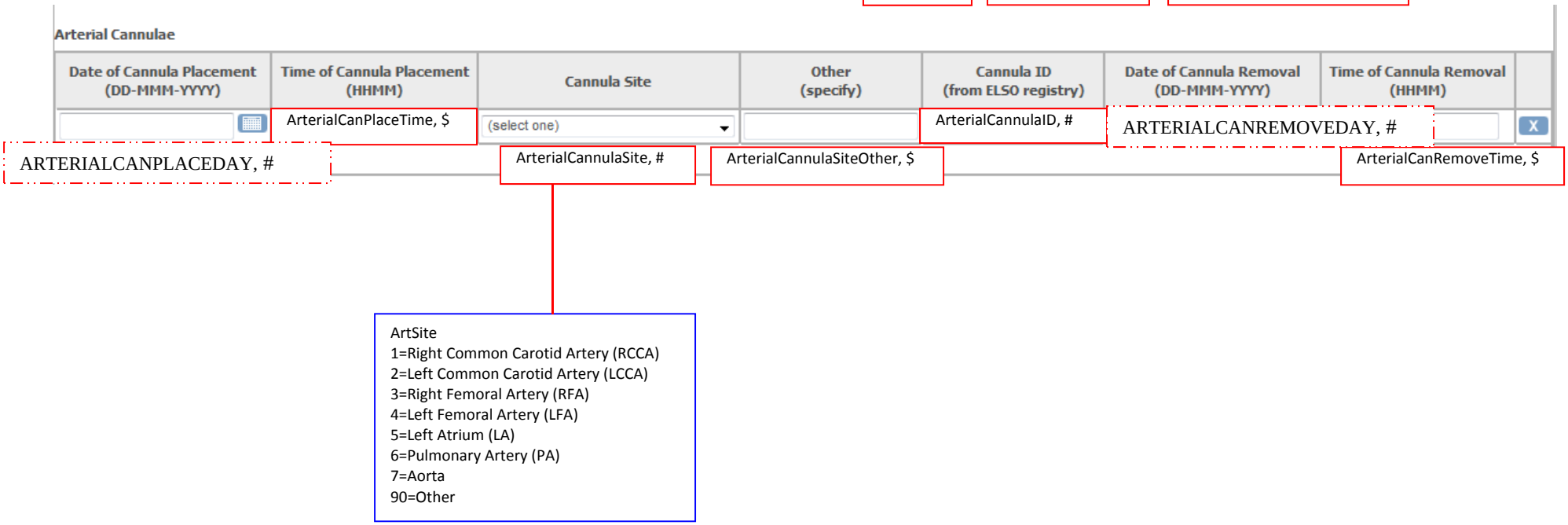
PudID # | Occurrence # | ItemGroupRepeatKey #



Cannulation_Arterial_v2 (1 of 1)

ECMO Cannulation Characteristics:

PudID # | Occurrence # | ItemGroupRepeatKey #

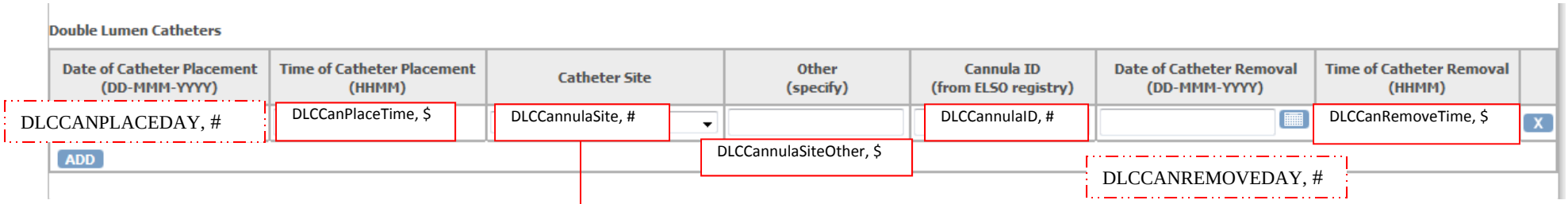


ArtSite
1=Right Common Carotid Artery (RCCA)
2=Left Common Carotid Artery (LCCA)
3=Right Femoral Artery (RFA)
4=Left Femoral Artery (LFA)
5=Left Atrium (LA)
6=Pulmonary Artery (PA)
7=Aorta
90=Other

Cannulation_DLC_v2 (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Cannulation Characteristics:

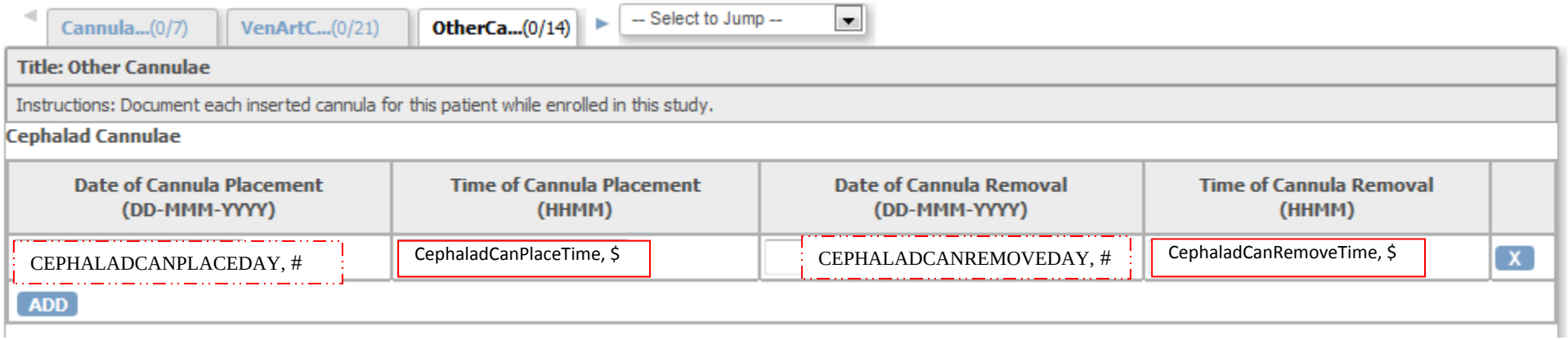


DLCSite
1=Right Internal Jugular Vein (RIJV)
2=Left Internal Jugular Vein (LIJV)
3=Right Femoral Vein (RFV)
4=Left Femoral Vein (LFV)
90=Other

Cannulation_Cephalad_v2 (1 of 1)

ECMO Cannulation Characteristics:

PudID # | Occurrence # | ItemGroupRepeatKey #



Cannulation_LAD_v2 (1 of 1)

ECMO Cannulation Characteristics:

PudID # | Occurrence # | ItemGroupRepeatKey #

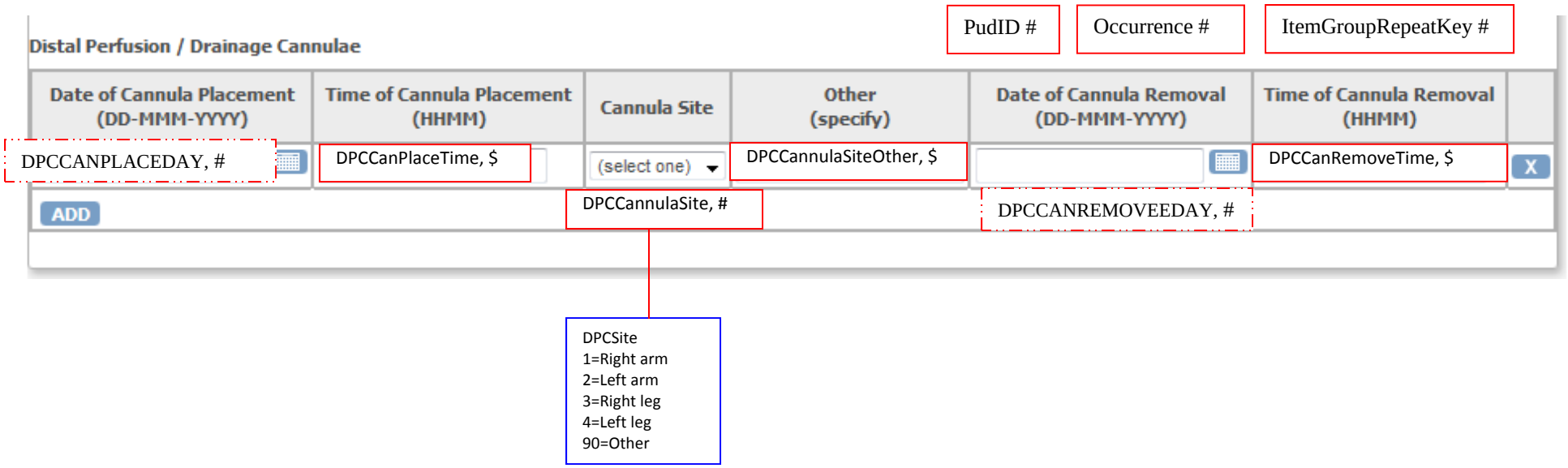
Left Atrial Drainage Cannulae

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

ADD

Cannulation_DPC_v2 (1 of 1)

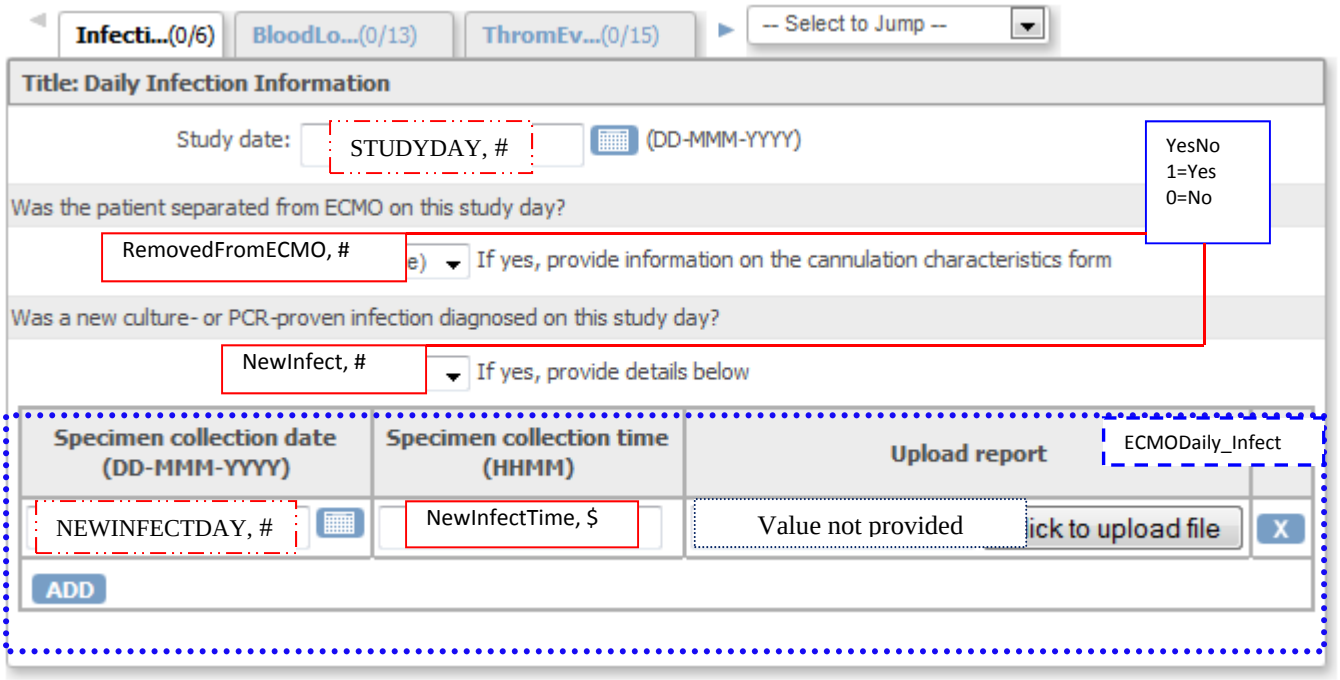
ECMO Cannulation Characteristics:



ECMODaily (1 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Related Daily Data v1.0:

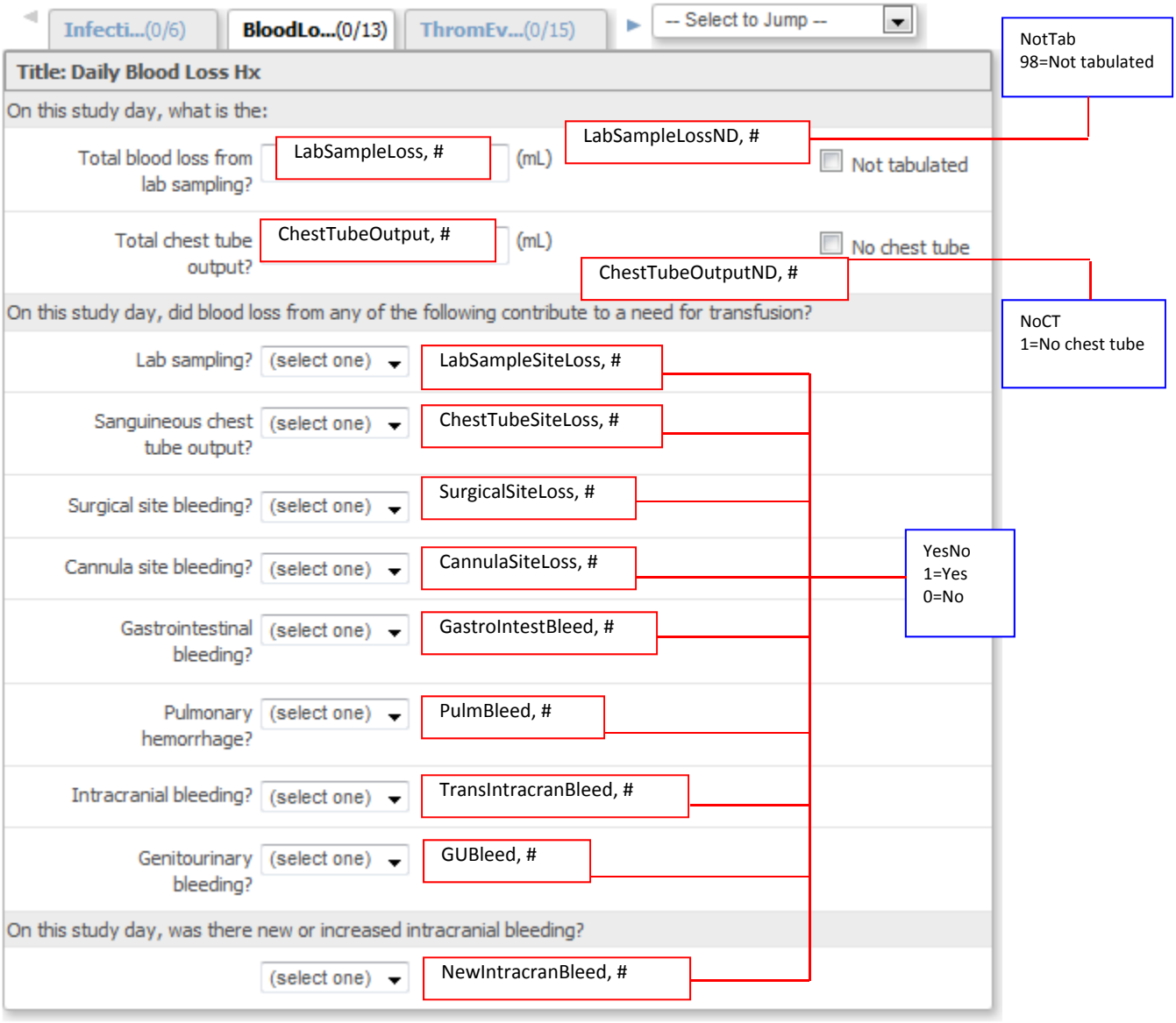


NOTE: Three versions of the ECMO Related Daily Data exist, including the tables embedded within the CRF; however, the raw dataset has stacked versions, ECMODAILY_ALLVERSIONS, ECMODAILY_INFECT_ALLVERSIONS.

ECMODaily (2 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

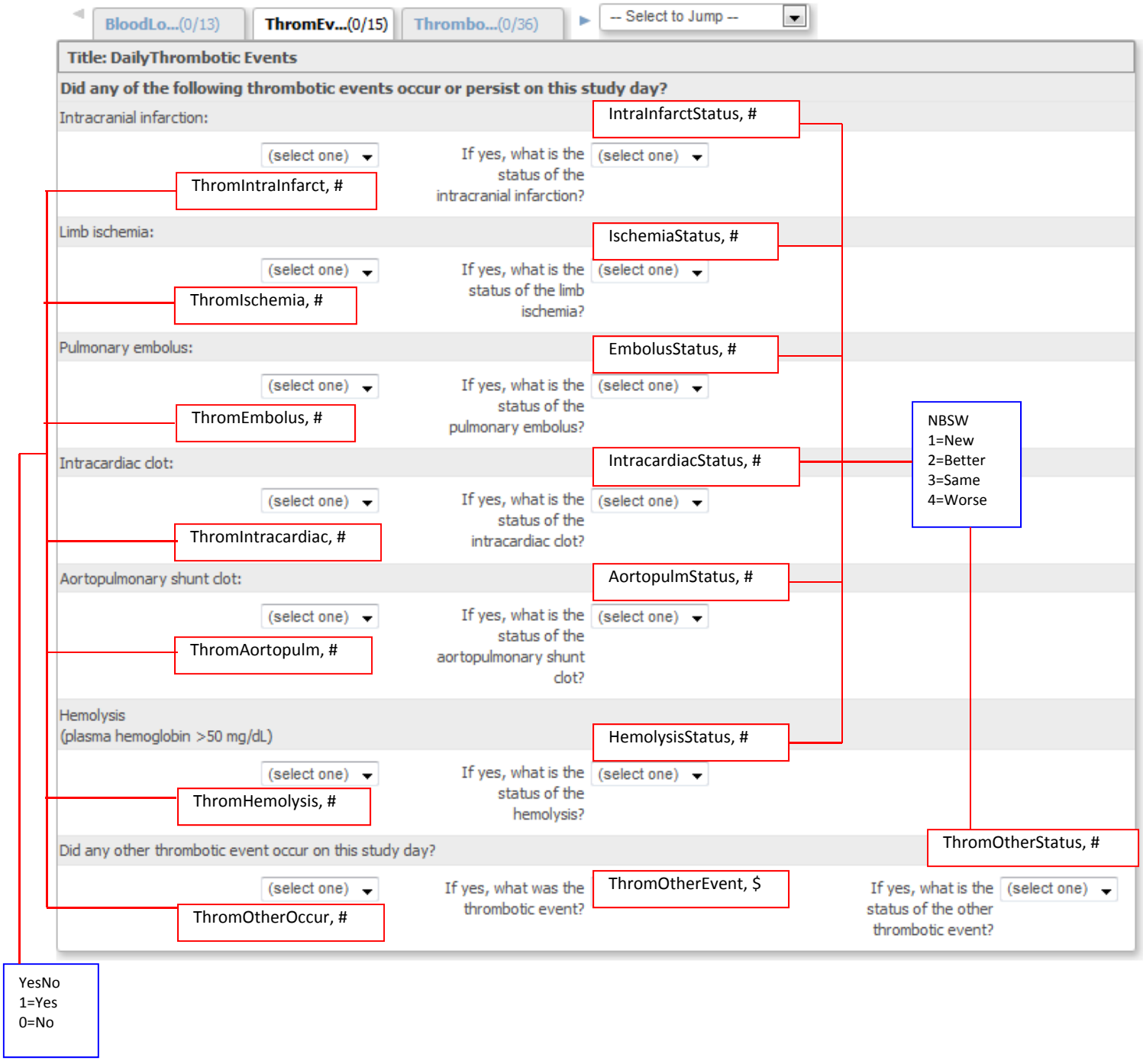
ECMO Related Daily Data v1.0:



ECMODaily (3 of 8)

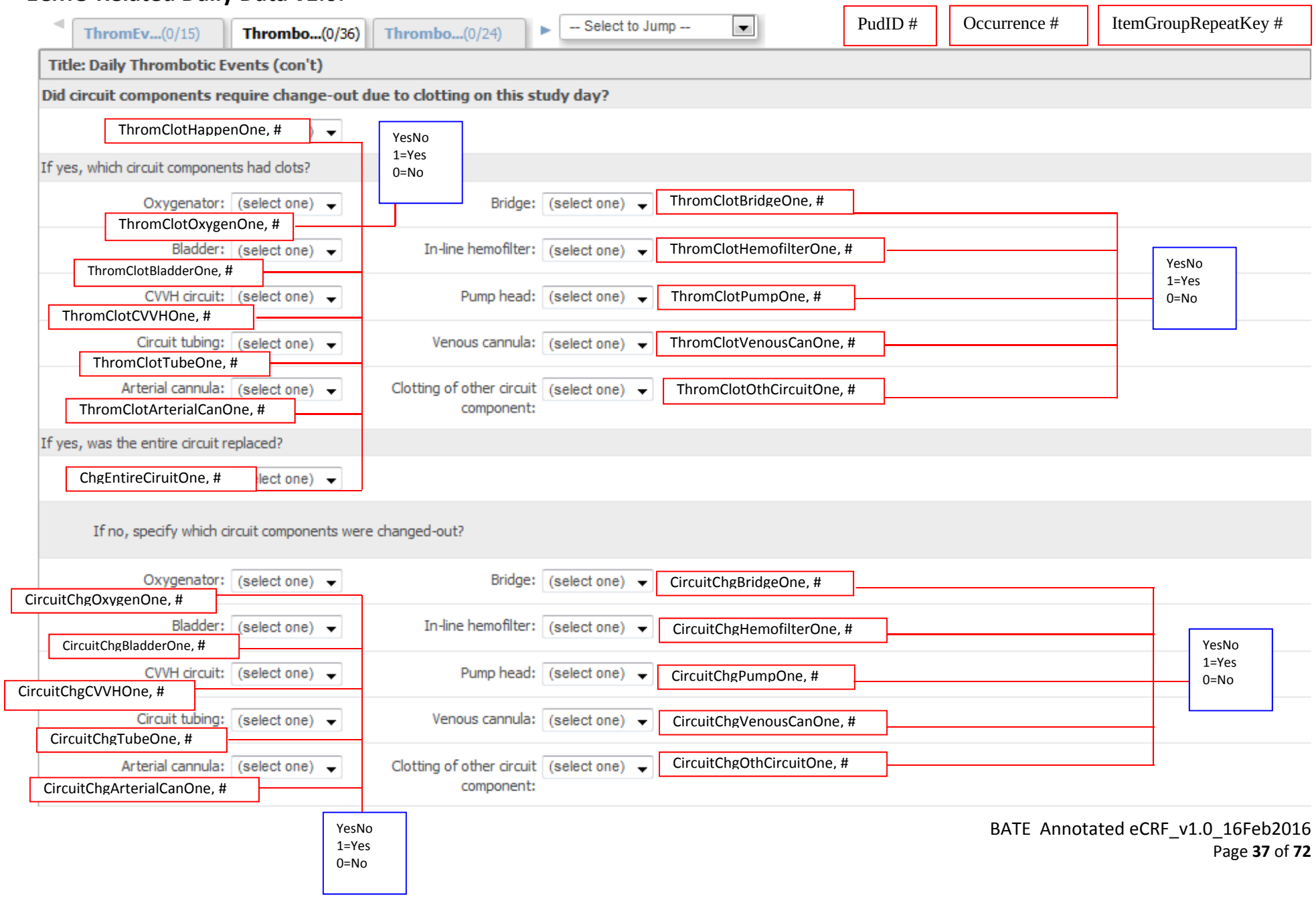
PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Related Daily Data v1.0:



ECMODaily (4 of 8)

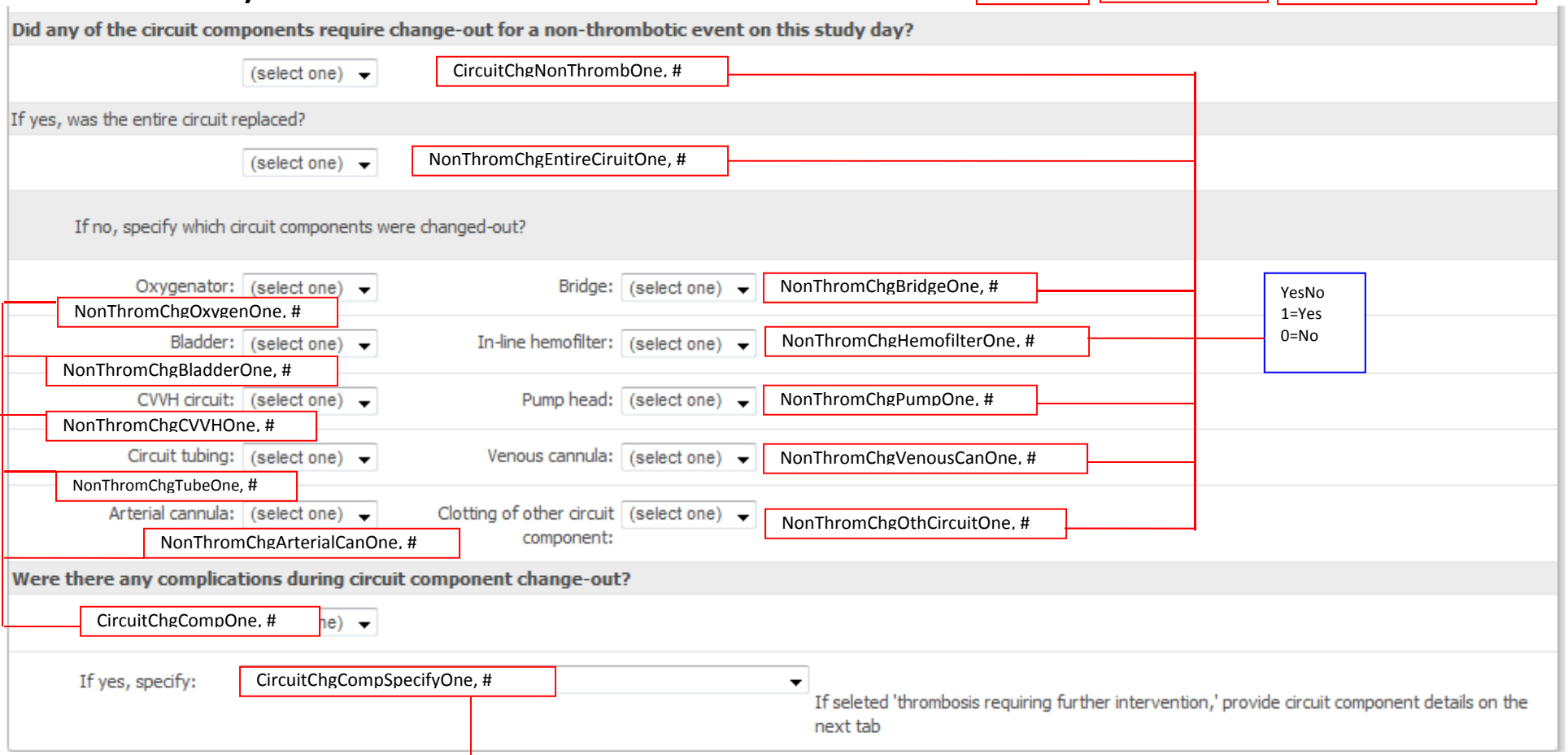
ECMO Related Daily Data v1.0:



ECMODaily (5 of 10)

PudID # | Occurrence # | ItemGroupRepeatKey #

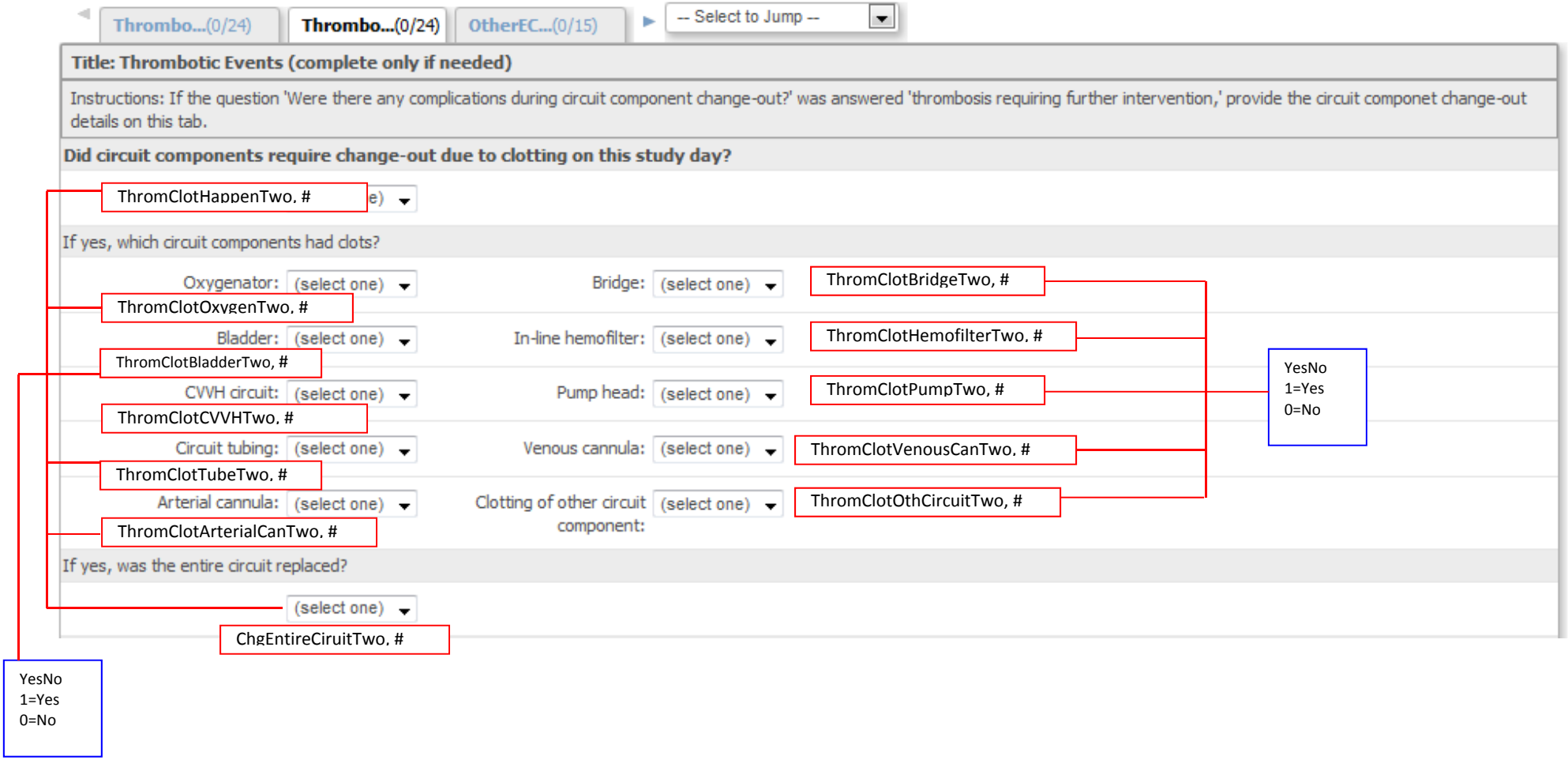
ECMO Related Daily Data v1.0:



ECMODaily (6 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

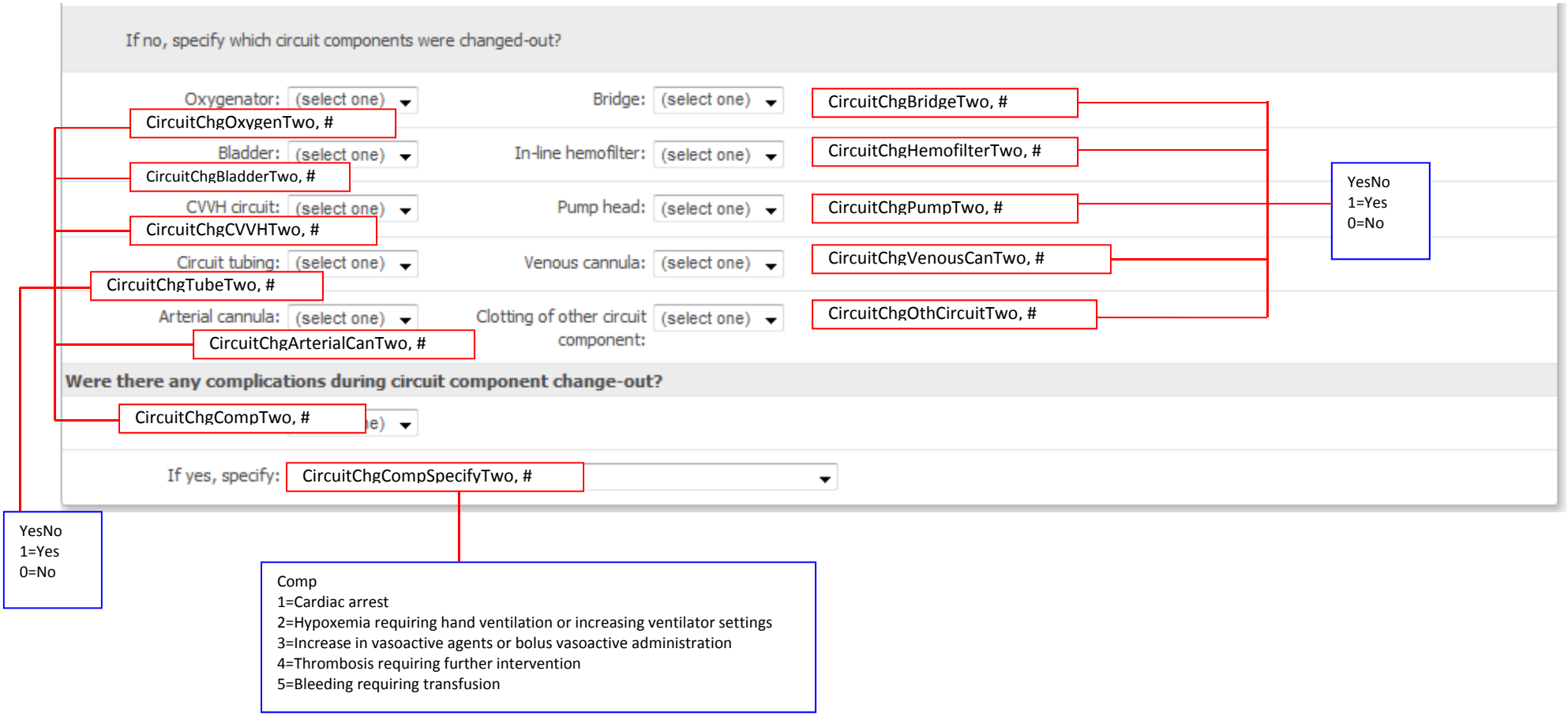
ECMO Related Daily Data v1.0:



ECMODaily (7 of 8)

ECMO Related Daily Data v1.0:

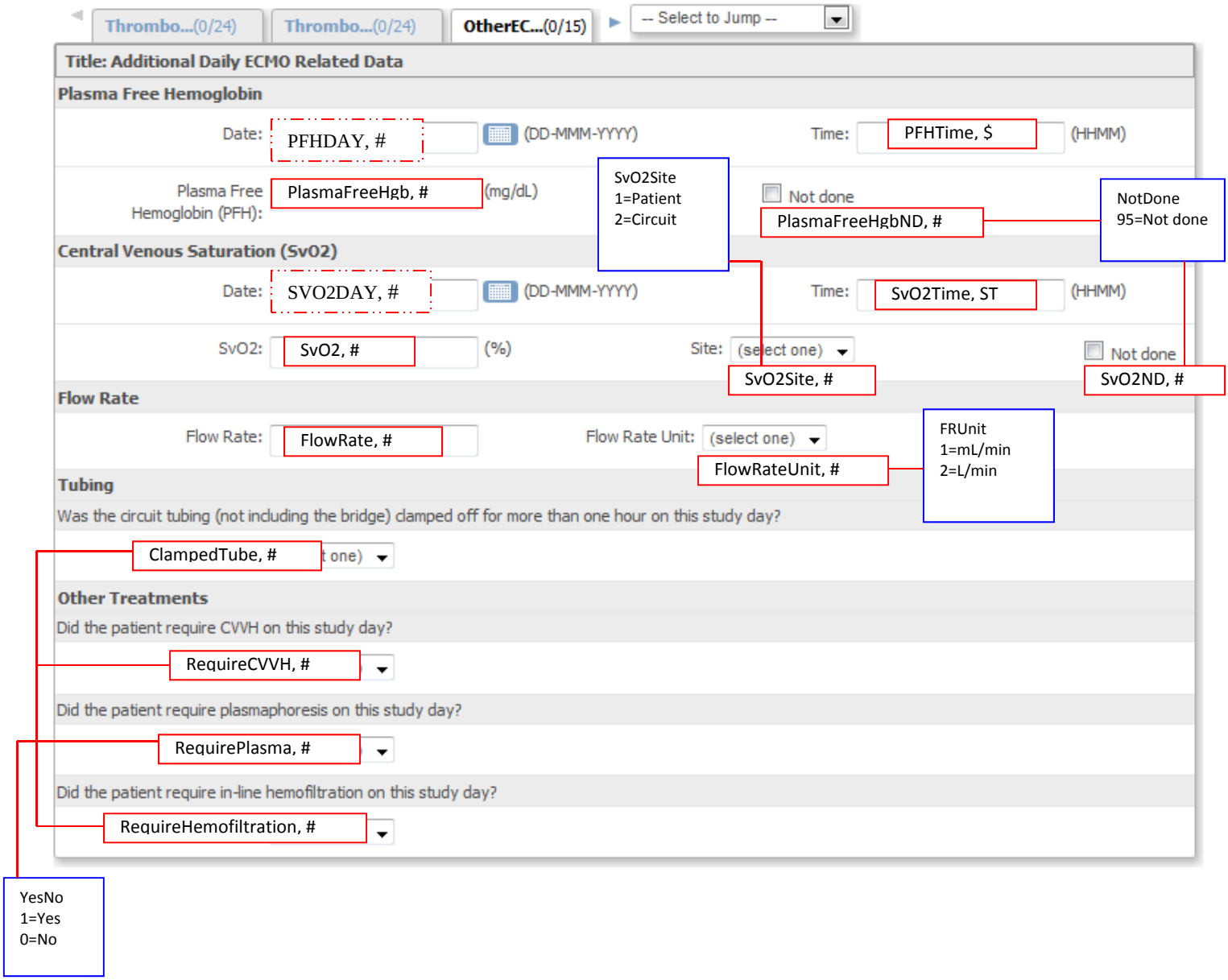
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily (8 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

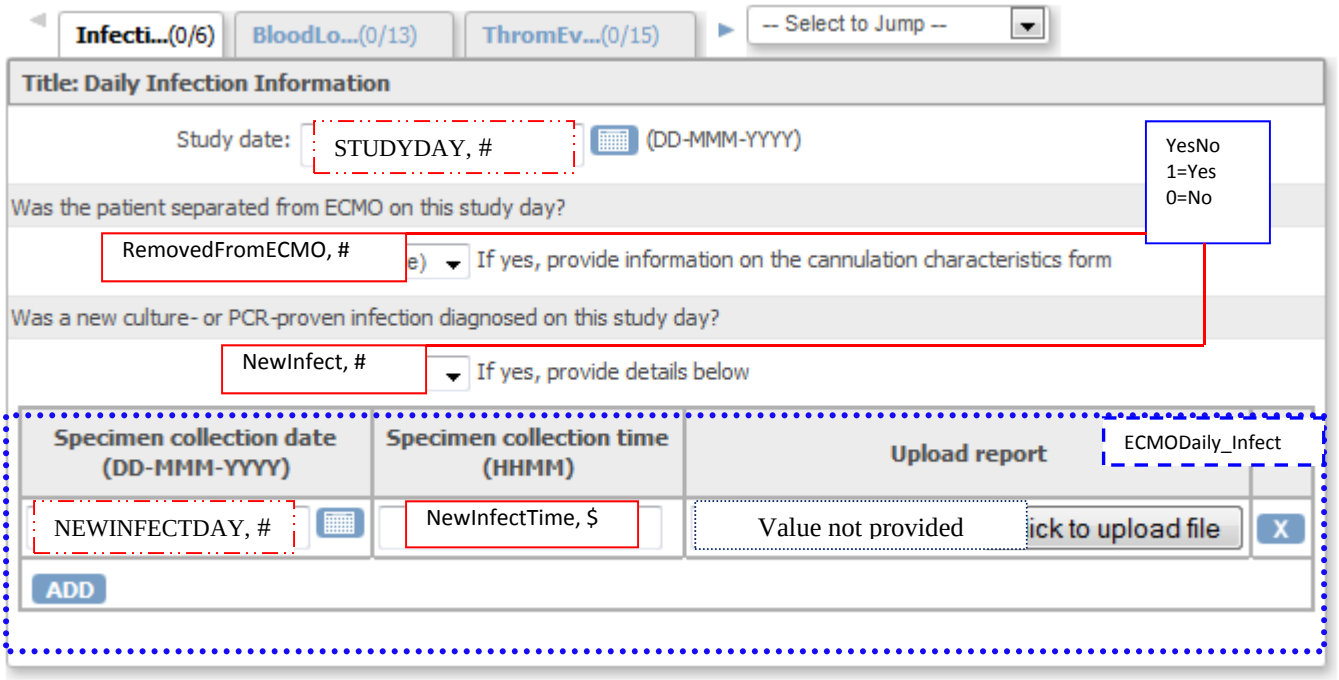
ECMO Related Daily Data v1.0:



ECMODaily_v2 (1 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

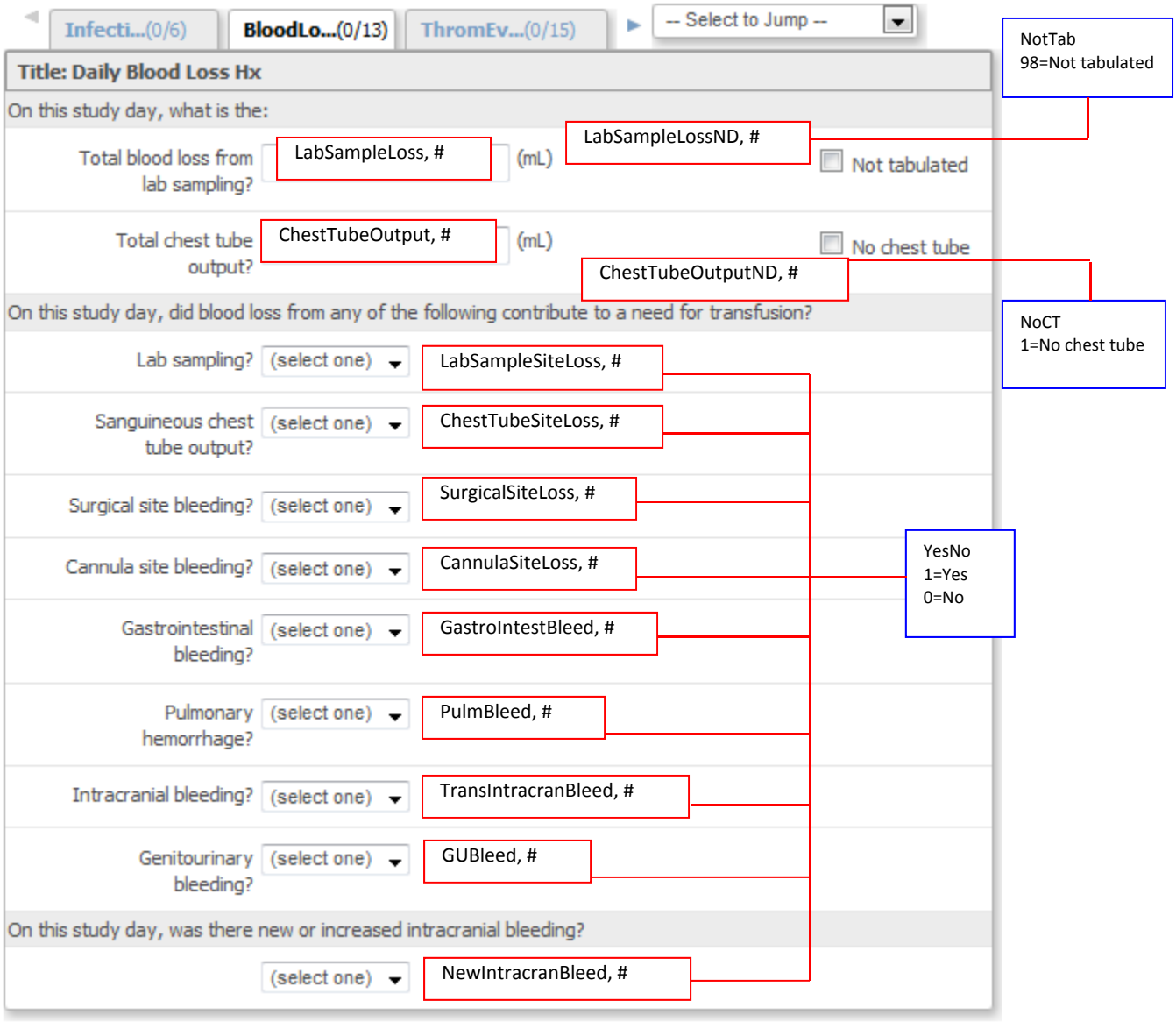
ECMO Related Daily Data v2.0:



ECMODaily_v2 (2 of 8)

ECMO Related Daily Data v2.0:

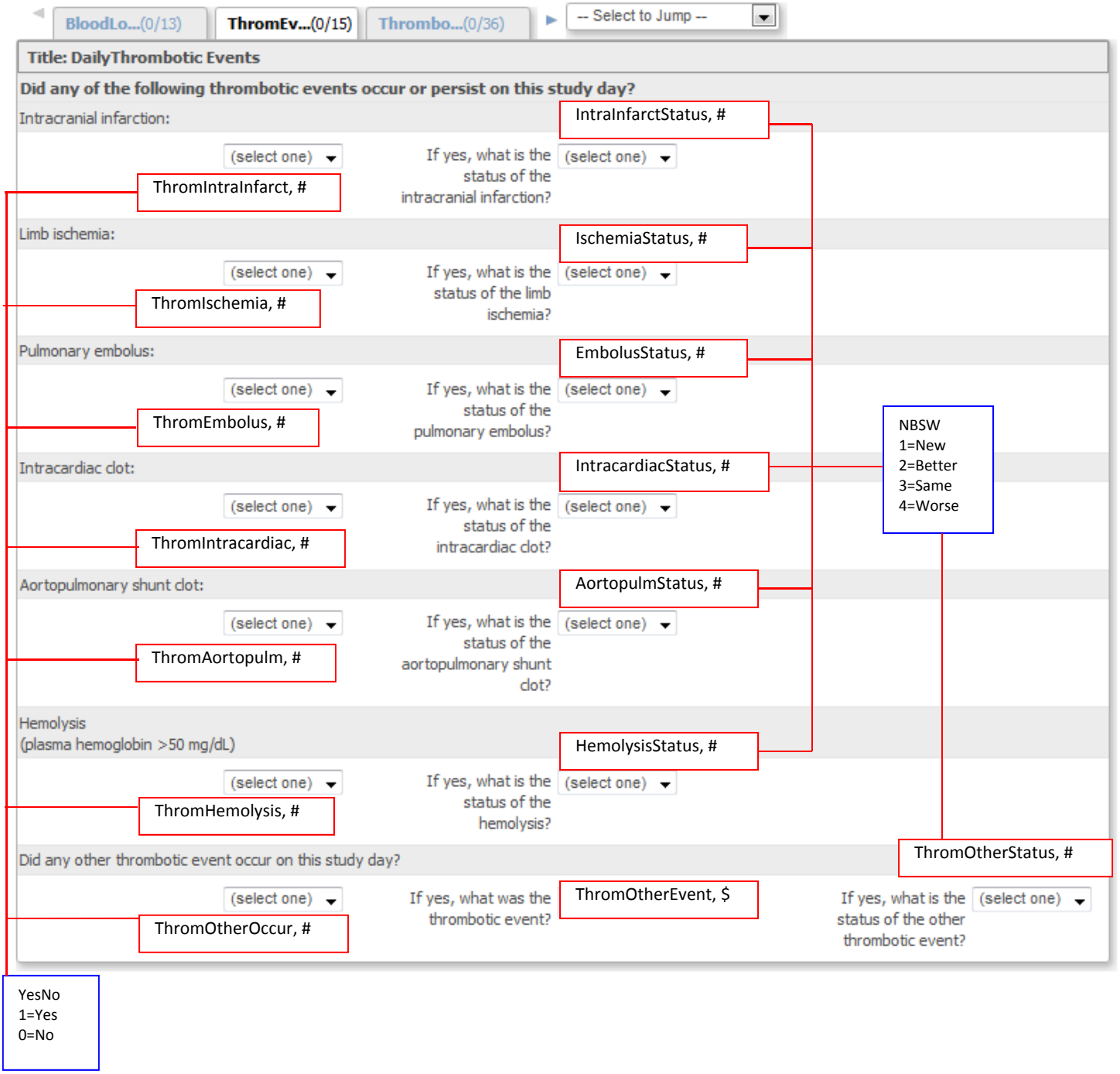
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v2 (3 of 8)

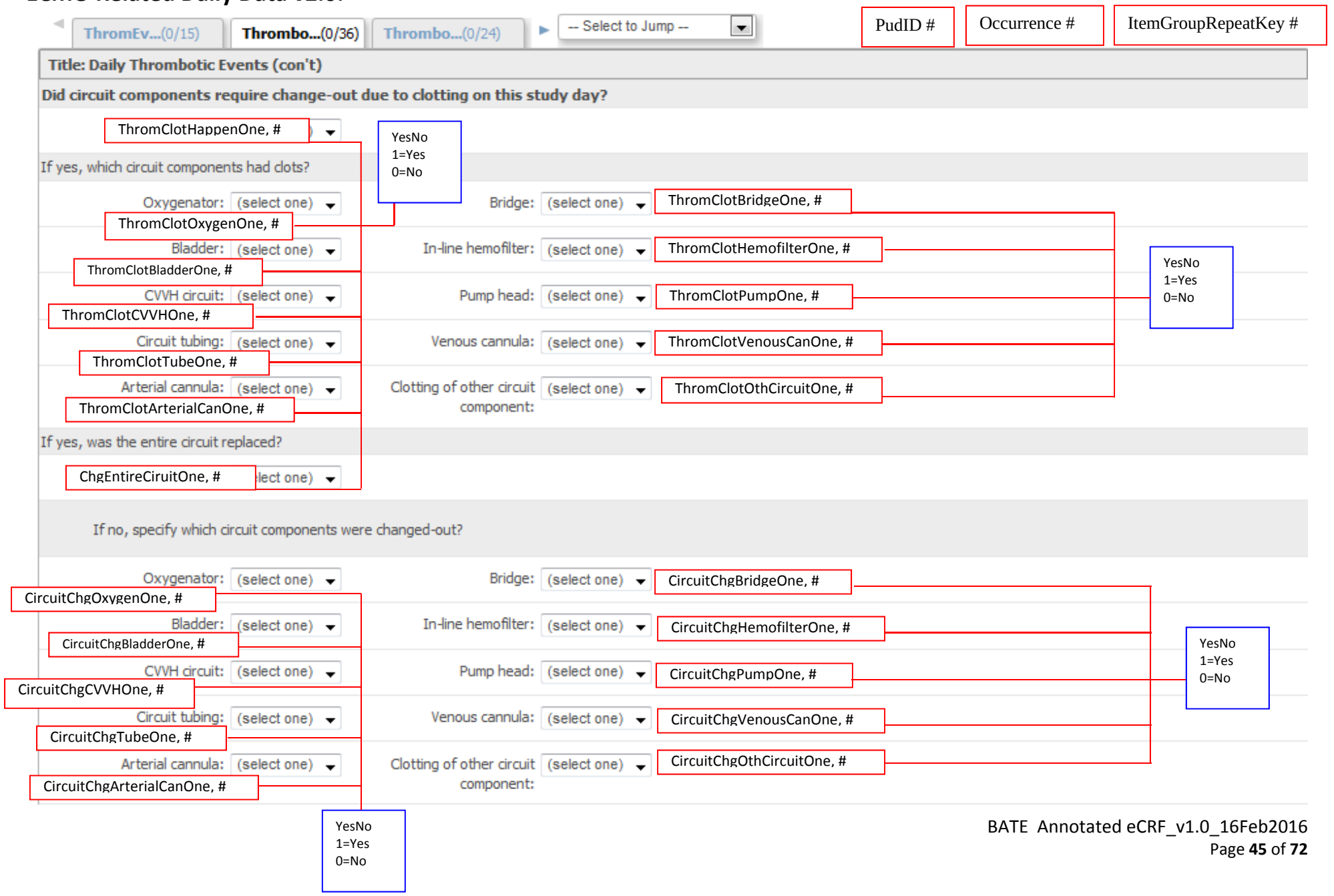
PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Related Daily Data v2.0:



ECMODaily_v2 (4 of 8)

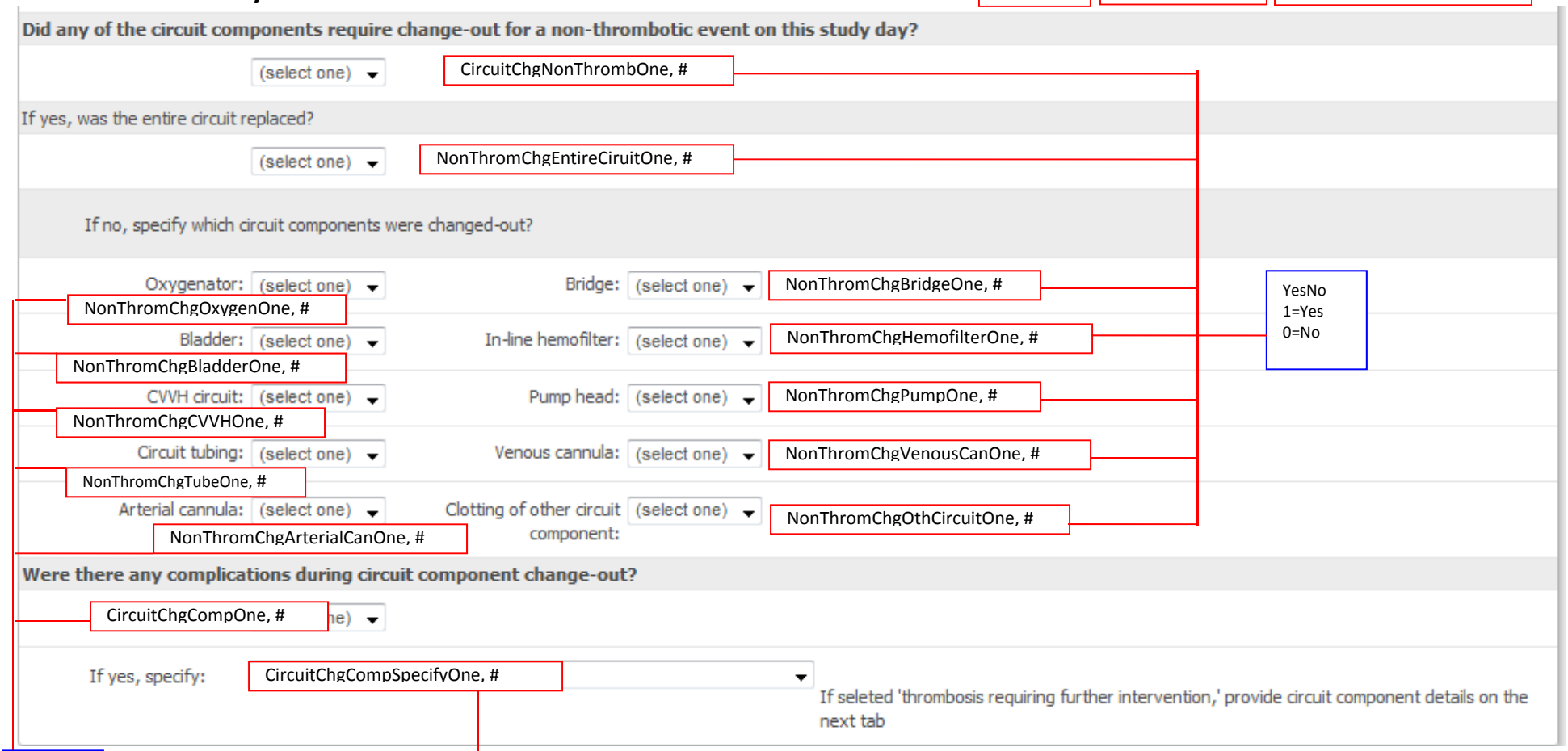
ECMO Related Daily Data v2.0:



ECMODaily_v2 (5 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

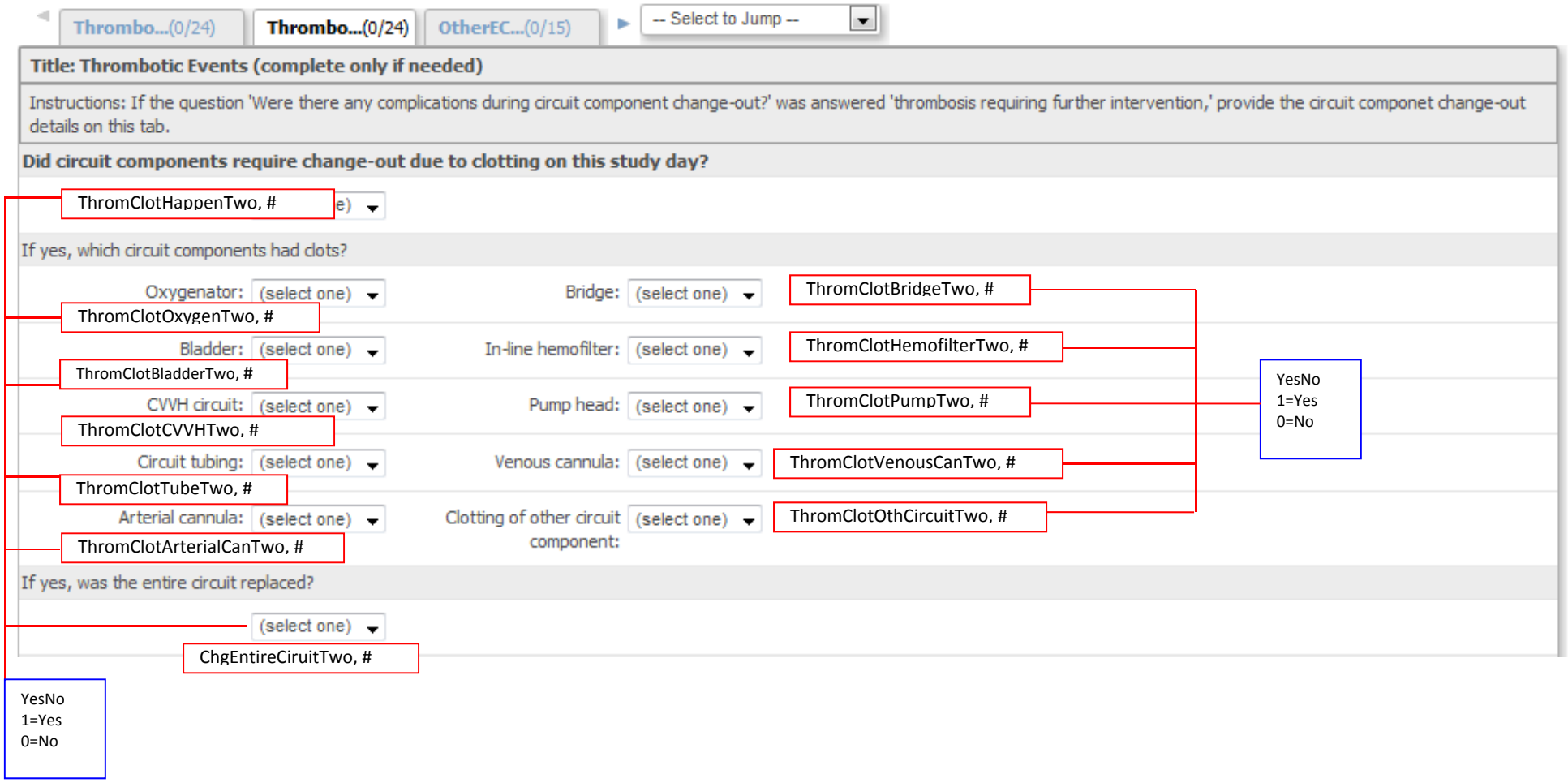
ECMO Related Daily Data v2.0:



ECMODaily_v2 (6 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

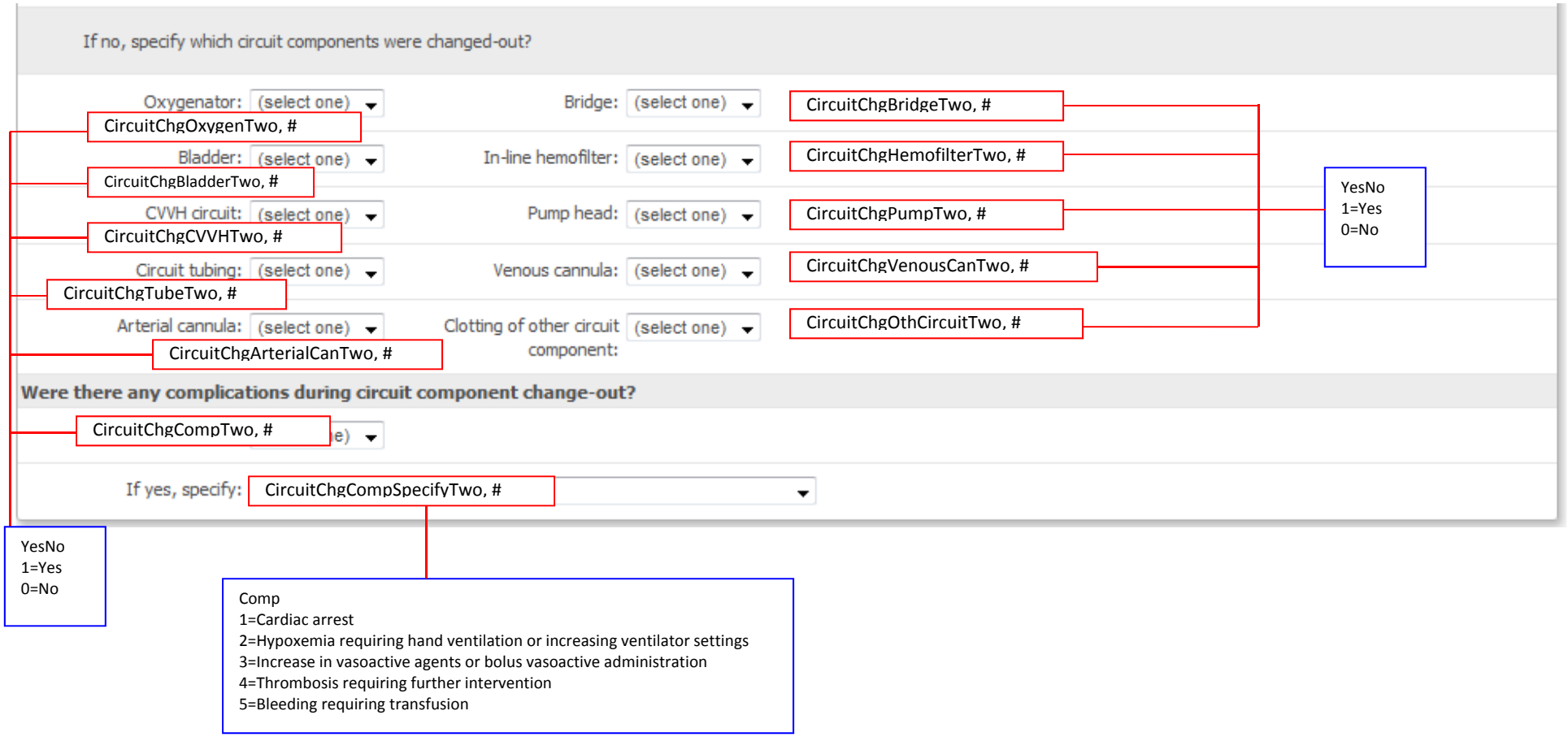
ECMO Related Daily Data v2.0:



ECMODaily_v2 (7 of 8)

ECMO Related Daily Data v2.0:

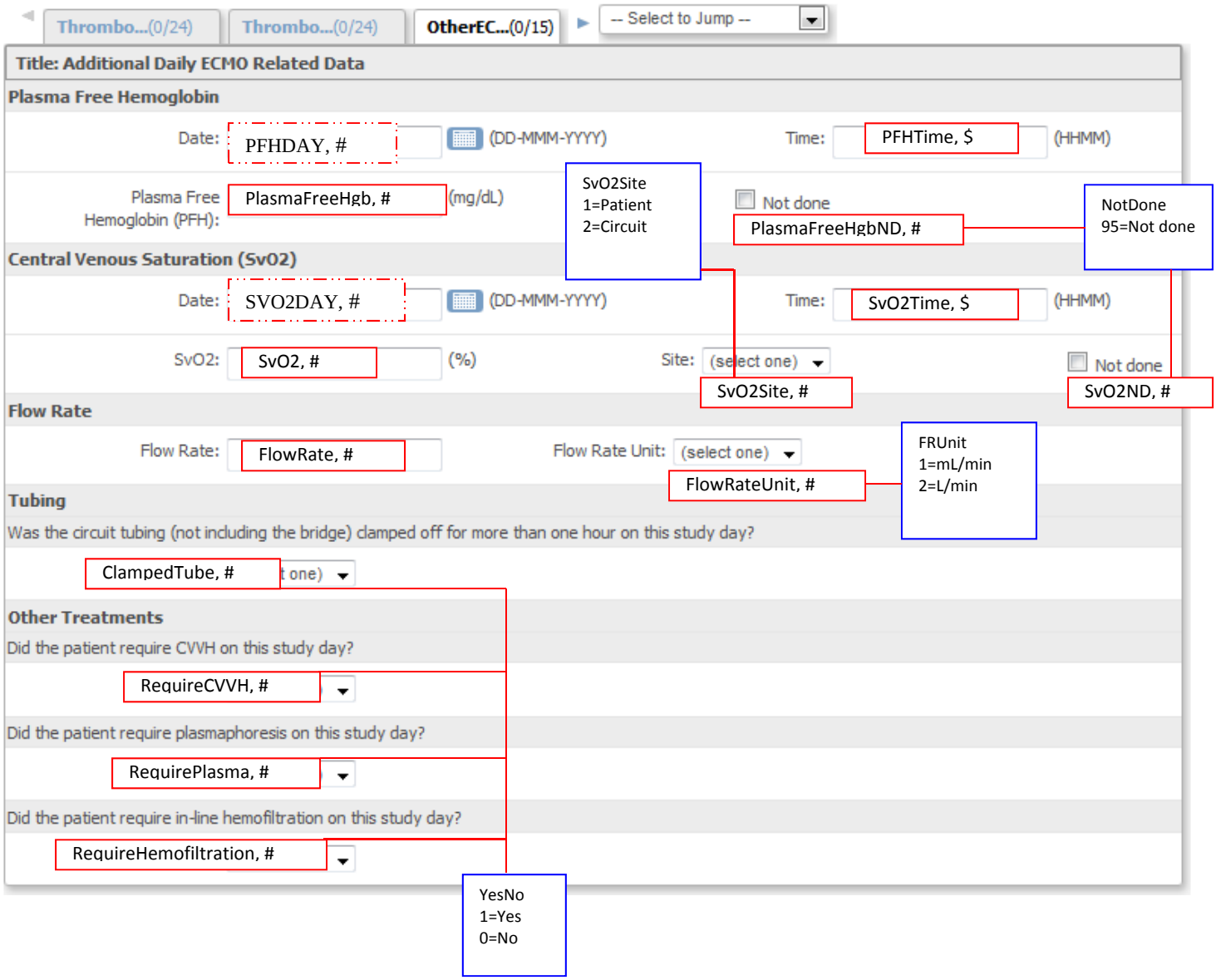
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v2 (8 of 8)

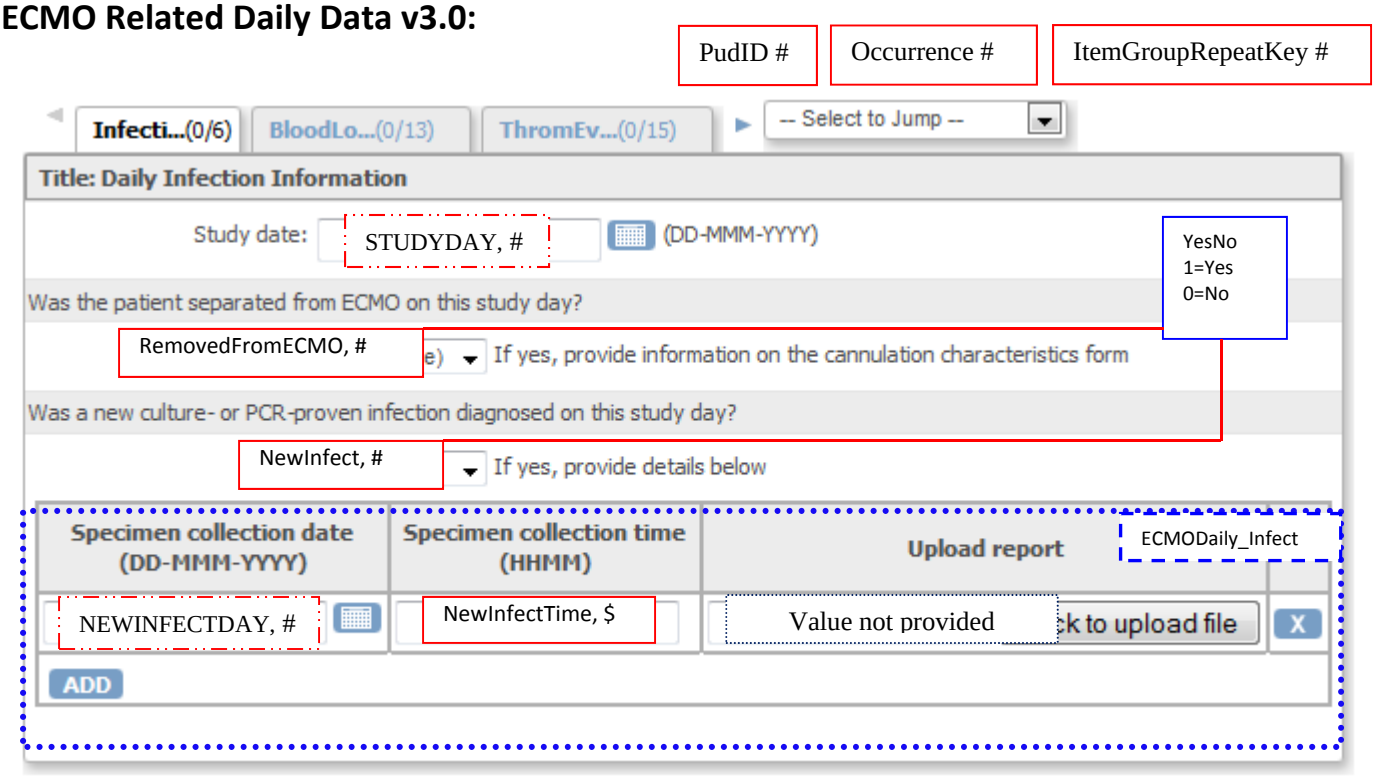
PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Related Daily Data v2.0:



ECMODaily_v3 (1 of 8)

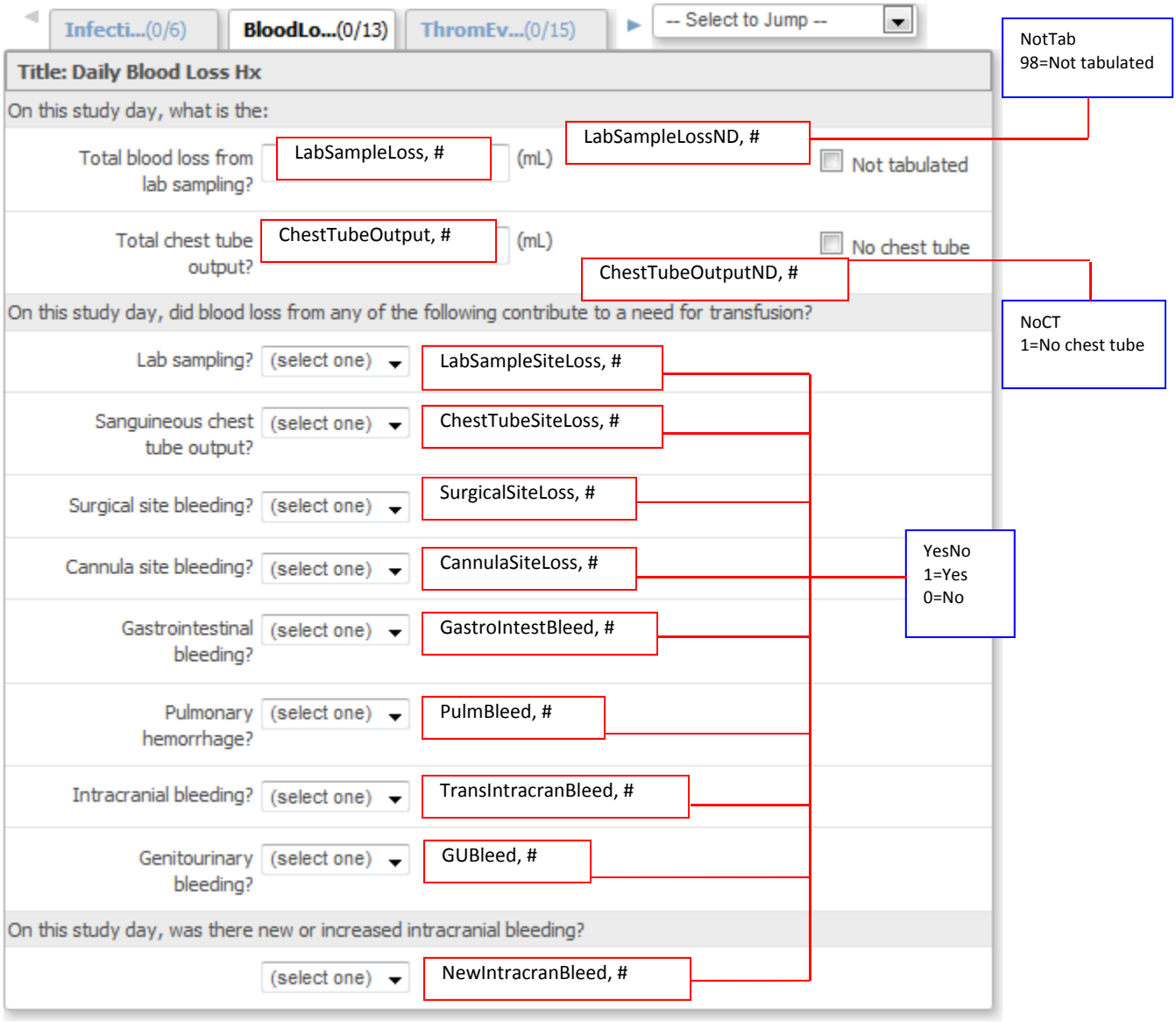
ECMO Related Daily Data v3.0:



ECMODaily_v3 (2 of 8)

ECMO Related Daily Data v3.0:

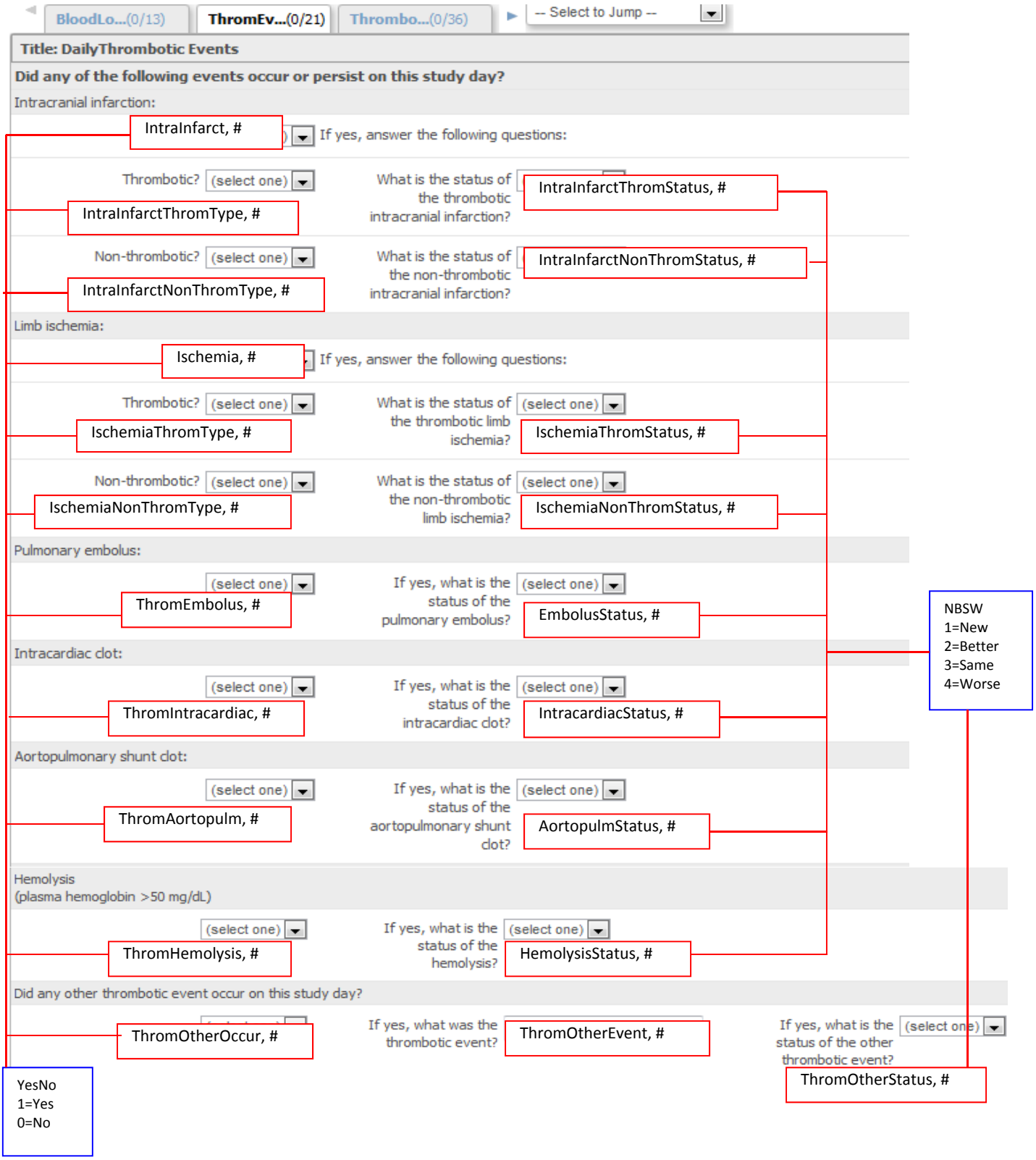
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v3 (3 of 8)

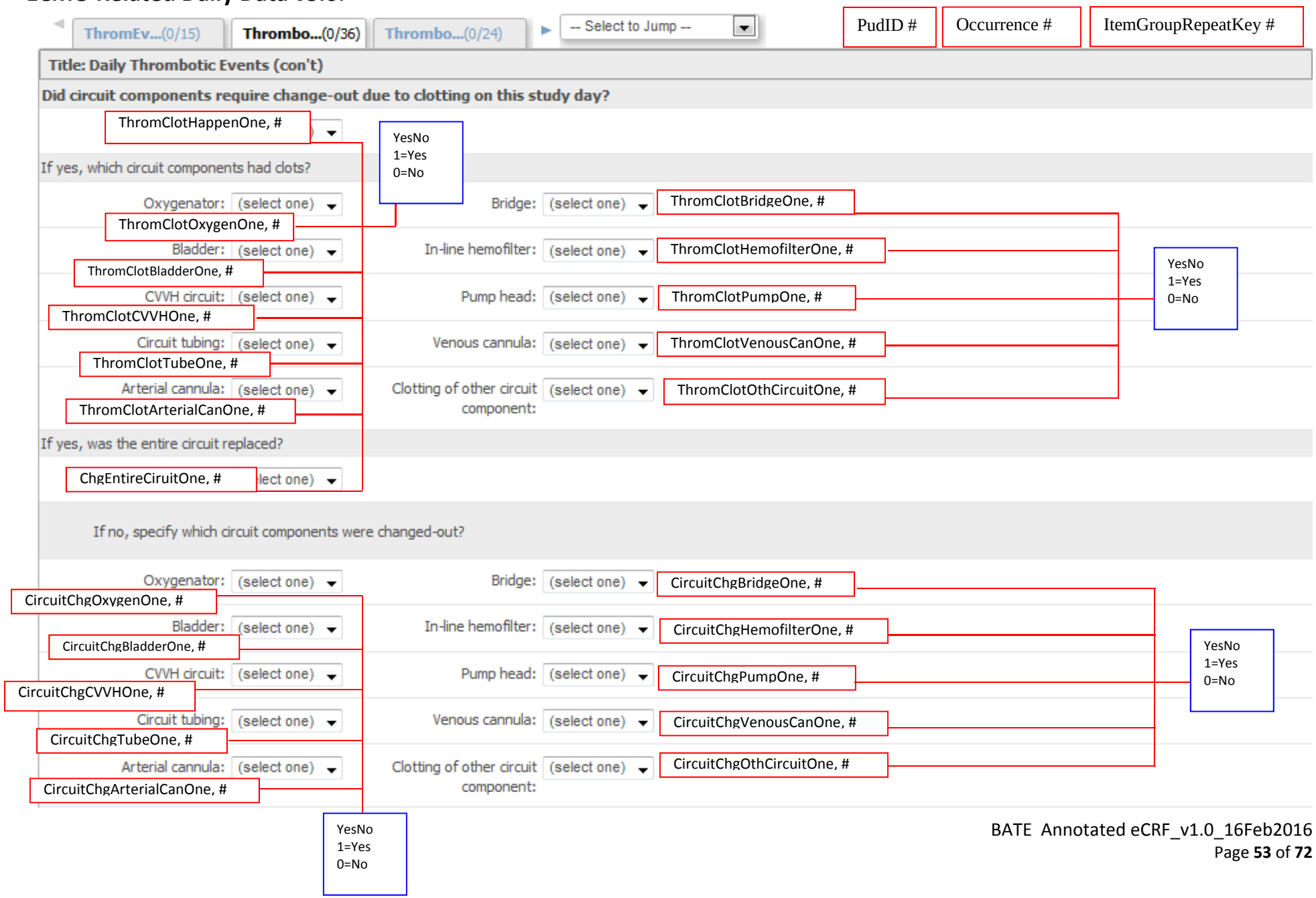
ECMO Related Daily Data v3.0:

PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v3 (4 of 8)

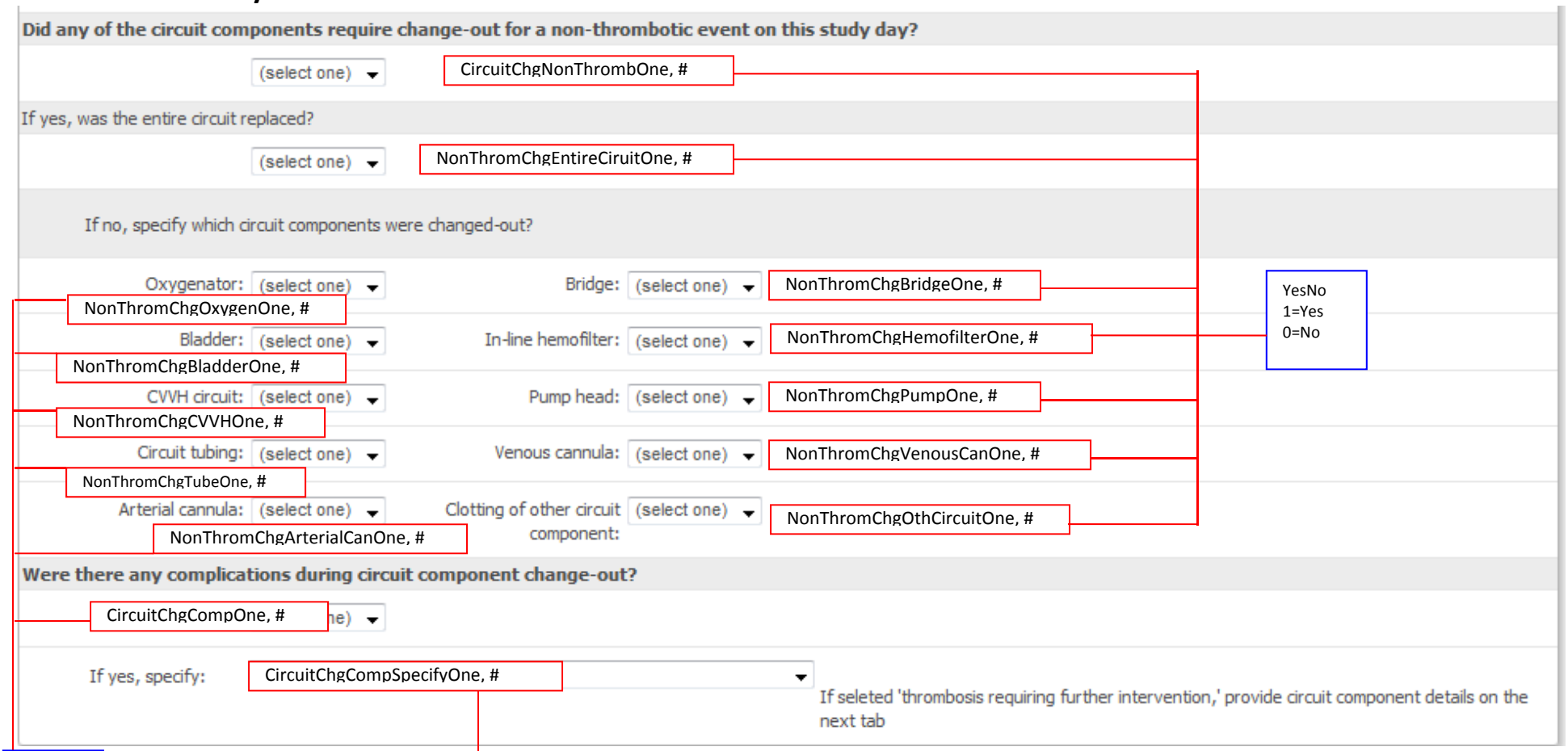
ECMO Related Daily Data v3.0:



ECMODaily_v3 (5 of 18

PudID # | Occurrence # | ItemGroupRepeatKey #

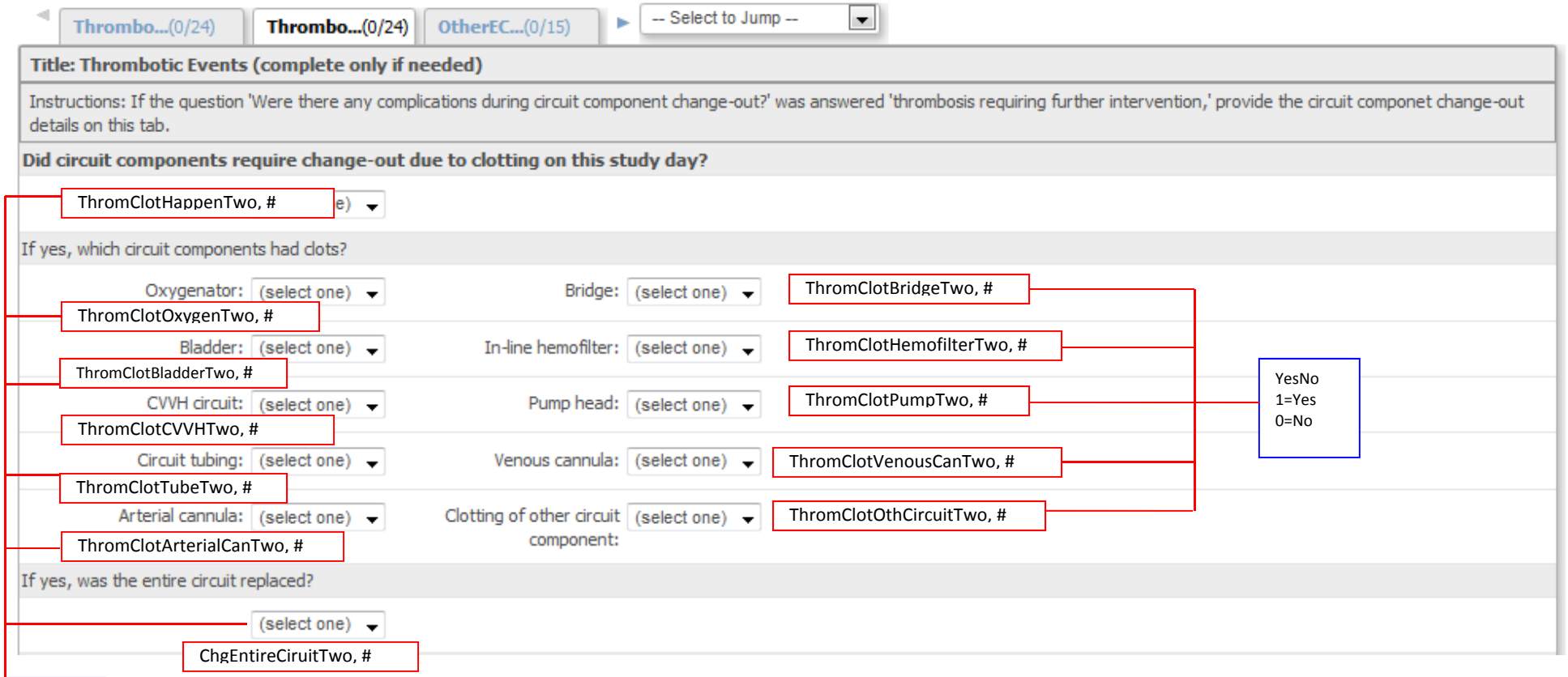
ECMO Related Daily Data v3.0:



ECMODaily_v3 (6 of 8)

ECMO Related Daily Data v3.0:

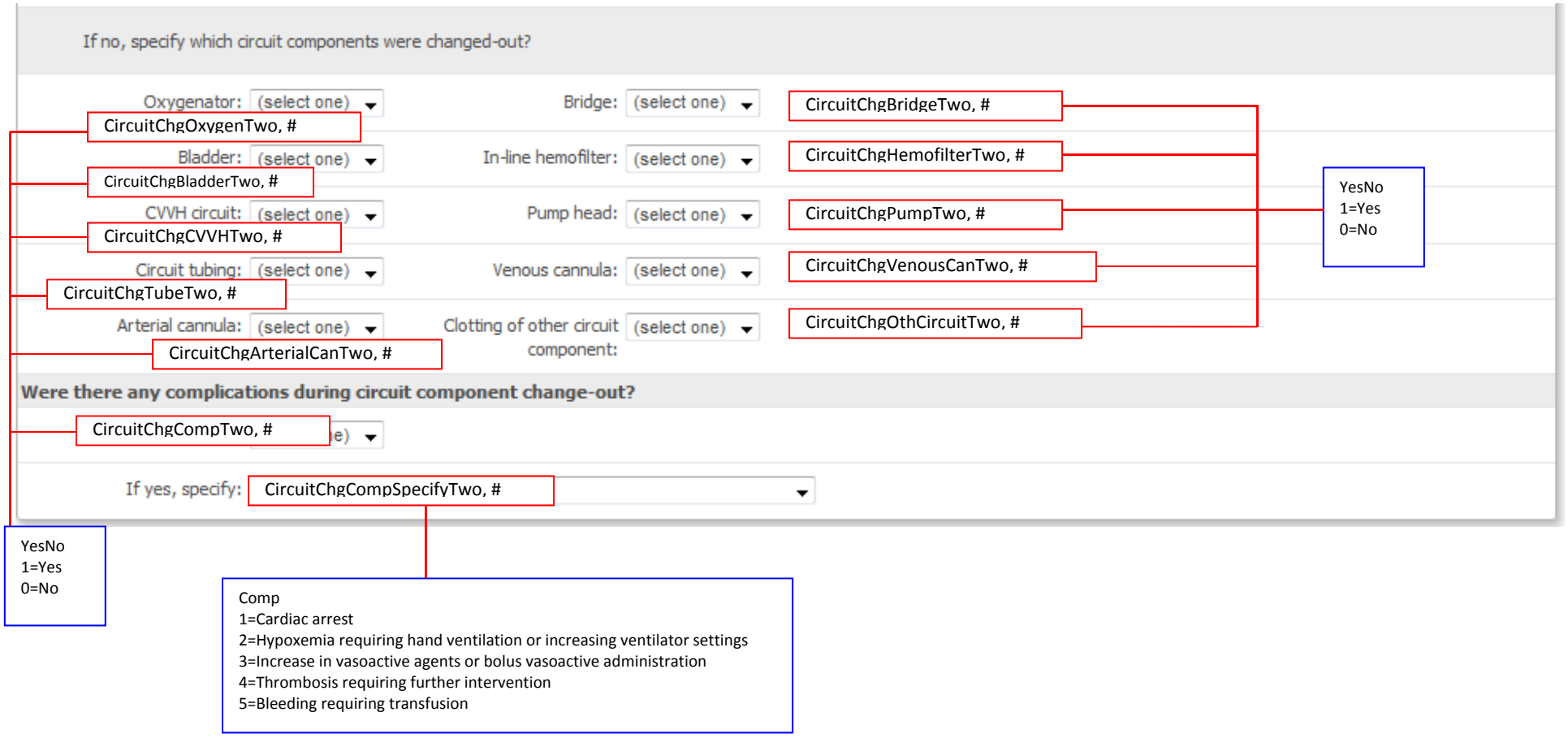
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v3 (7 of 8)

ECMO Related Daily Data v3.0:

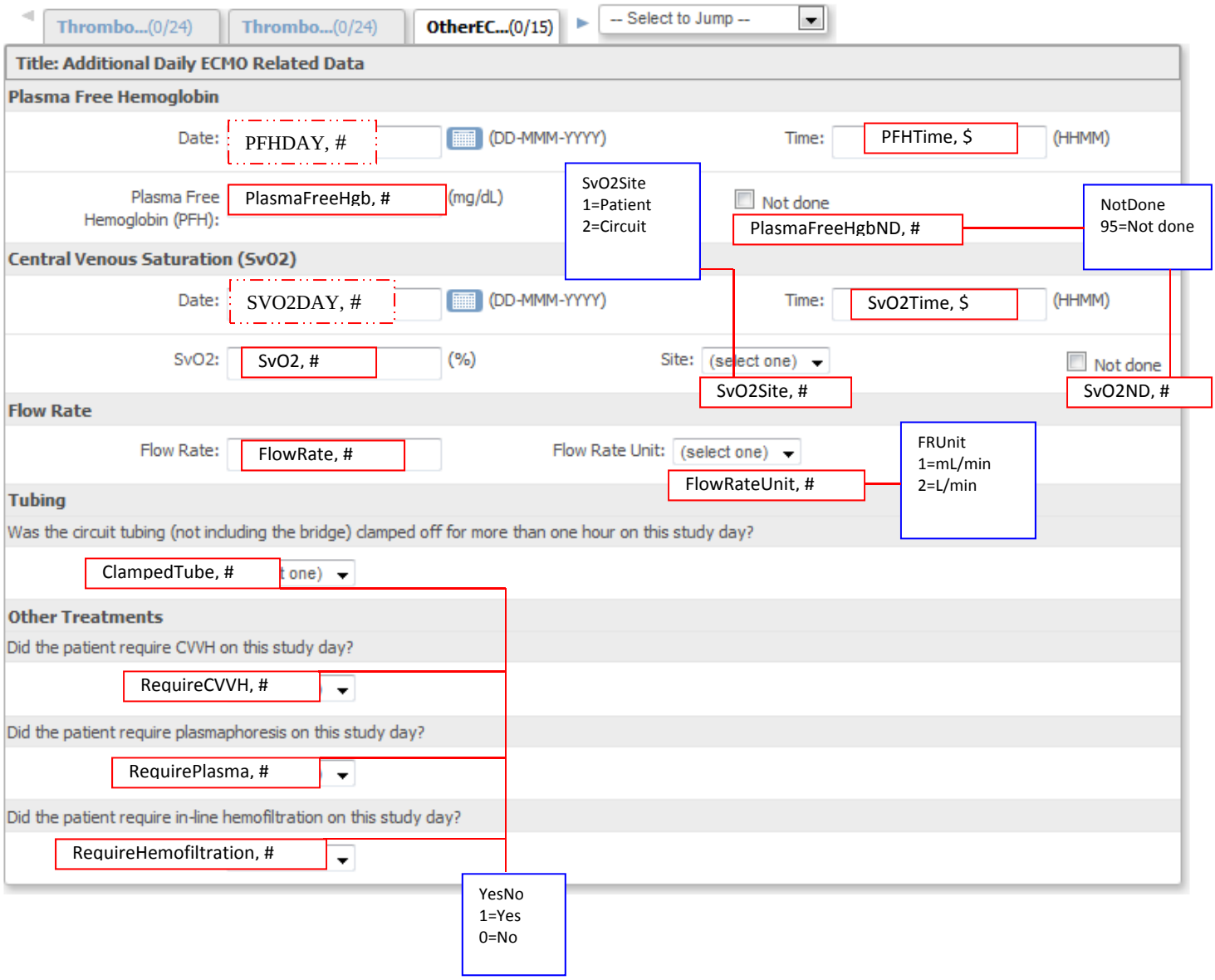
PudID # | Occurrence # | ItemGroupRepeatKey #



ECMODaily_v3 (8 of 8)

PudID # | Occurrence # | ItemGroupRepeatKey #

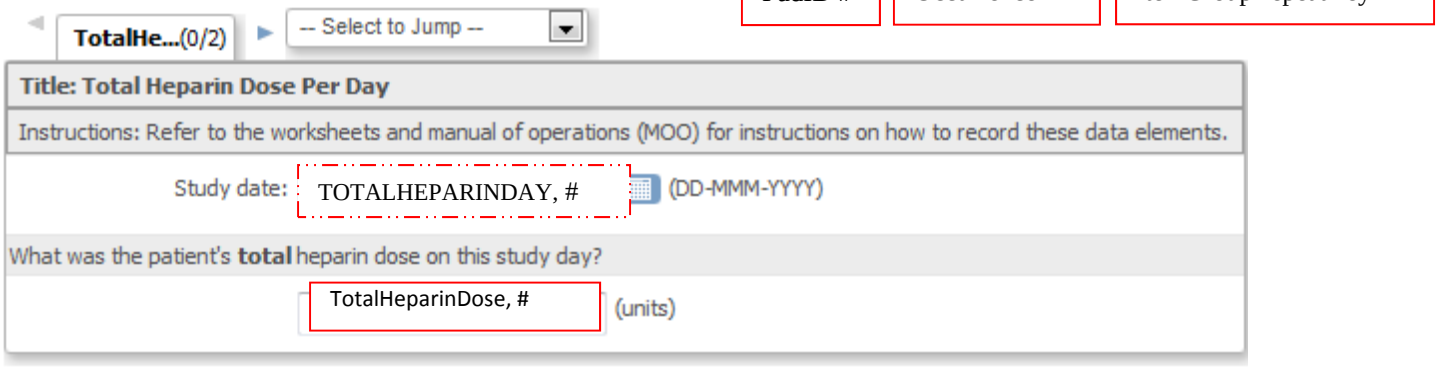
ECMO Related Daily Data v3.0:



HeparinTotal (1 of 1)

ECMO Total Heparin Dose per Day:

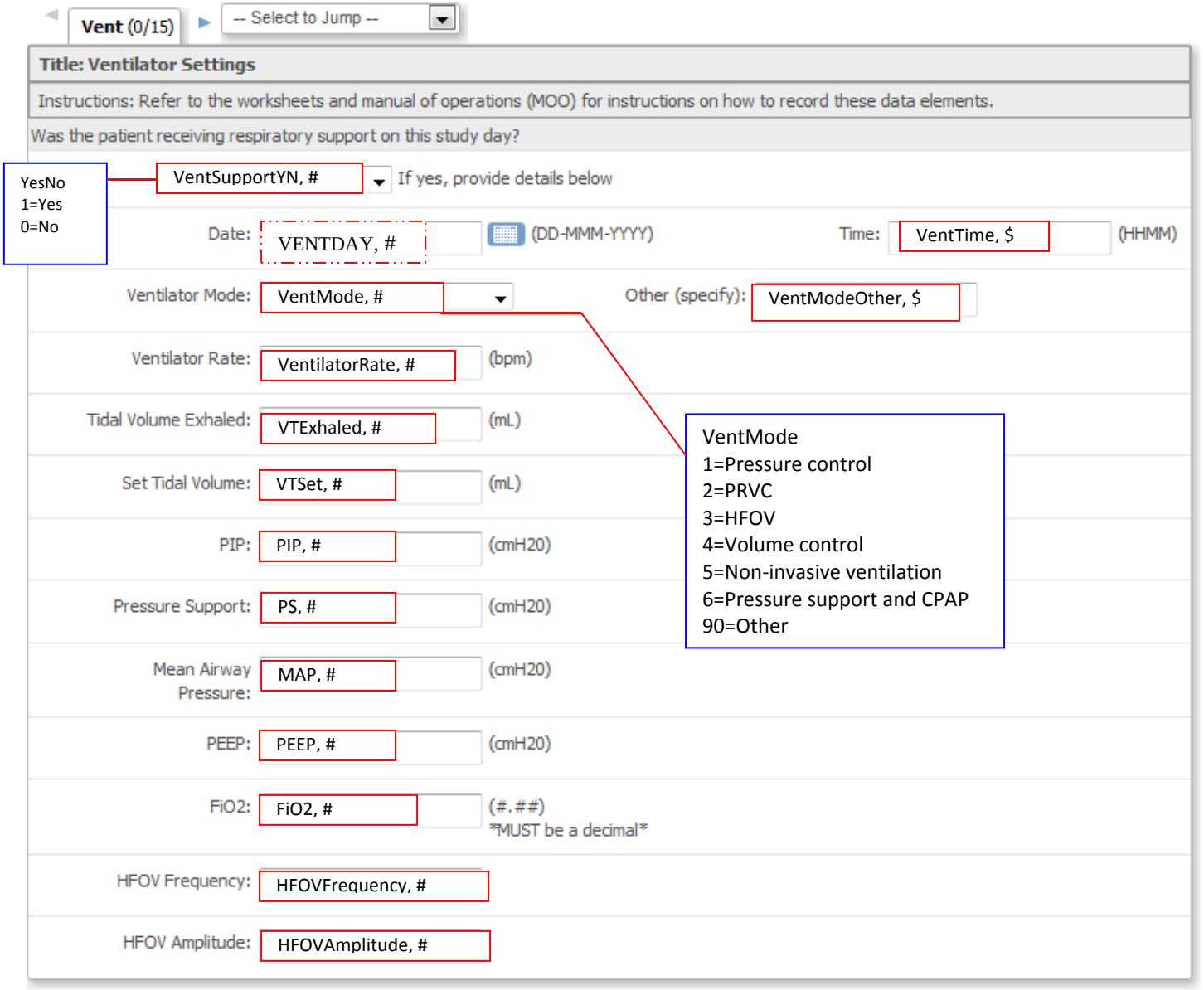
PudID # | Occurrence # | ItemGroupRepeatKey #



Vent (1 of 1)

ECMO Ventilator Settings:

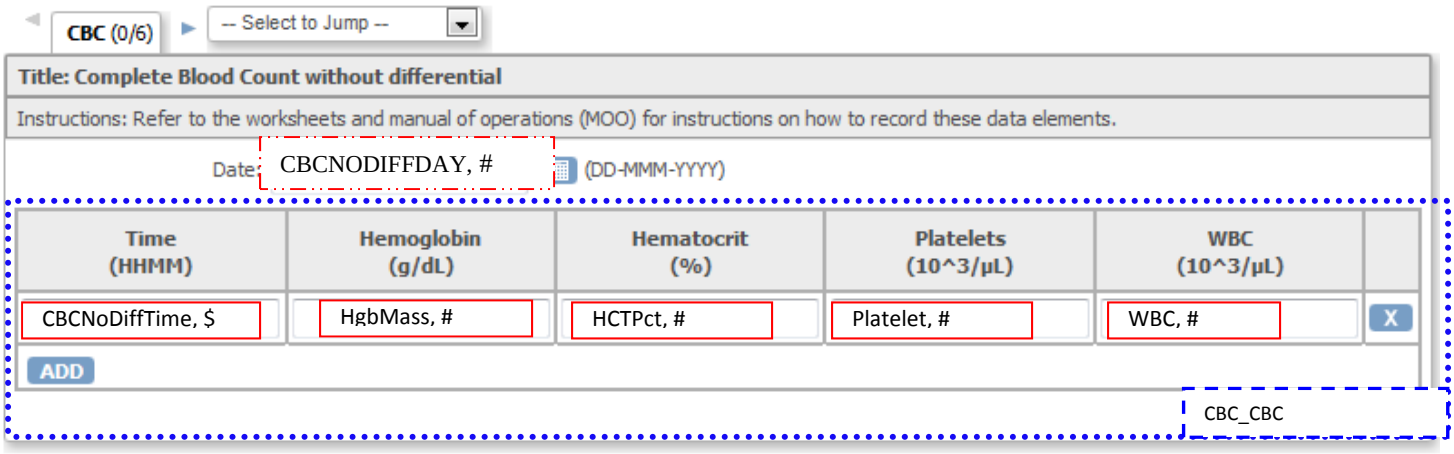
PudID # | Occurrence # | ItemGroupRepeatKey #



CBC (1 of 1)

ECMO Complete Blood Count w/o diff:

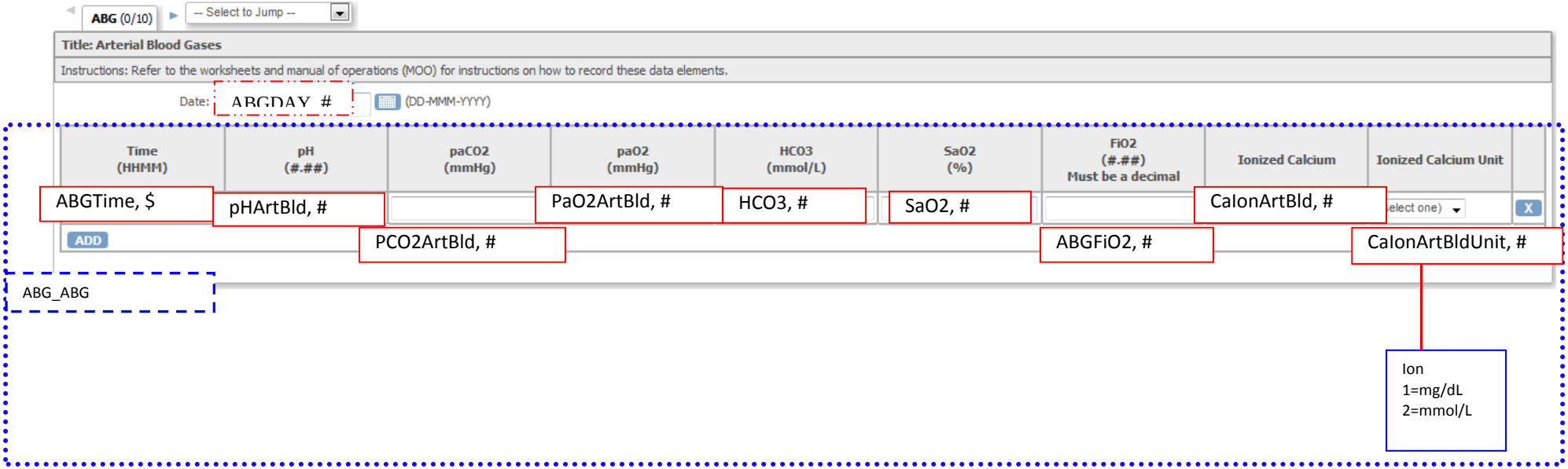
PudID # | Occurrence # | ItemGroupRepeatKey #



ABG (1 of 1)

PudID # | Occurrence # | ItemGroupRepeatKey #

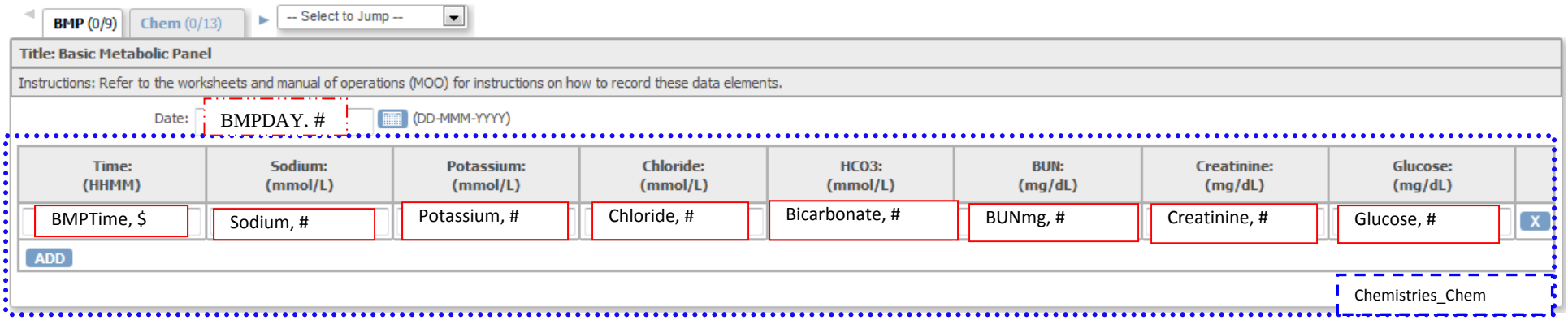
ECMO Arterial Blood Gases:



Chemistries (1 of 2)

ECMO Chemistries:

PudID # | Occurrence # | ItemGroupRepeatKey #

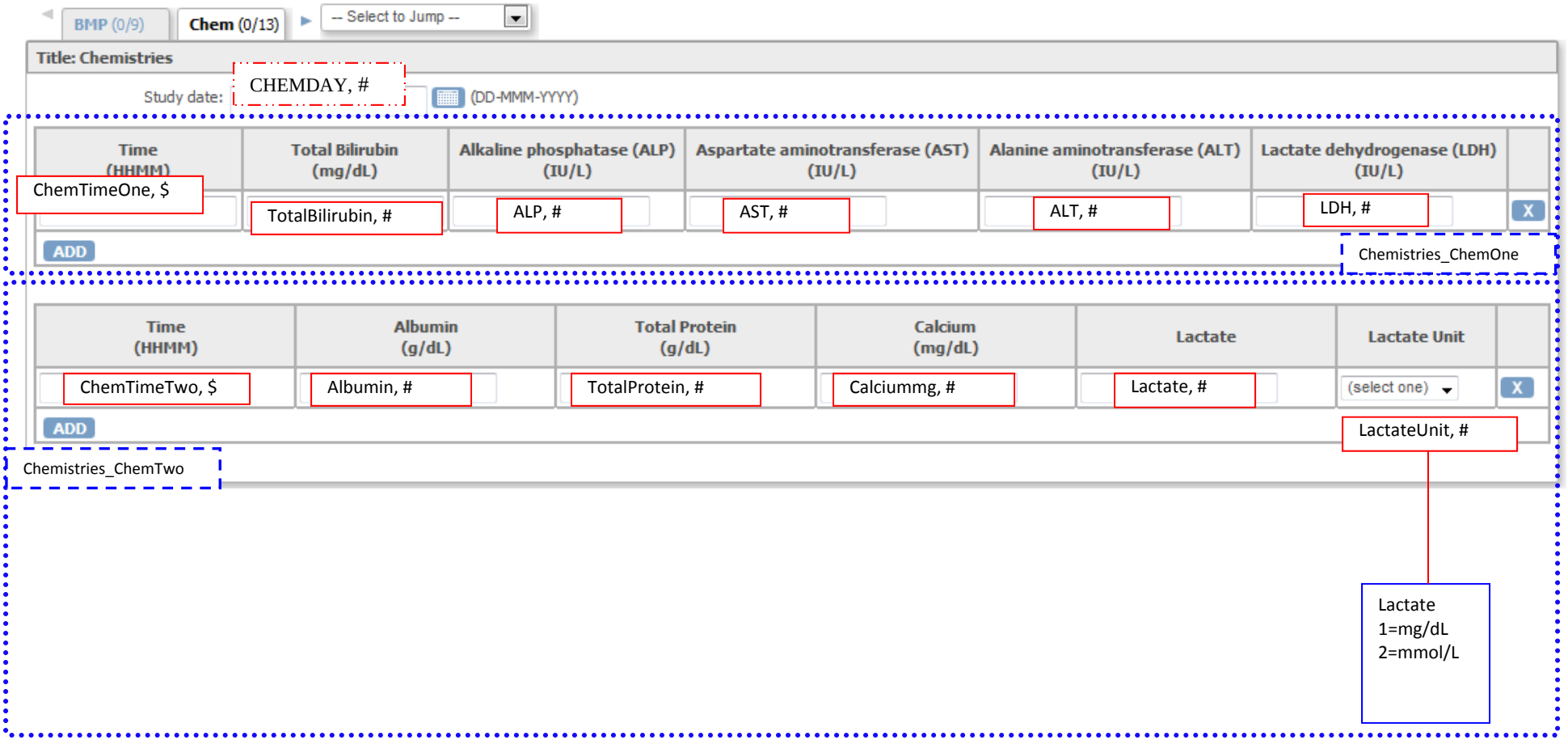


Note: Although the case report form reflects HCO3 as being collected, the lab value being provided in this data field represents total CO2.

Chemistries (2 of 2)

PudID # | Occurrence # | ItemGroupRepeatKey #

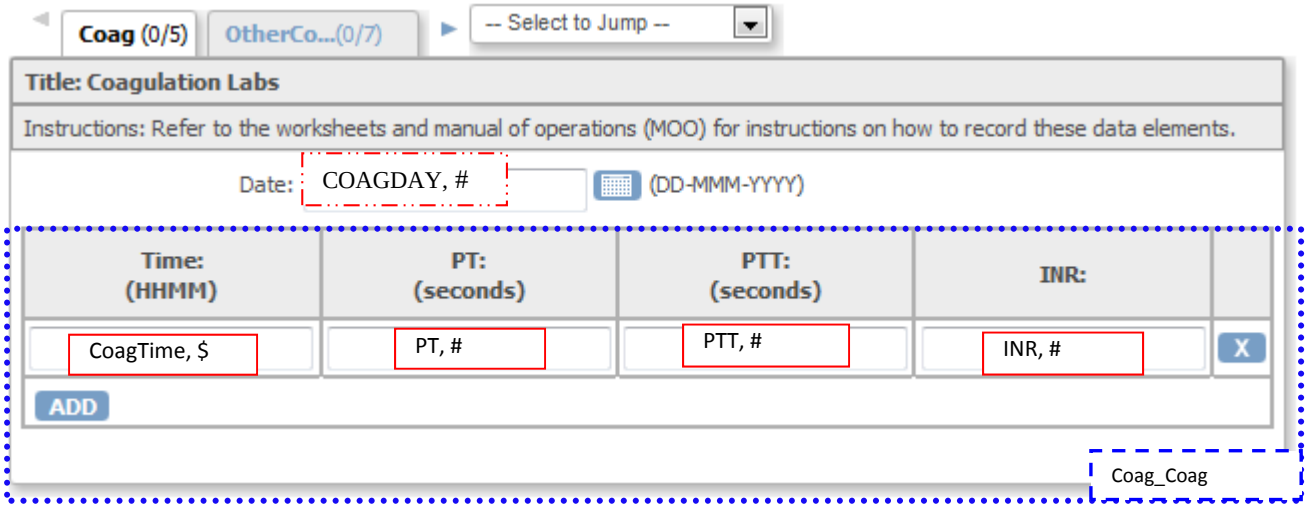
ECMO Chemistries:



Coag (1 of 2)

PudID # | Occurrence # | ItemGroupRepeatKey #

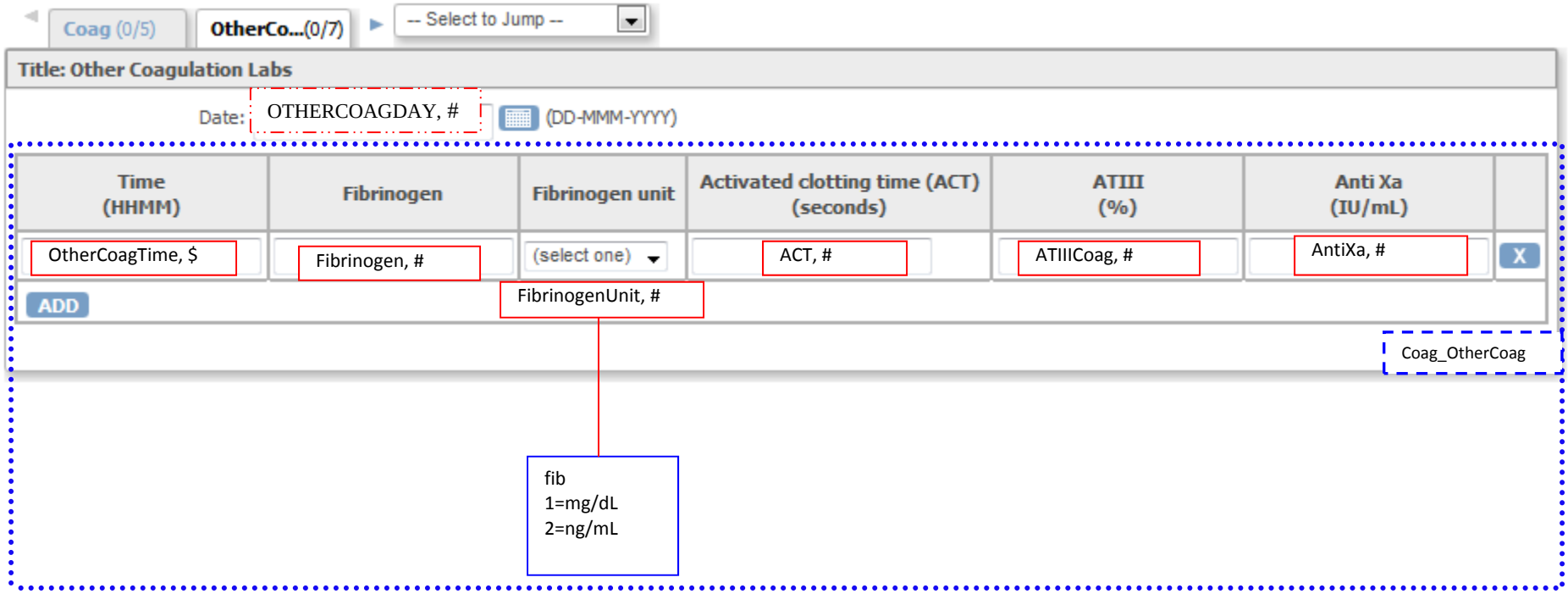
ECMO Coagulation Labs:



Coag (2 of 2)

PudID # | Occurrence # | ItemGroupRepeatKey #

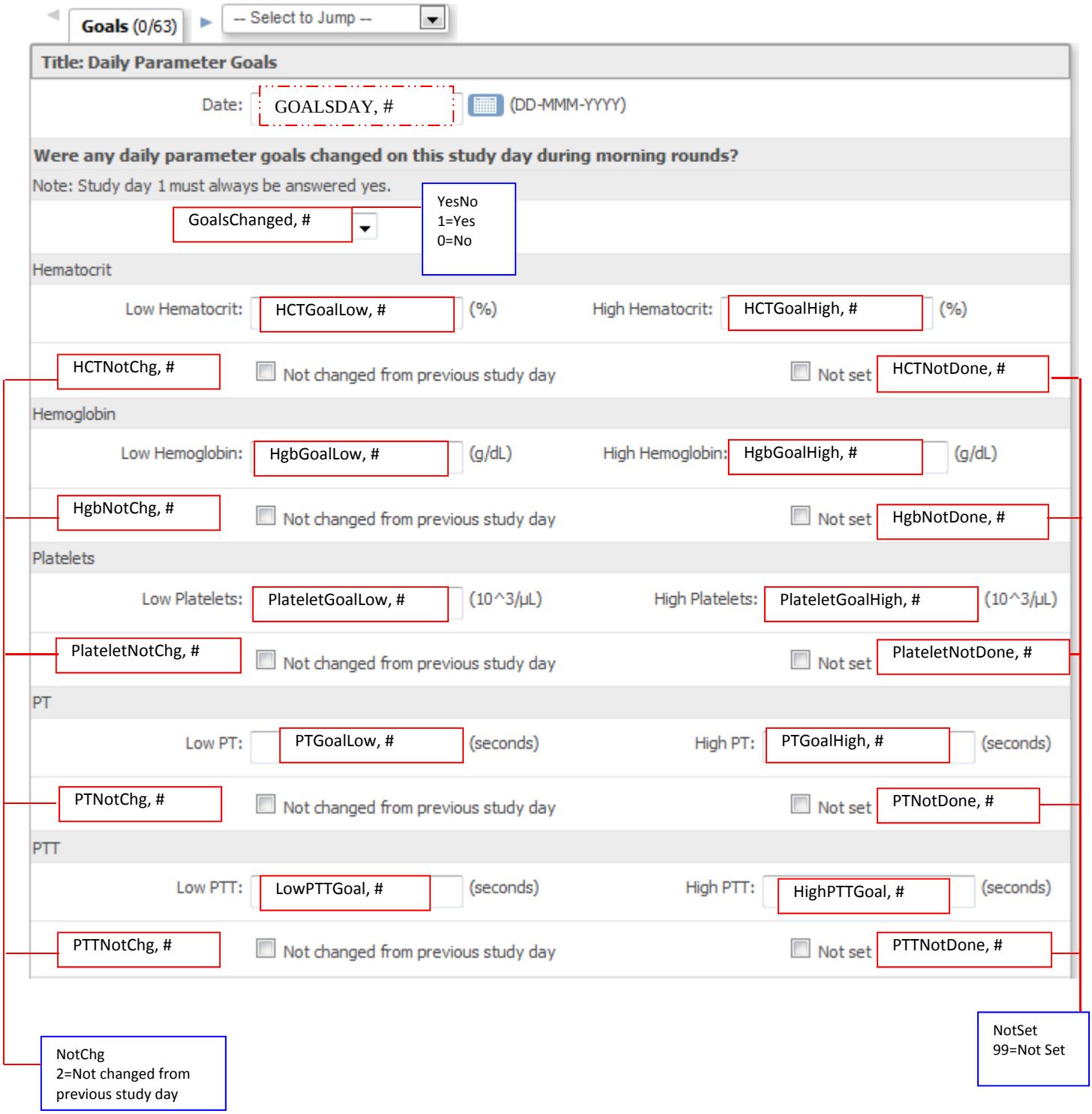
ECMO Coagulation Labs:



Parameter_v2 (1 of 3)

ECMO Daily Parameter Goals:

PudID # | Occurrence # | ItemGroupRepeatKey #



Parameter_v2 (2 of 3)

ECMO Daily Parameter Goals:

PudID # | Occurrence # | ItemGroupRepeatKey #

NotChg
2=Not changed from previous study day

fib
1=mg/dL
2=ng/mL

NotSet
99=Not Set

Parameter_v2 (3 of 3)

ECMO Daily Parameter Goals:

PudID # | Occurrence # | ItemGroupRepeatKey #

NotChg
2=Not changed from previous study day

NotSet
99=Not Set

Blood (1 of 2)

ECMO Blood Product & Medication Information:

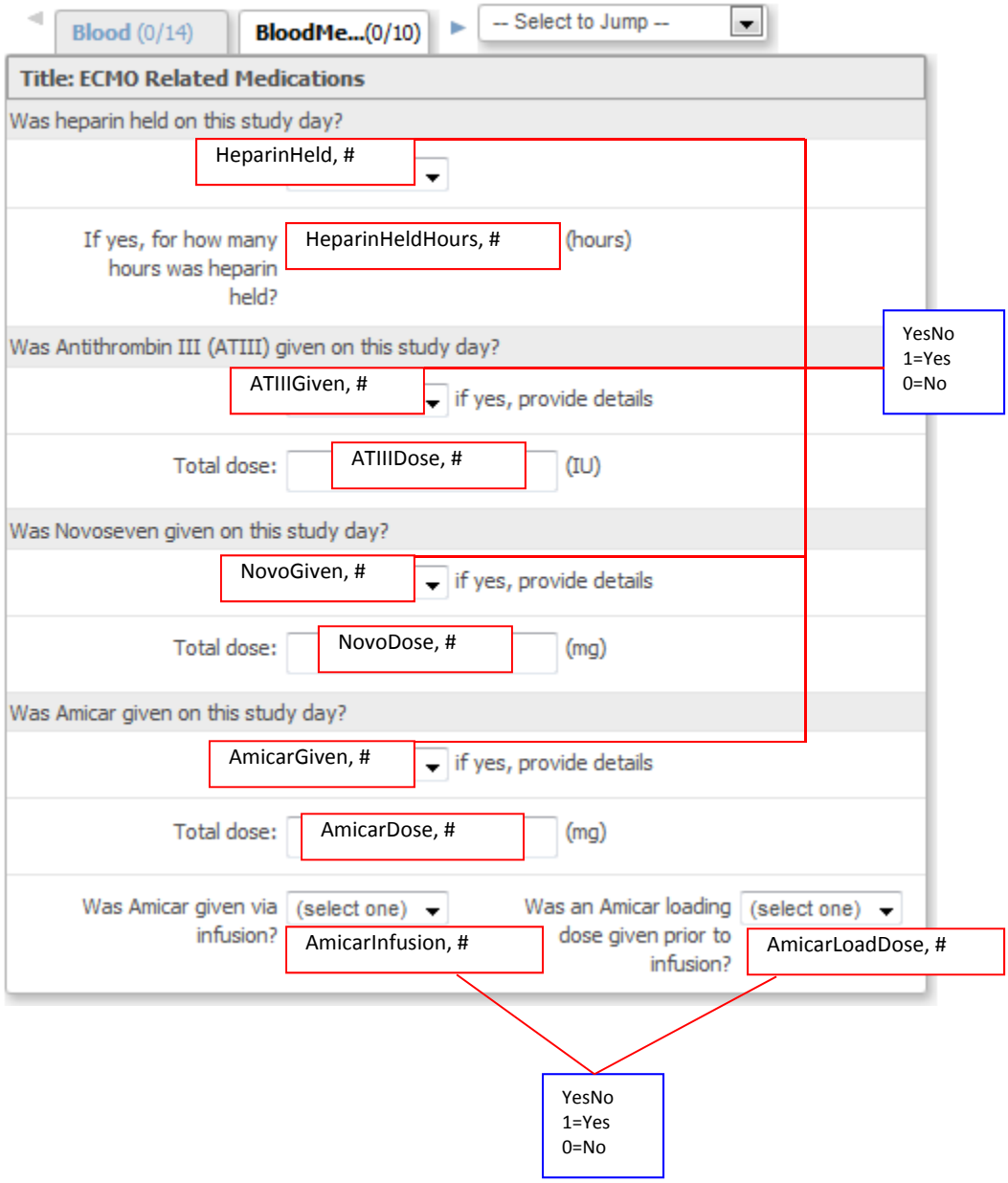
PudID # | Occurrence # | ItemGroupRepeatKey #

YesNo
1=Yes
0=No

Blood (2 of 2)

PudID # | Occurrence # | ItemGroupRepeatKey #

ECMO Blood Product & Medication Information:



Organ (1 of 1)

ECMO Organ Systems:

PudID # | Occurrence # | ItemGroupRepeatKey #