NIH ARDS Network
ARDSNet Study 07

EDEN

CRF Instructions
Version 4

June 16, 2009

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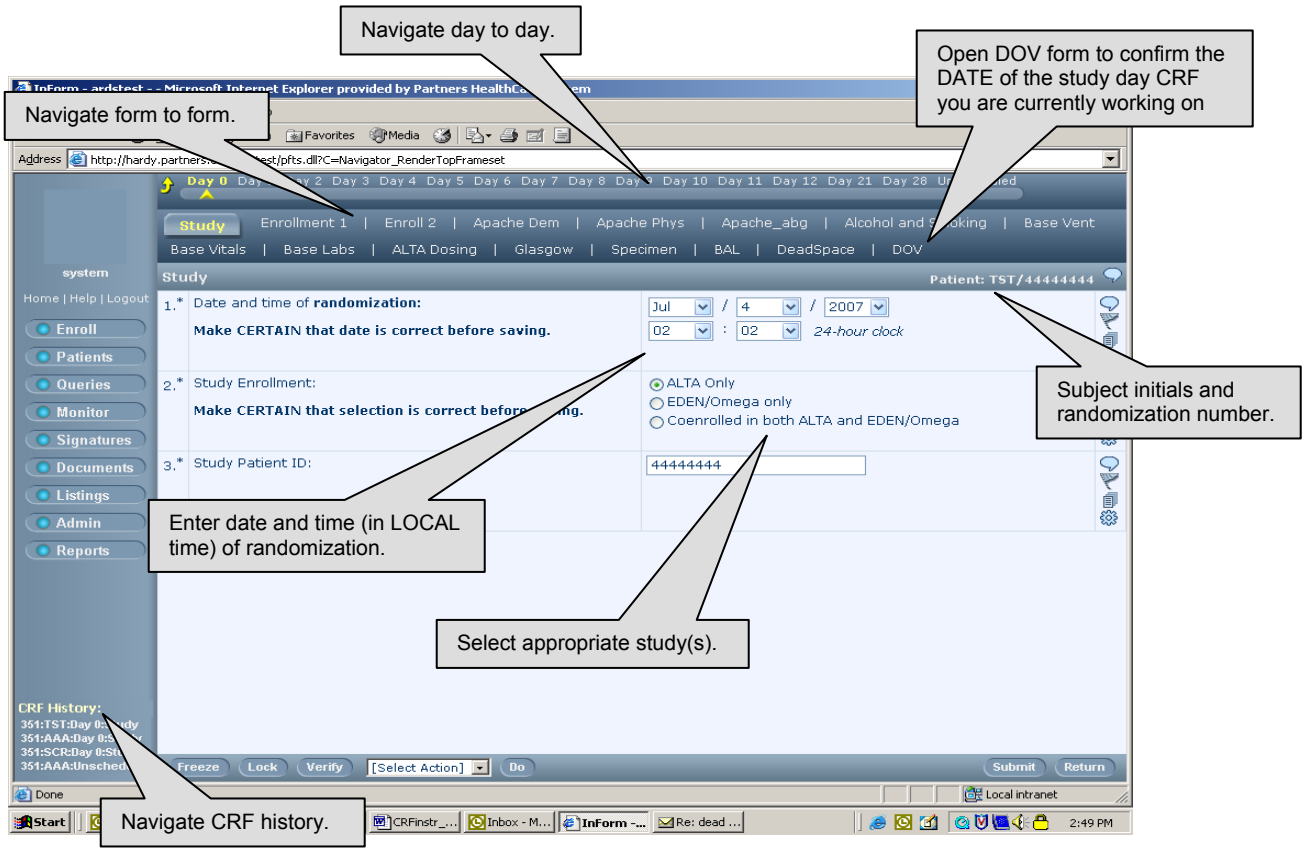
INITIATING A SUBJECT INTO INFORM

Screened only (not enrolled into either trial)

1. Log in to the INFORM system using your user name and password.
2. Choose “ENROLL” from the left hand column on the screen.
3. Click “Add Candidate” from the bottom right corner of the screen.
4. Complete the ALI Screening Form and “submit” form.
   NOTE: **Enter “SCR” for initials if patient is screened only (not enrolled).**
5. The electronic screening log should now be visible.
   NOTE: All patients should be entered into the ALTA_EDEN/Omega Screening log (Excel spreadsheet available on the ARDSNet web site).
6. For SCREENED only patients data entry is complete.

Enrolled

7. From the electronic screening log, click “Enroll” on the right side of the screen for the screened patient you are enrolling.
8. Enter the patients study ID (randomization number) and submit form. You will be asked to double enter this field to ensure accuracy.
9. Once you have confirmed that this is the patient you wish to enroll, click “enroll” at the bottom right corner of the screen.
10. **NEXT STEP:** Click “Go to first visit” at the bottom right corner of the screen. You will now see the following screen. It is **VERY IMPORTANT** to complete this form before entering any other data. This form will populate the dates and correct study CRFs.



ALI SCREENING

DAYS AVAILABLE: **DAY 0**

INSTRUCTIONS: Complete this form for all **screened but not enrolled AND enrolled** patients meeting the study inclusion criteria.

Inclusion criteria=Acute onset of:

- **$PaO_2/FiO_2 \leq 300$.** If altitude > 1000m, use $(PaO_2/FiO_2) \leq (300) \times (B.P./760)$
- **Bilateral infiltrates** consistent with pulmonary edema on frontal chest radiograph. The infiltrates may be patchy, diffuse, homogenous, or asymmetric.
- Requirement for **positive pressure ventilation** via endotracheal tube.
- **No** evidence of **left atrial hypertension** (if measured, pulmonary arterial wedge pressure < 18 mmHg x 12 hours).
- Intent to begin enteral feedings for EDEN/Omega only.

DATA ITEM	DETAILS	LOGIC RULES
1. Patient initials	If patient is screened but not enrolled in the trial, enter SCR.	Required
2. Did patient meet the following 3 inclusion criteria? ▪ Acute onset ▪ Presence of the following in the past 24 hours: P/F ≤ 300, bilateral infiltrates consistent with pulmonary edema, receiving PPV via ET tube ▪ No clinical evidence of LAH.	Select (Yes) or (No). ▪ Acute onset is defined as follows: PaO_2/FiO_2 ratio ≤ 300 (corrected for altitude) and bilateral infiltrates must be present for ≤ 28 days. If either is present continuously for > 28 days, the condition is not considered "acute", and the patient is not eligible for enrollment. ▪ Example of PaO_2/FiO_2 calculation: If PaO_2=89 and FiO_2= .50, then PaO_2/FiO_2=89/.50 = 178. ▪ The infiltrates may be patchy, diffuse, homogeneous, or asymmetric. Infiltrates must not be caused solely by atelectasis, effusions, mass, plump or indistinct vessels, or shadows known to be chronic. ▪ "Positive pressure ventilation" is defined as ventilation assistance wherein airway pressure is raised during inspiration and lowered during expiration. This excludes CPAP but includes Pressure Support, Pressure Control, and Assist/Control modes. "Endotracheal tube" may be an orotracheal, nasotracheal, or tracheostomy tube. ▪ If measured, pulmonary arterial wedge pressure ≤ 18 mmHg.	Required field.
3. Intent to begin enteral feedings.	Enter (yes) or (no) to indicate whether the primary team intends to continue or begin enteral feedings.	Required field
4. PaO_2	Enter the intubated PaO_2 and the FiO2 used to calculate the P/F ratio in 2 above (qualifying P/F).	Required fields.
5. FiO_2 (enter as decimal)		
6. Enter month of the year that patient met screening criterion.	Select the appropriate month to indicate when the patient met inclusion criteria.	Required field.
7. Gender	Select the appropriate option.	Required field.
8. Ethnicity	Select the option that best applies: ▪ Hispanic or Latino ▪ Not Hispanic or Latino	Required field.

DATA ITEM	DETAILS	LOGIC RULES
9. Race:	Select all that apply. NOTE: If the coordinator cannot obtain the race(s) from the patient, the patient's family, or from a source document, select "not reported".	Required field.
10. Age (in years)	Enter patient's age in years at last birthday. If >89, enter 89.	Required field.
11. Location	Select the option that indicates patient's current location (regardless of service): MICU, SICU, Cardiac SICU, CCU, Neuro ICU, Burn, Trauma, Cancer Unit, MICU/SICU, Other.	Required field.
12. Reason for exclusion	Select ALL options that apply. Refer to protocol for definitions of specified exclusion criteria. ▪ Choose "Exclusions" if patient meets any exclusion to either study. ▪ Choose "Not excluded" for enrolled patients who meet NO exclusion. ▪ If "NOT EXCLUDED and NOT ENROLLED", give reason in text box (Occasionally patients meet all inclusion criteria and no exclusion criteria but are not enrolled because they improve quickly or die quickly within the 48 hour enrollment window. For these patients, complete this item).	Required.
Lung Injury Category: Select primary, secondary or none for each of questions 13-18. Select one primary and 0-5 secondary causes of lung injury: Trauma, Aspiration, Sepsis, Multiple Transfusions, Other. The "primary" category should be the most immediate cause. E.g., a patient with multiple trauma who develops sepsis and then ALI: primary category = sepsis; secondary category = trauma.		
13. Trauma	Select primary, secondary or none as applicable	Required.
14. Sepsis	Select primary, secondary or none as applicable ▪ If Lung injury category=both sepsis and pneumonia, choose pneumonia as "primary" ▪ If sepsis if selected for primary category, indicate site from drop down menu.	Required.
15. Multiple transfusion	Select primary, secondary or none as applicable	Required.
16. Aspiration	Select primary, secondary or none as applicable	Required.
17. Pneumonia	Select primary, secondary or none as applicable ▪ If Lung injury category=both sepsis and pneumonia, choose pneumonia as "primary"	Required.
18. Other	Select primary, secondary or none as applicable ▪ Describe source if "other"	Required.

ENROLLMENT I

DAYS AVAILABLE**: 0**
INSTRUCTIONS: Complete for all ENROLLED patients. The data that is common to the ALI screening form will automatically populate. Only the following **additional** questions will need to be completed.

DATA ITEM	DETAILS	LOGIC RULES
2. Date/time of qualifying CXR:	Enter the date and time of the subject's qualifying CXR. If a subject first has a CXR meeting ARDSNet criteria on 1/2/07, but did not meet the remaining inclusion criteria until 1/6/07, the 2/1/07 CXR CANNOT be used for inclusion. A CXR meeting ARDSNet criteria within the same 24 hr period as the other criteria needs to be used.	Required.
3. CXR quadrants:	Enter (2-4) the number of quadrants with infiltrates on the qualifying CXR.	Required.
4. Date/time current intubation:	Enter the date and time of the subject's CURRENT intubation.	Required.
8. Date/time of qualifying P/F:	Enter the date and time of the subject's qualifying P/F. The P/F and the CXR need to occur in the same 24-hour period (the subject also needs to be on PPV).	Required.
9. First date all criteria exist:	Select the first calendar date when ALL inclusion criteria (#2 from ALI Screening form—include #3 for EDEN/Omega) first occur together (in the same 24 hour period). Example: If the P/F criterion was first met on 1/30/07 but the chest x-ray did not show bilateral infiltrates until 2/1/07 and the patient STILL met the P/F criterion on 2/1/07 (new value), then the first date both were met would be 2/1/07.	Required.
14. Is true age >89:	Select Yes or No. If subject is >89 years, enter true age.	Required.

ENROLLMENT II

DAYS AVAILABLE: **DAY 0**

INSTRUCTIONS: If a patient meets all inclusion criteria and is enrolled into **either** trial, this form should be completed.

DATA ITEM	DETAILS	LOGIC RULES
1. Has informed consent been obtained for participation in EDEN.	Informed consent must be obtained before any EDEN study procedures are initiated. Select YES if informed consent has been obtained. Select NO if informed consent has not been obtained.	Required field.
PATIENT OR SURROGATE CAN REFUSE THEIR CONSENT FOR GENETIC TESTING AND/OR other ancillary studies AND STILL PARTICIPATE IN THE ALTA or EDEN/Omega STUDIES (OR BOTH).		
2. Has informed consent been obtained for genetic testing related to this study?	Select YES or NO as appropriate.	Required fields.
3. For genetic testing related to future ARDS studies?	Select YES or NO as appropriate.	
4. For genetic research involved with other conditions?	Select YES or NO as appropriate.	
5. To contact subject for FUTURE studies?	Select YES or NO as appropriate. This is NOT the LTO study. If your IRB did not allow this question on the informed consent, select NO.	

STUDY

DAYS AVAILABLE: **0**

INSTRUCTIONS: The purpose of this form is to populate the dates and study specific forms. Complete **BEFORE** completing the remaining CRFs.

DATA ITEM	DETAILS	LOGIC RULES
1. Date and time of randomization:	Enter the date and time (in LOCAL time) of randomization. This information can be located on the randomization confirmation E-mail (you will need to convert to local time as the E-mail will state Eastern Time).	Required.
2. Study enrollment:	Select the appropriate study (studies) that subject is enrolled in.	Required.
3. Study patient ID:	This field will automatically populate with the randomization number you entered when initiating this patient into *Inform.*	N/A

APACHE III-DEMOGRAPHICS

DAYS AVAILABLE: **DAY 0**

INSTRUCTIONS: Complete for all patients enrolled.

DATA ITEM	DETAILS	LOGIC RULES
1. Hospital Admission Date	Enter the date the patient was admitted to the **study** hospital.	Required field.
2. Hospital Admission Type:	Select the appropriate category of hospital admission.	Required field.
3. ICU Admission Date	Enter the date of the current ICU admission.	Required field.
4. Time of ICU Admission	Enter the time the patient was admitted to the current ICU.	Required field.
5. Patient Admitted Directly From:	Select the location where the patient was **immediately prior** to this ICU admission (OR, Recovery Room, ER, Floor, Another Special Care Unit, Another Hospital, Direct Admit, Step-down Unit).	Required field.
6. Place of residence:	Select **best** answer for patient's place of **residence** prior to admission to hospital.	Required field.
7. Is the patient immediately post-operative from elective surgery?	Select the option that best applies.	Required field.
8. ICU Readmit?	During this hospitalization, was the patient in an ICU prior to this current ICU admission? (Yes/No)	Required field.
9. ICU Readmit within 24 hours?	If item 8 is answered "yes", was the readmission to the ICU within 24 hours of a previous ICU discharge?	Required field.
10. Chronic Health Information Available?	Select (Yes) or (No). Chronic health information may be updated at any time during the admission. If any of the following chronic health items (items 11-28) are diagnosed during the hospital admission AND **PRIOR** to study entry, record the item as present on study entry.	Required field. If item 9= (No), then skip to question 27.
11. Is the patient on chronic dialysis or peritoneal dialysis?	Select (Yes) or (No) to indicate if the patient required dialysis prior to hospitalization.	Required field only if 9 = (Yes).
12. AIDS?	Select (Yes) or (No). Enter (No) if HIV positive but without other AIDS criteria.	Required field only if 9 = (Yes).
13. Leukemia (AML, CML, all lymphocytic leukemia, multiple myeloma)	Select (Yes) or (No).	Required field only if 9 = (Yes).
14. Non-Hodgkin's Lymphoma	Select (Yes) or (No).	Required field only if 9 = (Yes).
15. Solid Tumor with metastasis	Select (Yes) or (No).	Required field only if 9 = (Yes).

DATA ITEM	DETAILS	LOGIC RULES
16. Immune Suppression	Select (Yes) or (No) to indicate if the patient is immunocompromised secondary to chemotherapy, radiation therapy, use of anti-rejection drugs taken after organ transplant, or the daily use of high doses of steroids (0.3 mg Prednisone kg/day or equivalent therapy) **within part of or the entire previous six months.**	Required field only if 9 = (Yes).
17. Hepatic Failure	Select (Yes) or (No) to indicate if the patient has decompensated cirrhosis (Hepatic Failure) as evidenced by one or more episodes of jaundice and ascites, upper gastrointestinal bleeding or hepatic encephalopathy or comas.	Required field only if 9 = (Yes).
18. Compensated cirrhosis.	Select "1" (Yes) or "2" (No) to indicate if the patient has cirrhosis without the stigmata indicated above in 17. If the patient has a functioning liver transplant, this chronic health item would not apply.	Required field only if 9 = (Yes).
19. Diabetes Mellitus	Select (Yes) or (No).	Required field only if 9 = (Yes).
20. Hypertension	Select (Yes) or (No).	Required field only if 9 = (Yes).
21. Prior myocardial infarction	Select (Yes) or (No).	Required field only if 9 = (Yes).
22. CHF	Select (Yes) or (No).	Required field only if 9 = (Yes).
23. Peripheral vascular disease	Select (Yes) or (No).	Required field only if 9 = (Yes).
24. Prior stroke with sequelae	Select (Yes) or (No).	Required field only if 9 = (Yes).
25. Dementia	Select (Yes) or (No).	Required field only if 9 = (Yes).
26. Chronic pulmonary disease	Select (Yes) or (No).	Required field only if 9 = (Yes).
27. Arthritis	Select (Yes) or (No).	Required field only if 9 = (Yes).
28. Peptic ulcer disease	Select (Yes) or (No).	Required field only if 9 = (Yes).
29. Vasopressors last 24 hours?	Select (Yes) or (No) to indicate if the pt has received any vasopressors in the 24 hours prior to randomization.	Required field.

APACHE III-PHYSIOLOGY

DAY(S) REQUIRED: **DAY 0**
INSTRUCTION: COMPLETE ON DAY 0. ALL DATA SHOULD BE TAKEN FROM **THE 24 HOURS PRECEDING RANDOMIZATION.** DO NOT INCLUDE INTRAOPERATIVE VALUES OR VALUES RELATED TO DEATH OR CARDIO/RESPIRATORY ARREST SITUATIONS.

For items on this table indicated with "*" (items 9-19), if no values were obtained for clinical purposes during the 24 hours preceding RANDOMIZATION, **the lab tests must be obtained (after obtaining pt/surrogate consent) but before initiating study procedures.**

DATA ITEM	DETAILS	LOGIC RULES
1. Temperature	Enter the highest and lowest temperatures in Centigrade or Fahrenheit. **Add 1 degree Centigrade or 2 degrees Fahrenheit if axillary temperatures.**	Required field.
2. Systolic BP	Enter the highest and lowest.	Required field.
3. Mean Arterial Pressure	Enter the highest and lowest.	Required field.
4. Heart Rate	Enter the highest and the lowest.	Required field.
5. Respiratory Rate	Enter the highest and the lowest.	Required field.
6. Was patient ventilated when the lowest respiratory rate occurred?	Select YES or NO.	Required field.
7. Was patient ventilated when the highest respiratory rate occurred?	Select YES or NO.	Required field.
8. Urine Output 24 hr	Enter the amount of urine output (ml) in the 24 hrs prior to randomization time. E.g., if time of randomization occurs on 2/1/07 at 1400, then the urinary output listed should be from 1/31/07 at 1400 to 2/1/07 at 1400). If a large volume of urine was inadvertently spilled or the urine was not measured, mark the field as "missing data". **A urine output value of zero indicates that data are available and the patient produced no urine.**	Required field.
9. Total fluid output 24 hr	Enter the **total** fluid intake (ml) in the 24 hrs prior to randomization. (See example in number 8). **This total should INCLUDE urine output and a negative CVVH balance.**	Required field.
10. Fluid intake 24 hr	Enter the **total** fluid intake (ml) in the 24 hrs prior to randomization. (See example in number 8). **This total should INCLUDE a positive CVVH balance.**	Required field.
11. Hematocrit*	Enter highest and lowest values rounded to the nearest whole number (e.g., "35", not " .35"). **If only one value is present for 24-hour period, enter this value in the "only column".**	Required field.

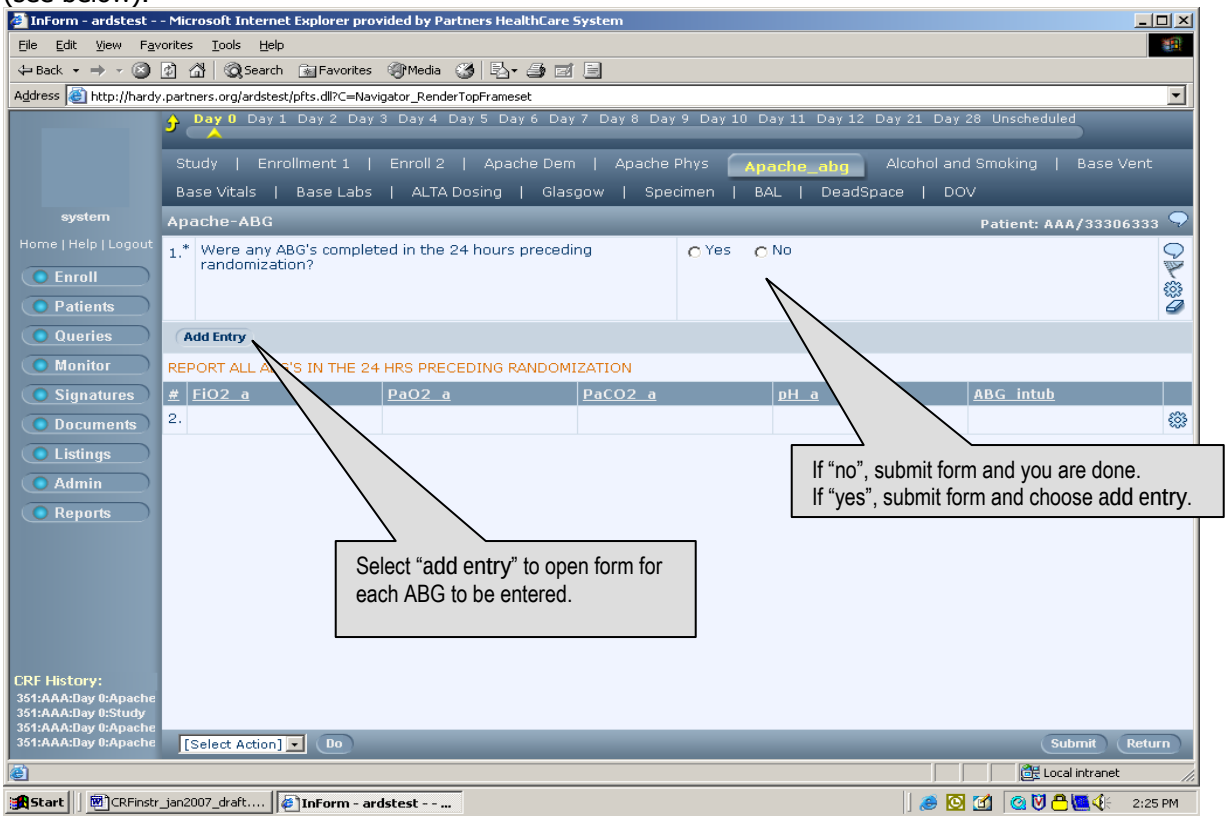
DATA ITEM	DETAILS	LOGIC RULES
12. WBC* (White Blood Cell count).	Enter highest and lowest as "00000" (e.g., a WBC of 14.2 should be entered as "14200"). **If only one value is present for 24-hour period, enter this value in the "only column".**	Required field.
13. Platelets*	Enter only the lowest value during the 24 hours. Enter as "000" (e.g., a platelet count of 258,000 should be entered as "258").	Required field.
14. Serum Sodium*	Enter highest and lowest. **If only one value present for 24-hour period, enter this value in the "only column".**	Required field.
15. Serum Potassium*	Enter highest and lowest. **If only one value present for 24-hour period, enter this value in the "only column".**	Required field.
16. Serum BUN*	Enter only highest value.	Required field.
17. Serum Creatinine*	Enter highest and lowest. If only one value present for 24-hour period, enter this value in the "only column". **If only one value present for 24-hour period, enter this value in the "only column".**	Required field.
18. Serum Glucose*	Enter highest and lowest. If only one value present for 24-hour period, enter this value in the "only column". **If only one value present for 24-hour period, enter this value in the "only column".**	Required field.
19. Serum Albumin*	Enter highest and lowest. If only one value present for 24-hour period, enter this value in the "only column". **If only one value present for 24-hour period, enter this value in the "only column".**	Required field.
20. Serum Bilirubin*	Enter only highest value.	Required field.
21. Serum Bicarbonate*	Enter only lowest value.	Required field.

APACHE ARTERIAL BLOOD GASES

DAYS REQUIRED: **DAY 0**
INSTRUCTION: Record **ALL ABGs in the 24 hours preceding RANDOMIZATION.**
Select YES or NO to indicate if the patient was intubated (with or without positive pressure ventilation) when each ABG was obtained.

DATA ITEM	DETAILS	LOGIC RULES
1. Were any ABG's completed in the 24 hours preceding randomization?	**Select YES** if any ABG values are available in the 24 hours prior to randomization, and then **submit** form to enter the ABG values. **Select NO** if no ABG values are available 24 hours prior to randomization (One ABG is required for the study; however, this ABG might be more than 24 hours prior to randomization).	Required.
2. Fi02	Enter the values for each ABG available in the 24 hours preceding randomization. **For non-intubated gases, FiO2 = 0.21 + .03N (where N = number of liters of oxygen per minute). E.g. if a patient is using 3 liters/min, then his FiO2 would be .30.**	Required if ABG available.
PaO2		
PaCO2		
pH		
Intubated?	Select YES or NO to indicate if the subject was intubated at the time of each ABG.	Required if ABG available.

InForm instructions: This is an "**ADD ENTRY**" form. You will need to "**add**" a new entry for each ABG entered (see below).



BASELINE VITAL SIGNS

DAYS REQUIRED: **DAY 0**

INSTRUCTION: VALUES SHOULD BE OBTAINED IN THE **4-HOUR INTERVAL THAT PRECEDES RANDOMIZATION.** IF THERE ARE NO VALUES AVAILABLE IN THIS 4-HOUR PERIOD, USE VALUES PRESENT WITHIN THE PRECEDING 24 HOURS. IF MORE THAN ONE VALUE IS AVAILABLE DURING THIS INTERVAL, RECORD THE VALUE **CLOSEST** TO THE TIME OF RANDOMIZATION.

DATA ITEM	DETAILS	LOGIC RULES
1. Heart Rate	Use last value prior to study randomization.	Required field.
2. Systolic BP	Use last value prior to study randomization.	Required field.
3. Diastolic BP	Use last value prior to study randomization.	Required field.
4. CVP	Use last value prior to study randomization.	Required if available.
5. Mean Arterial Pressure	Use last value prior to study randomization. MAP required **only** if arterial line present.	Required field if arterial line present.
6. Temperature	Use last value prior to study initiation. Prefer rectal, tympanic, or core temperature. If axillary used, add 1 degree Centigrade or 2 degrees Fahrenheit.	Required field.
7. **Measured** Height	**Record patient's height from heel to crown**. Patient should be supine with legs straight (no flexion or extension of hips and knees, if possible), during measurement. This value should be documented in the source documents (ie, pt chart or study file).	Required field.
8. **Measured** Weight	Enter most recent measured body weight. If weight not available during preceding 24 hours, **enter most recent weight**.	Collect data, if available.
PBW (Predicted Body Weight)	**This field will populate automatically.**	**N/A**
9. IV vasopressor or inotrope?	Select YES or NO as appropriate. If 9 =YES, indicate the infusion rate for the drugs listed **at the time of randomization.**	Required field.

BASELINE VENTILATOR PARAMETERS

DAYS REQUIRED**: DAY 0**
INSTRUCTION: CAPTURE THE MOST RECENT VALUES PRIOR TO **TIME OF RANDOMIZATION.**

DATA ITEMS	DETAILS	LOGIC RULES
1. Ventilator mode:	Select all modes that apply immediately prior to randomization. If **Pressure Support** or **Pressure Assist** is selected, please enter the level.	Required field.
2. Calculated Delivered Tidal Volume	Enter the corrected inspired tidal volume: inspired tidal volume (ml) set on the ventilator minus any additional tidal volume added to correct for has compression and ventilator tube expansion (this should = the tidal volume called for by the protocol; this will not = the volume set on the ventilator unless the ventilator makes automatic adjustments for gas compression/tube expansion). Puritan-Bennett 7200's and some other ventilators make this correction automatically (for these vents, the value set on the vent = the calculated delivered tidal volume).	Required field for A/C modes.
3. Set Rate	Enter the rate set on the ventilator if the patient is on SIMV, SIMV with Pressure Support, Assist/Control, or Pressure Control mode. (This is the minimum **rate set** on the ventilator, not the patient rate).	Required if available.
4. Total Respiratory Rate	Enter the total respiratory rate, which may exceed the Set Rate above if the patient is making additional inspiratory efforts.	Required field.
5. Total Minute Ventilation (VE)	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field.
6. PEEP	Enter the PEEP applied on the ventilator in cmH_2O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.
7. FiO2	Enter FiO2 prior to randomization.	Required field.
8. SpO2	Enter SpO2 prior to randomization.	Required field.
9. Plateau Pressure (Pplat)	Enter the value for plateau pressure measurement in cm H_20. The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	Required field if available.
10. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field.
11. Mean Airway Pressure	Enter the mean airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field.
If ABG clinically available this calendar day, complete the remaining questions. If more than one ABG available, select the ABG closest to 0800.		
12. FiO2 at time of ABG	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%) at the time of the ABG.	Record if available.

13-15. PaO_2, PaCO2, and Arterial pH	Enter results of the arterial blood gas available closest to the 0800 on this calendar date.	Record if available
16. SpO2 at time of ABG.	Enter SpO2 at time of ABG.	Record if available.
After initial vent change, if any, on a tidal volume of 6-8 ml/kg PBW:		
13. Calculated delivered tidal volume:	Enter the corrected inspired tidal volume, on 6-8 ml/kg PBW (after initial vent change).	Required if available.
14. Pplat:	Enter the value for plateau pressure measurement in cm H_20, on 6-8 ml/kg PBW (after initial vent change). The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	Required if available.
15. PEEP:	Enter the PEEP applied on the ventilator in cmH_2O, on 6-8 ml/kg PBW (after initial vent change).	Required if available.

BASELINE LABS

DAYS REQUIRED: **DAY 0**

INSTRUCTION: RECORD VALUES CLOSEST TO THE TIME PRECEDING **RANDOMIZATION**. THESE LABS ARE REQUIRED FOR THE STUDY.

IF A VALUE WAS NOT OBTAINED FOR CLINICAL PURPOSES, IT MUST BE DRAWN PRIOR TO THE FIRST DOSE OF STUDY DRUG.

DATA ITEM	DETAILS	LOGIC RULES
1. Hgb	Enter in g/dL	Required field.
2. Sodium	Enter serum sodium in mEq/L	Required field
3. Potassium	Enter serum potassium in mEq/L	Required field
4. Glucose	Enter serum glucose in mg/dL	Required field
5. Serum bicarb.	Enter serum bicarbonate in mEq/L	Required field.
6. Serum Phosphorus	Enter serum phosphorus in mg/dL	Required field.
7. Serum Magnesium	Enter serum magnesium in mEq/L	Required field.
8. Total protein	Enter serum total protein in g/dL	Required field.
9. Albumin	Enter serum albumin in g/dL	Required field.
10. Prothrombin time	Enter is available	Enter if available
11. Lowest glucose of the day	Select lowest value from all sources including POC.	Required.

BASELINE ENTERAL FEEDING PROCEDURES

DAYS REQUIRED: **DAY 0**

INSTRUCTION: Complete for all EDEN/Omega patients. Questions 5-19 should cover the time from randomization until **the end of day zero**. If you will be recording totals based on a 7A-7P ICU flow sheet, this data should be from randomization until 7 AM on study day 1 (see FAQ).

DATA ITEM	DETAILS	LOGIC RULES
1. Propofol infusion rate at time of randomization:	Enter the rate of propofol infusion at the time of randomization. ▪ Enter "0" if not on propofol infusion when randomized.	Required field.
2. Enteral feeding group:	Select the feeding randomization assignment **(tropic or full calorie).**	Required field.
3. Feedings in the 12 hrs prior to randomization?	Select yes or no to indicate if the patient received ANY enteral feedings in the 12 hours prior to randomization. ▪ If yes, enter the 12-hour volume of feeds.	Required field.
4. Date/time of initiation of **protocol specified enteral feeds:**	Enter the date and time that the protocol specified feeds were started. **Example:** If patient is enrolled, already receiving enteral feeds enter the date and time that the patient was switched to the protocol specified rate/formula.	Required field.
The following data should be taken from the **time of randomization through the end of day zero**. If you will be recording totals based on a 7A-7P ICU flow sheet, this data should be from randomization until 7 AM on study day 1 (see FAQ)		
5. Enteral feeds on any part of this 24-hour period?	Select Yes or No to indicate whether patient received enteral feeds for any part of this 24-hour period.	Required field.
6. Initial tube feeding goal rate this 24 hours:	Indicate the goal rate in cc/hr (see protocol section 5.1.3).	Required if 1 = YES.
7. Did goal rate change during this 24-hour period?	Select Yes or No to indicate whether the goal rate was CHANGED during this 24-hour period. (**Example**: if the goal rate indicated in question 2 was the protocol specified 25-35 kcal/kg/day, and you now have a new goal rate based on the nutrition evaluation, enter the new rate here).	
If yes, enter new goal rate:	If 7 = Yes, enter the new goal rate in cc/hr.	
8. Enteral formula #1 this 24 hours:	Enter brand name of enteral formula used. **Note: There are some formulas that are NOT permitted.** Examples of feeding formulas **NOT** permitted for the trial include: Oxepa®, Impact®, Peptamen AF®, Crucial®, Optimental® and Pivot 1.5®.	
9. Volume of #1 this 24 hours:	Total volume of formula listed in question 8 for this 24-hour period.	
10. Enteral formula #2 this 24 hours:	If applicable, enter brand name of 2nd enteral formula used this 24-hour period.	Required if applicable.
11. Volume of #2 this 24 hours:	Total volume of formula listed in question 10 for this 24-hour period.	

DATA ITEM	DETAILS	LOGIC RULES
12. Total hours of enteral feeds this 24 hours:	Enter the total number of hours that patient received enteral feedings this 24-hour period.	Required if 1 = YES.
13. Were feeds turned off or held for any part of these 24 hours?	Select Yes or No to indicate if the enteral feedings were turned off or held for > 30 mins. If YES, select all reason(s) that apply for interruption of feeding.	Required if 1 = YES.
14. Any GI intolerance these 24 hours?	Select Yes or No to indicate whether the patient experienced any GI intolerance (as defined by EDEN/Omega Protocol) this 24-hour period. If YES, select all intolerances (s) that apply.	Required if 1 = YES.
15. Insertion site of feeding tube:	Select correct option to indicate insertion site of feeding tube.	Required if 1 = YES.
16. Feeding tube size:	Indicate small or large bore feeding tube. If **14 French or larger**, choose **LARGE BORE**. **Reminder:** The larger the number, the larger the feeding tube bore (14 = large bore, 10 = small bore).	Required if 1 = YES.
17. Distal position of tube:	Select gastric or post pyloric as appropriate. **Example:** NG tube or G-Tube = “gastric”, Dobbhoff = “post-pyloric”.	Required if 1 = YES.
18. Was distal position confirmed during this 24-hour period?	Select Yes or No.	Required if 1 = YES.
If yes, how confirmed:	Select method of confirmation.	Required if 18 = yes.
19. Was rate advanced to full calorie these 24 hours?	Select Yes or No to indicate if the rate was advanced to the full calorie goal this day.	Required if 1 = YES.
If yes, time full calorie reached:	Select time as appropriate.	Required if 19 = yes.

ON STUDY ENTERAL FEEDING PROCEDURES

DAYS REQUIRED: **DAY 1-12** or until patient reaches UAB.

Instruction: Volume of enteral feeds may be collected in a 24-hour period that is the most convenient for you.
Example: If your ICU flow sheets record totals at 7 AM rather than midnight, you may use the 24-hour period from 0700 on the study day until 0700 on the following day. (Day 2 total should cover 0700 on day 2-0700 on day 3)
If your totals are done at midnight, use totals for that calendar day.

DATA ITEM	DETAILS	LOGIC RULES
1. Enteral feeds on any part of this 24-hour period?	Select Yes or No to indicate whether patient received enteral feeds for any part of this 24-hour period.	Required field.
2. Initial tube feeding goal rate this 24 hours:	Indicate the goal rate in cc/hr (see protocol section 5.1.3).	Required if 1 = YES.
3. Did goal rate change during this 24-hour period?	Select Yes or No to indicate whether the goal rate was CHANGED during this 24-hour period. (**Example**: if the goal rate indicated in question 2 was the protocol specified 25-35 kcal/kg/day, and you now have a new goal rate cased on the nutrition evaluation, enter the new rate here).	
If yes, enter new goal rate:	If 3 = Yes, enter the new goal rate in cc/hr.	
4. Enteral formula #1 this 24 hours:	Enter brand name of enteral formula used. **Note: There are some formulas that are NOT permitted.** Examples of feeding formulas **NOT** permitted for the trial include: Oxepa®, Impact®, Peptamen AF®, Crucial®, Optimental® and Pivot 1.5®.	
5. Volume of #1 this 24 hours:	Total volume of formula listed in question 4 for this 24-hour period.	
6. Enteral formula #2 this 24 hours:	If applicable, enter brand name of 2nd enteral formula used this 24-hour period.	Required if applicable.
7. Volume of #2 this 24 hours:	Total volume of formula listed in question 6 for this 24-hour period.	
8. Total hours of enteral feeds this 24 hours:	Enter the total number of hours that patient received enteral feedings this 24-hour period.	Required if 1 = YES.
9. Were feeds turned off or held for any part of these 24 hours?	Select Yes or No to indicate if the enteral feedings were turned off or held for > 30 mins. If YES, select all reason(s) that apply for interruption of feeding.	Required if 1 = YES.
10. Any GI intolerance these 24 hours?	Select Yes or No to indicate whether the patient experienced any GI intolerance (as defined by EDEN/Omega Protocol) this 24-hour period. If YES, select all intolerances (s) that apply.	Required if 1 = YES.
11. Insertion site of feeding tube:	Select correct option to indicate insertion site of feeding tube.	Required if 1 = YES.

DATA ITEM	DETAILS	LOGIC RULES
12. Distal position of tube:	Select gastric or post pyloric as appropriate. **Example:** NG tube or G-Tube = “gastric”, Dobbhoff = “post-pyloric”.	Required if 1 = YES.
13. Was distal position confirmed during this 24-hour period?	Select Yes or No.	Required if 1 = YES.
If yes, how confirmed:	Select method of confirmation.	Required if 13 = yes.
14. Was rate advanced to full calorie these 24 hours?	Select Yes or No to indicate if the rate was advanced to the full calorie goal this day.	Required if 1 = YES.
If yes, time full calorie reached:	Select time as appropriate.	Required if 14 = yes.

ON STUDY VITAL SIGNS

DAYS **REQUIRED: DAY 1-10 or until 48 hours UAB.**
INSTRUCTION: Complete using values closest to 0800 each day.

DATA ITEM	DETAILS	LOGIC RULES
1. Heart rate:	Use value closest to 0800.	Required.
2. Systolic BP:	Use value closest to 0800.	
3. Diastolic BP:	Use value closest to 0800.	
4. Temperature:	Use value closest to 0800. Enter the highest and lowest temperatures in Centigrade or Fahrenheit. **Add 1 degree Centigrade or 2 degrees Fahrenheit if axillary temperatures.**	
5. CVP:	Use value closest to 0800.	Required if available.
6. CXR quadrants:	Indicate the number of quadrants with infiltrates if CXR clinically available this day.	Required if available.
7. IV or PO corticosteroids totaling more than 20 mg methylprednisolone equivalents given this calendar date? **20 mg methylprednisolone equivalents:** ≥3.75 mg dexamethasone ≥20 mg methylprednisolone ≥25 mg prednisone ≥100mg hydrocortisone	Enter yes or no as appropriate.	Required.
8. Vasopressors/inotropes this calendar day:	Select YES or NO to indicate whether the patient received vasopressors or inotropes this calendar day. If 7=YES, indicate infusion rates at 0800. If none infusing at 0800, enter "none" in the "other" field.	Required.

ON STUDY LABS

DAYS REQUIRED: **Complete on study days 1-12**
Instruction: Use value **closest to 0800** on this calendar date. RECORD IF CLINICALLY AVAILBLE UNLESS OTHERWISE INDICATED.

DATA ITEM	DETAILS	LOGIC RULES
1. Hgb	Enter in g/dL	Collect if available closest to 0800.
2. Sodium	Enter serum sodium in mEq/L	
3. Potassium	Enter serum potassium in mEq/L	
4. Glucose	Enter serum glucose in mg/dL	
5. Serum bicarb.	Enter serum bicarbonate in mEq/L	
6. Serum Phosphorus	Enter serum Phosphorus in mEq/L	Required on days 1,3, 8 for **EDEN/Omega**
7. Serum Magnesium	Enter serum magnesium in mg/dL	
8. Total protein	Enter serum total protein in g/dL	Required on days 1,7,12 for **EDEN/Omega**
9. Albumin	Enter serum albumin in g/dL	
10. Prothrombin time	Enter if available	Enter if available
If receiving insulin:		
11. Insulin drip rate at time of glucose value	Enter drip rate in u/hr. Enter "0" if no insulin infusion at time of glucose value.	Required if receiving insulin
12. Total SQ insulin given in the 6 hours preceding the glucose value	Enter total dose of SQ insulin given in the 6 hours prior to the glucose value in question 4. Enter "0" if no sq insulin given in the 6 hrs proceeding the glucose value	Required if receiving insulin.
13. Lowest glucose value this day.	Enter the lowest glucose value recorded for this day (including glucometer readings).	Required.

ON STUDY VENTILATOR PARAMENTERS

DAYS REQUIRED: **1-4, 7, 12, 21, AND 28**

INSTRUCTION: COMPLETE IF THE PATIENT IS ON **ASSISTED BREATHING** OR IS ATTEMPTING TO **WEAN**. USE VALUES FROM THE REFERENCE PERIOD 06:00-10:00; IF MORE THAN ONE VALUE AVAILABLE **USE THE VALUE CLOSEST TO 08:00**. **If values not available during reference period, use value closest to 08:00 on that calendar date.**

DATA ITEMS	DETAILS	LOGIC RULES
1. Ventilator mode:	Select all modes that apply. If **Pressure Support** or **Pressure Assist** is selected, please enter the level.	Required.
2. Calculated delivered tidal volume	Enter the corrected inspired tidal volume: inspired tidal volume (ml) set on the ventilator minus any additional tidal volume added to correct for has compression and ventilator tube expansion (this should = the tidal volume called for by the protocol; this will not = the volume set on the ventilator unless the ventilator makes automatic adjustments for gas compression/tube expansion). Puritan-Bennett 7200's and some other ventilators make this correction automatically (for these vents the value set on the vent = the calculated delivered tidal volume).	Required field for A/C modes.
3. Set Rate	Enter the rate set on the ventilator if the patient is on SIMV, SIMV with Pressure Support, Assist/Control, or Pressure Control mode. (This is the minimum rate set on the ventilator, not the patient rate).	Record if available.
4. Total Respiratory Rate	Enter the total respiratory rate, which may exceed the Set Rate above if the patient is making additional inspiratory efforts.	Required field.
5. Total Minute Ventilation (VE)	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field.
6. PEEP	Enter the PEEP applied on the ventilator in cmH_2O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.
7. FiO2 at 0800	Enter FiO2 value at 0800. Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%)	Required.
8. SpO2 at 0800	Enter SpO2 value at 0800.	Required.
9. Plateau Pressure (Pplat)	Enter the value for plateau pressure measurement in cm H_20. The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	Record if available.
10. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Record for SIMV and A/C modes.
11. Mean Airway Pressure	Enter the mean airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Record if available.
If ABG clinically available this calendar day, complete questions 19 through 23. If more than one ABG available, select the ABG closest to 0800.		
12. FiO2 at time of ABG	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%) at the time of the ABG.	Record if available.

DATA ITEM	DETAILS	LOGIC RULES
13-15. PaO_2, PaCO2, and Arterial pH	Enter results of the arterial blood gas available closest to the 0800 on this calendar date.	Record if available
16. SpO2 at time of ABG.	Enter SpO2 at time of ABG.	Record if available.

INTAKE AND OUTPUT

DAYS REQUIRED: **Days 1-8**
INSTRUCTIONS: Daily fluid totals should capture the total for the PREVIOUS day.
Example: When completing the day 3 CRF, enter the totals for day 2
Volume of enteral feeds may be collected in a 24-hour period that is the most convenient for you.
Example: If your ICU flow sheets record totals at 7 AM rather than midnight, you may use the 24-hour period from 0700 on the study day until 0700 on the following day. (Day 2 total should cover 0700 on day 2-0700 on day 3 and should be entered on the **DAY 3** CRF)
If your totals are done at midnight, use totals for that calendar day.

PLEASE NOTE:
For patients on CVVH/dialysis, add the NET negative balance to **"total fluid out",** add a positive balance to "**total fluid in".**

DATA ITEM	DETAILS	LOGIC RULES
1. **TOTAL** fluid intake last 24h:	Enter the **total** fluid intake for the PREVOUS 24 hours (totals for day 2 should be entered on the day 3 CRF). **(CVVH positive balance should be included).**	Required.
2. PRBC in last 24h:	Enter the total number units of PRBCs for the PREVIOUS 24 hours.	Required.
3. FFP last 24h:	Enter the total number units of FFP for the PREVIOUS 24 hours.	Required.
4. **TOTAL** fluid output last 24h:	Enter the **total** fluid output for the PREVOUS 24 hours (this 24 hours **should include UOP and a negative CVVH balance)**.	Required.
5. Total **URINE** out last 24h:	Enter the **total** UOP only for the previous 24 hours.	Required.

RANDOM PROTOCOL CHECK

DAYS REQUIRED: **Days 1-7 while on assisted breathing**

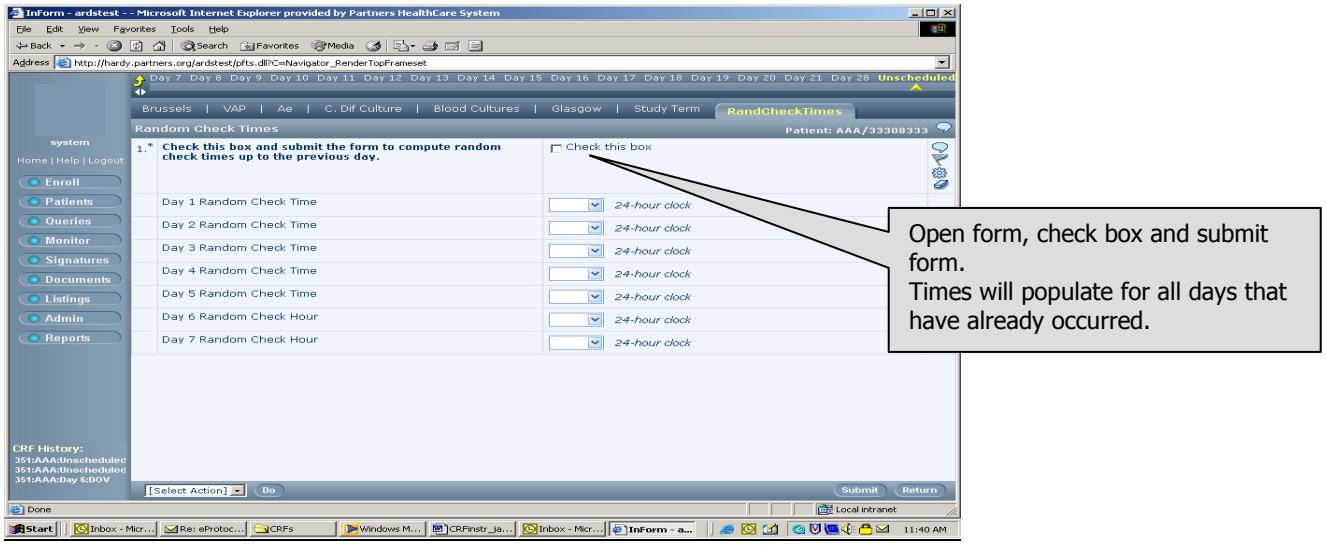
INSTRUCTIONS: Random check times for each day can be obtained from the **Random Check Times** CRF *(available with the unscheduled forms in Inform).* You will NOT be able to access the random check times in advance. You will only be able to obtain the times for days that have already passed **(see instructions below).**

DATA ITEM	DETAILS	LOGIC RULES
1. Vasopressors in the 12h prior to the random check time?	Select yes or no as appropriate.	Required.
2. MAP <60 mmHg in the 12h prior to the random check time?	Select yes or no as appropriate.	Required.
3. IV maintenance fluids in the 4h prior to the random check time?	Select yes or no as appropriate.	Required.
4. Lasix given in the 4h prior to the random check time?	Select yes or no as appropriate.	Required.
5. Fluid bolus given in the 12h prior to the random check time?	Select yes or no as appropriate.	Required.
6. **INADEQUATE UOP?** (Average UOP in the 4h prior to the random check time < 0.5 ml/kg/hr)?	Select yes or no as appropriate.	Required.
7. CVP or PAOP for random check time:	Enter the most recent CVP or wedge prior to the time of random check.	Required if available.
Complete question 8 on days 1-3 only.		
8. Enrolled in EDEN or co-enrolled?	Select yes or no to indicate whether the subject was enrolled in the EDEN trial. ▪ If yes, enter propofol infusion rate at time of random check.	Required on days 1-3.

Random Check Times

Access the random check times from the "unscheduled" forms in Inform.

- Check the "check box" in question 1 and submit the form.
- The form will be populated with the random check times prior to the present day.
- To access the remaining times, open form on a later day and follow the above instructions. Once all days are populated, the form is complete.



ALCOHOL and SMOKING SURVEY

DAYS AVAILABLE: **Day 0**

Instructions: The subject or surrogate should complete this survey on paper; answers should then be entered into the electronic case report form.

Please review the form once the subject/surrogate has completed. Clarify answers that were completed inadvertently (Example: if 1-never, questions 2-8 should be left blank. If surrogate has answered these, please clarify before entering data into Inform)

DATA ITEM	DETAILS	LOGIC RULES
1. How often do you have a drink containing alcohol?	If "never", SKIP to question 9.	Required.
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	Select appropriate choice.	Required if 1 does NOT equal "never".
3. How often do you have six or more drinks on one occasion?	Select appropriate choice.	
Skip to Q9 if 1=never; Skip to Q9 if patient consumes MORE than 4 drinks per day and Q3=never.		
4. How often during the last year have you found you were not able to stop drinking once you had started?	Select appropriate choice.	Required if patient consumes 1-4 drinks/day and 3 does NOT equal "never"
5. How often during the last year have you failed to do what was normally expected from you because of drinking?	Select appropriate choice.	
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Select appropriate choice.	
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Select appropriate choice.	
8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Select appropriate choice.	
9. Have you or someone else been injured as a result of your drinking?	Select appropriate choice.	Required.
10. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?	Select appropriate choice.	Required.
Smoking History		
11. Ever smoker? (>100 cigarettes in lifetime)	Select Yes or No.	Required.
12. If 11=yes, estimate pack years:	Pack years = (# packs/day) x (# years smoked)	Required if 11=yes.
13. If 11=yes, current smoker?	Select yes or no. ▪ If NO, enter date patient quit smoking.	Required if 11=yes.

GLASGOW COMA

DAYS REQUIRED: **0, 7, AND HOSPTIAL DISCHARGE (or day 28, whichever comes first)**
INSTRUCTION: USE THE OPTIONS LISTED ON THE CRF TO CALCULATE THE **WORST** GCS FOR THIS CALENDAR DATE. **ALL THREE COMPONENTS SHOULD ORIGINATE FROM THE SAME TIME POINT.**

Inform instructions: GCS form is REQUIRED on day 0, day 7 and day 28 (or date of discharge if before day 28). If patient is discharged on any other day prior to 28, complete the GCS form located with the "unscheduled form" and enter the date of the score.

DATA ITEM	DETAILS	LOGIC RULES
Complete answers for the WORST GCS of the day.		
1. Pt on sedative or neuromuscular blocker?	Select YES or NO to indicate if the pt was sedated or receiving a paralytic at time of GCS assessment.	Required field.
2. Eye Opening Score	Select the option that indicates the best response. If patient's eyes are swollen shut, estimate best response.	Required field.
3. Motor Response Score	Select the option that indicates the best response.	Required field.
4. Verbal Response Score	Select the option that indicates the best response. If patient was intubated on this date select from the "on vent" pick-list and use clinical judgment to estimate best response. If unsure, enter "3-questionably oriented".	Required field.
5. GCS-total score:	Computer calculated total Glasgow Coma Score.	Calculated value.

BLOOD CULTURES (EDEN)

DAYS REQUIRED: Unscheduled
REQUIRED: PLEASE RECORD ALL **NEW** POSITIVE BLOOD CULTURES COLLECTED **AFTER STUDY ENROLLMENT** THROUGH DAY 28.
Inform instructions: This is an "Add Entry" from. Click "add entry" to open form for **EACH** new positive blood culture collected after study enrollment.

DATA ITEMS	DETAILS	LOGIC RULES
1a. Date and time	Enter the date (mm/dd/yyyy) and time that each **positive** blood culture was **COLLECTED** (not the date that the results were reported)	Record if available
1b. Organism	Select the corresponding organism for each positive culture from the list provided. If the organism is not listed, select OTHER.	Required field for items with a date entered.

CLOSTRIDIUM DIARRHEA (EDEN)

DAYS REQUIRED: Unscheduled
REQIRED: PLEASE RECORD ALL **NEW** POSITIVE C. Dif CULTURES COLLECTED **AFTER STUDY ENROLLMENT** THROUGH DAY 28.
Inform instructions: This is an "Add Entry" from. Click "add entry" to open form for **EACH** new positive blood culture collected after study enrollment.

DATA ITEMS	DETAILS	LOGIC RULES
Date and time of stool specimen.	Enter the date (mm/dd/yyyy) and time that each positive C. Dif stool specimen was **COLLECTED** (not the date that the results were reported).	Record if available

CONCOMITANT MEDICATIONS (EDEN)

DAYS REQUIRED: 1-12 OR UNTIL PATIENT REACHES UAB.
INSTRUCTION: COMPLETE THIS FORM FOR ALL **EDEN/Omega** SUBJECTS.

DATA ITEMS	DETAILS	LOGIC RULES
1. Narcotics this calendar date?	Please select **Yes or No** to indicate if any narcotics were given this calendar date (see examples listed on CRF).	Required.
2. Paralytics this calendar date?	Please select **Yes or No** to indicate if any paralytics were given this calendar date (see examples listed on CRF).	Required.
3. Parakinetics this calendar date?	Please select **Yes or No** to indicate if any parakinetics were given this calendar date (see examples listed on CRF).	Required.
4. Anti-emetics this calendar date?	Please select **Yes or No** to indicate if any anti-emetics were given this calendar date (see examples listed on CRF).	Required.
5. Anti-diarrheals this calendar date?	Please select **Yes or No** to indicate if any anti-diarrheals were given this calendar date (see examples listed on CRF).	Required.
6. Laxatives this calendar date?	Please select **Yes or No** to indicate if any laxatives were given this calendar date (see examples listed on CRF).	Required.

VENTILATOR ASSOCIATED PNEUMONIA (EDEN)

DAYS REQUIRED: **Unscheduled**

Only one episode will be considered to be present during the 28-day period due to difficulty in defining successful therapy during this time period. **Once you have confirmed the diagnosis for the first time there is no need to continue VAP assessments.**

DATA ITEM	DETAILS	LOGIC RULES
1. Date of VAP diagnosis:	Enter date of VAP diagnosis based on the following criteria.	Required.
A positive diagnosis of VAP (for the purposes of this study) requires that **at least two of the three criteria** listed below be present in a **48-hour period**. **Within a period of 48 hours did the patient have:**		
2. CXR shows new infiltrate that persisted for 48h?	Select **YES or NO** to indicate if pt has a chest film that shows a new infiltrate persistent for 48 hours.	Required.
3. New fever of hypothermia or leukocytosis or leukopenia?	Select **YES or NO** to indicate if any of these conditions were met. ▪ T≥ 38.3 C or increase ≥ 1C over the previous 24 hour T_{max} if T already 38.3 ▪ T≤ 36.0 C ▪ Increase in WBC (WBC > 10,000 and a 25% increase or an increase in band forms to > 10% of total WBC ▪ New decrease in WBC to < 4,000.	Required.
4. Bacteriological confirmation of pulmonary infection?	**Select YES if any of the following are present:** -Quantitative culture of tracheal secretions with > 10^6 cfu/mm^3 -Quantitative culture of bronchoalveolar lavage with > 10^4 cfu/mm^3 -Quantitative culture of protected specimen brush with > 10^3 cfu/mm^3 -Positive Gram stain with ≥ 3+ of at least one type of bacteria -Positive semi-quantitative sputum culture with ≥ 3+ growth of at least one type of potentially pathogenic bacteria -Positive blood culture for bacterial pathogen also identified in sputum or other respiratory specimens -Positive Gram stain or culture of pleural fluid for bacterial pathogen	Required.

BRUSSELS TABLE

DAYS REQUIRED**: DAILY UNTIL DAY 28.**
INSTRUCTION: COMPLETE THIS FORM USING ***CLINICALLY AVAILABLE*** DATA ON ALL DAYS UNTIL DEATH OR STUDY HOSPITAL DISCHARGE, WHICHEVER COMES FIRST. **NOTE:** SEE PROTOCOL TO IDENTIFY LABS THAT ARE **REQUIRED** ON CERTAIN DAYS.

Record the **worst** values for the calendar day for each of the five variables shown at the headings of the columns.
Worst values are defined as:

- Systolic — **Lowest** value for the date.
- P/F Ratio — **Lowest** value for the date.
- Platelets — **Lowest** value for the date.
- Creatinine — **Highest** value for the date.
- Total Bilirubin — **Highest** value for the date.

- **Vasopressors yes/no:** Select (Yes) to indicate that one or more vasopressors were used on the calendar date. Select (No) if no vasopressors were used on the calendar date. **"Vasopressor" is defined as:** Dopamine ≥ 6 mcg/kg/min and Neo-Synephrine, epinephrine, vasopressin, or Levophed at any rate. **Dobutamine is NOT considered a vasopressor.**

Inform instructions: Access the Brussels form from the "Unscheduled CRFs". **NOTE:** Complete data for FULL days before submitting the form to avoid the "change data log". Example: If you complete SBP and P/F on days 1-5, but do NOT complete the remaining questions on those days, you will be prompted to enter a reason for changed data for each of the remaining fields on those days when you re-open the form to complete. To avoid this, complete full days before saving. You can enter the data on the days you are completing in any order prior to submitting form.
NOTE: You do not need to enter a comment for values not clinically available—simply leave the field blank.

DATA ITEMS	DETAILS	LOGIC RULES
For the day 0.5 Brussels, collect the WORST values from the time of randomization until midnight.		
▪ SBP	Record the **lowest** value for each calendar day.	Required.
▪ P/F	Record the **lowest** intubated value for each calendar day.	Required if available and **intubated.**
▪ Platelets	Record the **lowest** value for each calendar day.	Required if available.
▪ Creatinine	Record the **highest** value for each calendar day.	Required if available.
▪ Bilirubin	Record the **highest** value for each calendar day.	Required if available.
▪ Vasopressors	Select (Yes) to indicate that one or more vasopressors were used on the calendar date. Select (No) if no vasopressors were used on the calendar date. **"Vasopressor" is defined as:** Dopamine ≥ 6 mcg/kg/min and Neo-Synephrine, epinephrine, vasopressin, or Levophed at any rate. **Dobutamine is NOT considered a vasopressor.**	Required.

ADVERSE EVENT REPORTING

DAYS REQUIRED

EDEN/Omega: Monitor daily for adverse events until day 23 OR ICU discharge, WHICHEVER OCCURS FIRST.
ALTA: Monitor daily for adverse events until 72 hours after final dose of study drug.

INSTRUCTION: This form should be used to capture All CLINICALLY IMPORTANT **and** UNEXPECTED adverse events that occur from time of initiation of the first study procedure until study day 21 or until ICU discharge, whichever occurs first. See the Adverse Event Sections of the protocols for description of reporting procedures.

Deaths will be captured on the study termination form and will NOT require a "death report form". Deaths resulting from an adverse event will fall under the reporting requirements of an IMMEDIATELY REPORTABLE AE outlined below.

The Adverse Event Form should not be used as the primary method to capture organ failures related to ARDS; these are systematically captured by the protocol.

IMMEDIATELY REPORTABLE AE= SERIOUS + UNEXPECTED + STUDY RELATED:
All SERIOUS **AND** UNEXPECTED **AND** STUDY-RELATED adverse events should be reported to the Clinical Coordinating Center *within 24 hours by phone*. The investigator must submit a detailed, written report to the Clinical Coordinating Center within **5 working days**. The Institutional Review Board should be notified based on institutional policy, but no later than 5 working days after the event is discovered.

☒ **NOTE: To report a serious AE that occurs over the weekend or after hours page the on-call investigator.**

A COMPUTER FILE OF THE ***COSTART*** PICKLIST IS NEEDED TO COMPLETE QUESTION 5. SELECT THE **BEST** TERM FROM THE SEARCH WINDOW, THEN HIGHLIGHT IT AND **CUT AND PASTE** INTO QUESTION 5 (file available on the ARDSNet web site under General Study Tools).

ITEM	DEFINITION	DATA RULES
1. Date of event	Enter the calendar date that the event first occurred.	Required field.
2. Time of event	Enter the time (military) the event began.	Required field.
3. Protocol specified **EDEN AE?**	Select YES or NO. **If yes**, select the protocol specified AE from the list. **For ALTA only** patients, select "Not enrolled in EDEN/Omega".	Required field.
4. Name of event if not a protocol specified event:	Select the term from the COSTART pick-list (located in the COSTART file available on the ARDSNet web site under General Study Tools) that BEST categorizes the event.	Required if 3 and 4=No
5. Description of the event:	Give a brief narrative description of the event. Include: ➢ Course of events that lead to the AE, ➢ Relationship of the time of the event to the time of a study procedure, if applicable. ➢ Include same elements for description of a death for a fatal AE.	Required field.

ITEM	DEFINITION	DATA RULES
6. Severity of event	Select one: **MILD-**Any event that is usually transient requires no special treatment and does not interfere with the patient's daily activities. **MODERATE**- Any event that introduces a low level of inconvenience or concern to the patient and may interfere with daily activities. Usually ameliorated by simple measures. **SERIOUS**-Any event that if fatal or immediately life threatening, is permanently disabling, or severely incapacitating, or requires or prolongs inpatient hospitalization.	Required field. CCC MUST BE NOTIFIED WITHIN 24 HOURS FOR **SERIOUS, UNEXPECTED** AND **STUDY RELATED** EVENTS!!!!!
7. Unexpected or more severe than expected for ALI/ARDS patients receiving enteral nutrition?	Select Yes or No or Unknown to indicate the expectedness of the AE for EDEN.	
8. Causal relationship to **Enteral feeds?**	Select the answer, which best describes the event's relationship to the EDEN/Omega protocols. **1= Definitely Associated- The event follows:** a) A reasonable, temporal sequence from a study procedure; b) Cannot be explained by the known characteristics of the patient's clinical state or other therapies; c) Evaluation of the patient's clinical state indicates to the investigator that the experience is definitely related to study procedures. **2=Probably or 3=Possibly Associated:** The event should be assessed following the same criteria for "Definitely Associated". If in the investigator's opinion at least one or more of the criteria are not present, then "probably" or "possibly" associated should be selected. **4=Probably Not Associated:** The event occurred while the patient was on the study but can reasonably be explained by the known characteristics of the patient's clinical state or other therapies. **5=Definitely Not Associated:** The event is definitely produced by the patient's clinical state or by other modes of therapy administered to the patient. **6=Uncertain Association:** The event does not meet any of the criteria previously outlined.	Required fields.
9. Causal relationship to other study procedures?		
10. Were the **EDEN** (enteral feedings) study procedures permanently discontinued because of this event?	Select Yes or No as appropriate.	Required field.

ITEM	DEFINITION	DATA RULES
11. Status of the EVENT at time of initial AE report.	Select Recovered, date, AE present, no tx, AE present, being treated, Residual effect/no tx, Residual effect/being treated, or Deceased as a result of this event. ***Select deceased ONLY if the patient died as a result of the event.***	Required field.
If recovered, date:	If the answer selected is **Recovered**, select the date (either from the pop-up calendar or enter in mm/dd/yyyy) of recovery from the event.	Required field if "recovered" selected. Form is complete if 11=recovered/dated
12. FINAL outcome of AE	The patient should be followed until the reported event is RESOLVED or until 48 hours UAB, which ever occurs first. Enter the date (mm/dd/yyyy) of resolution.	Required fields if #15 = any answer except "recovered" or "deceased".

SPECIMEN COLLECTION

DAYS REQUIRED: Baseline, 1, 3, 6, and 12

Inform Instruction: CRF is available on all required days. You can complete all data for ALL days by opening it on any of the available days. Once you have completed the form on any of the days, the data entered will also appear on the remaining days.

- **ALL baseline** specimens should be collected **BEFORE** initiating study procedures.
- Plasma for pharmacokinetics (albuterol, fatty acids and epinephrine) should be collected on the **assigned** day.
- The urine and plasma for "research" specimens (repository specimens) can be collected **+/- one day** (Example: day 6 urine can be collected on day 5, 6, or 7).
- Whole blood for DNA should be collected at baseline if possible, but can be collected later if necessary.

DATA ITEM	DETAILS	LOGIC RULES
Study Day 0 (baseline)		
1. SeraCare Day zero accession number:	Enter the ACCESSION number from the label set used for day 0.	Required.
2. Date BASELINE specimens collected:	Complete DATE of baseline specimen collection.	Required.
3. Cytokine and coagulation parameters sample collected?	Select Yes or No to indicate whether the sample was obtained. If No, indicate reason.	Required.
4. Urine sample collected?	Indicate date of genetics sample collection.	
5. Genetics sample collected?		
Study Day 3		
6. SeraCare Day 3 accession number:	Enter the ACCESSION number from the label set used for day 3.	Required if patient still on study.
7. Cytokine and coagulation parameters sample collected?	Select Yes or No to indicate whether the sample was obtained. If Yes, complete date of collection. If No, indicate reason.	
8. Urine sample collected?		
Study Day 6		
9. SeraCare Day 6 accession number:	Enter the ACCESSION number from the label set used for day 6.	Required if patient still on study.
10. Cytokine and coagulation parameters sample collected?	Select Yes or No to indicate whether the sample was obtained.	
11. Urine sample collected?	If Yes, complete date of collection. If No, indicate reason.	
Study Day 12		
12. SeraCare Day 12 accession number:	Enter the ACCESSION number from the label set used for day 12.	Required if patient still on study.
13. Cytokine and coagulation parameters sample collected?	Select Yes or No to indicate whether the sample was obtained. If Yes, complete date of collection. If No, indicate reason.	

STUDY TERMINATION

DAYS REQUIRED**: DAY 28 AND UP THROUGH DAY 90**
INSTRUCTION: **BEGIN COMPLETION OF THIS FORM BY DAY 28.**

- If status at Day 28 is "other", follow to Day 90, **update this field to reflect the change.**
- PATIENTS WHO ARE NOT YET HOME WITH UNASSISTED BREATHING (UAB) SHOULD BE FOLLOWED THROUGH DAY 90.
- **Up to Day 90 Capture**: 1) ICU discharge date (and ALL ICU re-admissions in study hospital if applicable); 2) Study hospital discharge date AND vital status at discharge; and 3) On/Off assisted breathing dates.

ITEM	DEFINITION	DATA RULES
1. Patient Status (through Day 90):	**Select "home with UAB**" if the patient is home with unassisted breathing at any time up through day 90. "Home" is defined as the place the patient lived prior to study hospital admission (i.e., pt living in a nursing home→admitted to study hospital and enrolled into study→DC'd back to nursing home on UAB. The nursing home would qualify as "home on UAB". Pts previously living at home who are discharged to a rehab facility on UAB from study hospital would NOT qualify as being "home on UAB".) **Select "Dead**…" if the patient died prior to discharge home with unassisted breathing or died prior to achieving unassisted breathing at home for 48 hours. **Select "Other**" if neither condition above applies. E.g., if the patient went home on assisted breathing and has not achieved unassisted breathing for 48 hours, continues on assisted breathing, or has been transferred to another facility, other than home, on unassisted breathing.	Required field.
	Enter the appropriate **date of discharge** home with unassisted breathing (if condition 1 above), **date of death** prior to discharge home with unassisted breathing (if condition 2, above), or date of last KNOWN patient status, i.e., date that the patient was last know to be alive and does not meet the other 2 criteria (if condition 3 above).	Required field. There should be only ONE date entered to correspond with the selected status option.
2. Was pt permanently withdrawn from the trial?	Choose the check box for the trial the subject is enrolled in and indicate whether the patient was *withdrawn* from participation in that trial. Do NOT answer "yes" for patients who have met criteria for COMPLETION of the protocol.	Required field.
Date and reason for patient withdrawal from trial:	If subject withdrawn from either trial, please enter the date and reason for withdrawal.	Required if 2 = Withdrawn.
3. Did patient reach full calorie feeding rate?	Select YES or NO for all EDEN/Omega patients and indicate date and time full calorie rate was **FIRST** reached.	Required for EDEN/Omega

4. Patient discharged alive from study hospital?	Select YES or NO to indicate if the patient was discharged alive from the **study hospital** up through Day 90. If Yes, enter date.	Required field.
5. Did patient meet criteria for SBT prior to day 29?	**Select Yes or No.** **If yes, enter the FIRST date that patient met criterion for SBT.**	Required.
6. Did subject **tolerate** SBT prior to day 29?	**Select Yes or No** The following protocol criteria should be used to assess whether the SBT was tolerated: Monitor for tolerance using the following: 1. $SpO_2 \geq 90\%$ and / or $PaO_2 \geq 60$ mmHg 2. Mean spontaneous tidal volume ≥ 4 ml / kg PBW (if measured) 3. Respiratory Rate ≤ 35 / min 4. pH ≥ 7.30 (if measured) 5. No respiratory distress (defined as 2 or more of the following): a. Heart rate ≥ 120% of the 0600 rate (≤ 5 min at > 120% may be tolerated) b. Marked use of accessory muscles c. Abdominal paradox d. Diaphoresis e. Marked subjective dyspnea. **If yes, enter date that patient FIRST tolerated the SBT.**	
7. Did subject reach 48 hours of UAB prior to day 29?	**Select Yes or No.** Example: if patient reaches criteria for UAB on 1/1/07 at 1000, and remains on UAB, then the first time the subject reaches 48 hours of UAB would be 1/3/07 at 1000. If yes, enter the date that the subject FIRST reached 48 hours UAB.	Required.
8. Was subject extubated prior to study day 28?	**Select Yes or No.** If yes, enter the date that the subject was FIRST extubated.	Required.
9. Did subject undergo tracheostomy prior to day 29?	**Select Yes or No.** If yes, enter the date of tracheostomy.	Required.
FOR QUESTION 10-18, DOCUMENT ALL INCIDENCES OF ICU ADMISSIONS AND DISCHARGES *DURING THE STUDY HOSPITALIZATION* UP THROUGH DAY 90		
10. Was patient discharged from an ICU?	Select the option that best applies. Enter the date of **ICU discharge.**	Questions are required until a "No" response is selected, and then skip to # 19.
11. Was patient readmitted to an ICU?	Was the pt readmitted to an ICU during study hospitalization? This includes **any ICU within the study hospital**. Enter the date of ICU readmission.	Required if 10 =Yes

12. Was patient discharged a 2nd time from an ICU?	Was the pt discharged from the ICU after readmission to the ICU? Enter date of ICU discharge.	Required if 11 = Yes.
13-18.	Use these questions to capture all other ICU readmissions and discharges, occurring in study hospital, up through Day 90 when applicable.	
VENTILATOR HISTORY: FOR QUESTIONS 19-25 CAPTURE ALL INCIDENCES OF UNASSISTED BREATHING UNTIL DC HOME, DEATH, OR UNTIL PT HAS BEEN FOLLOWED TO DAY 90 **A VENTILATOR DAY IS:** ANY DAY IN WHICH THE PT RECEIVED ASSISTED BREATHING; EXCEPTION: ASSISTED BREATHING FOR <24 HRS FOR A PROCEDURE OR SURGERY.		
19. Did patient achieve UAB?	Select Yes or No. **If Yes:** Enter the first date that the pt was on UAB from **midnight to midnight** (i.e., If the pt reached UAB on Day 2 and remained off the vent through Day 3, Day 3 would be the date of first **UAB**).	Questions are required until a "No" response is selected.
20. Did patient return to AB?	Select Yes or No. **If yes:** Enter date that patient returned to assisted breathing.	Required if 19 = yes.
21-25.	Use these questions to capture ALL other incidences of UAB occurring at any location until dc home, death, or pt is followed to Day 90.	
26. End of life decision-making?	This field is intended to capture information on end of life decision making for ALL patients. "Life Support" includes (but is not limited to): mechanical ventilation, vasopressors, IV fluids, antibiotics, dialysis, and blood products. *Select the option that best applies: 1) No DNR decision made (includes pts receiving aggressive management, including failed CPR) 2) DNR Decision made: withhold only CPR (includes pts receiving aggressive management up to *but not including* CPR) 3) DNR Decision made: withhold life support *in addition to* CPR. (Includes pts with an identified antemortem decision to withhold some form of life support, i.e., in the event of renal failure will not dialyze or if respiratory failure occurs will not re-intubate). 4) DNR Decision made: withdraw life support (includes **removal** of mechanical ventilation, dialysis, or discontinuation of vasopressors or antibiotics). 5) Diagnosis of Brain Death (per study site institutional standards for brain death criteria). 6) Unknown/can't tell	Required.
27. Was written consent obtained from subject during study hospitalization?	Select yes or No to indicate whether the SUBJECT provided written consent (continued consent if subject initially consented by surrogate).	Required.

28. Require dialysis during study hospitalization?	Select Yes or no. If Yes, enter first and last day of dialysis.	
29. Received TPN?	Please select Yes or No to indicate whether patient received TPN between the time of enrollment and ICU discharge (or study day 21).	

***** Criteria for DNR grading adapted from: Prendergast T, Claessens M, and Luce J. *A National Survey of End-of-life Care for Critically Ill Patients*. Am. J. Respir. Crit. Care Med., Volume 158, Number 4, October 1998, 1163-1167