

ARDSNet (OMEGA) Case Report Forms (CRFs)

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oldaltajan08 : System Enrollment (Enroll) table = enroll	
1.	Study ID: subject xxxxxxxx (30000000 =< n < 50000000)
2.	Verify Study ID: xxxxxxxx (30000000 =< n < 50000000)

oldaltajan08 : Study (Study) table = study	
1.	<p>Date and time of randomization: randomdtm</p> <p>Make CERTAIN that date is correct before saving.</p>
	<p>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>Req <input type="text"/> : Req <input type="text"/> 24-hour clock</p>
2.	<p>Study Enrollment: study</p> <p>Make CERTAIN that selection is correct before saving.</p>
	<p>[1] <input type="radio"/> ALTA Only</p> <p>[2] <input type="radio"/> EDEN/Omega only</p> <p>[3] <input type="radio"/> Coenrolled in both ALTA and EDEN/Omega</p>
3.	<p>Study Patient ID:</p>
	<p>A255</p>

oldeden : Enrollment Form I (Enrollment 1) table = enroll1	
COMPLETE FOR ENROLLED PATIENTS MEETING CRITERIA IN DESIGNATED ICU'S	
1. Did patients meet the following 3 criteria: allcrit	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
i. Acute Onset (Defined on screening form)	
ii. Within past 24 hrs patient had ALL of the following? -PaO2/FiO2 less than or equal to 300 mmHg? -Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph? -Receiving positive pressure ventilation via endotracheal tube?	
iii. No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure < or = 18 mmHg)?	
2. Date and time of qualifying CXR: qualdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3. Number of quadrants with opacities (2-4): quads	x (2 <= n <= 4)
4. Date and time of current intubation intubdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
5. Intent to begin/continue enteral feedings? intfeed	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
6. PaO2: pao2screen	xxx (n >= 3) mmHg
7. FiO2: fio2screen	x.xx (0.21 <= n <= 1.0)
8. Date and time of qualifying P/F: qualpfdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
9. First date that all these criteria exist simultaneously: critdt	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)
10. Gender: gender	[1] <input type="radio"/> Male [2] <input type="radio"/> Female
11. Ethnicity: ethnic	[1] <input type="radio"/> Hispanic or Latino [2] <input type="radio"/> Not Hispanic or Latino
12. Race (Check all that apply):	[1] <input type="checkbox"/> American Indian or Alaskan Native [2] <input type="checkbox"/> Asian [5] <input type="checkbox"/> White [3] <input type="checkbox"/> Black or African American [4] <input type="checkbox"/> Native Hawaiian or other Pacific Islander [5] <input type="checkbox"/> Not Reported
13. Age as appears on screening form (in years): age	xxx (n >= 13)
14. Is patient's true age greater than 89? agegt89	[1] <input type="radio"/> Yes, patient is older than 89 years. True age is: agettrue

native
asian
white
afamer
island
norace

		<input type="radio"/> No
15.	Location: locat	<input type="radio"/> [1] MICU <input type="radio"/> [2] SICU <input type="radio"/> [3] Cardiac SICU <input type="radio"/> [4] CCU <input type="radio"/> [5] Neuro ICU <input type="radio"/> [6] Burn <input type="radio"/> [7] Trauma <input type="radio"/> [8] Cancer Unit <input type="radio"/> [9] MICU/SICU <input type="radio"/> [10] Other locatoth
16.	Reason for Exclusion excluded	<input type="radio"/> [1] Exclusions: agelt13 <input type="checkbox"/> Age younger than 13 years gt48hr <input type="checkbox"/> Greater than 48 hours since all inclusion criteria met nmdis <input type="checkbox"/> Neuromuscular disease that impairs ability to ventilate without assistance preg <input type="checkbox"/> Pregnant or breast-feeding chronresp <input type="checkbox"/> Severe chronic respiratory disease burns <input type="checkbox"/> Burns greater than 40% total body surface area sixmthmort <input type="checkbox"/> Malignancy or other irreversible disease or condition for which 6-month mortality is estimated to be greater than 50% marrowtrans <input type="checkbox"/> Allogeneic bone marrow transplant in the last 5 years notcomm <input type="checkbox"/> Patient, surrogate, or physician not committed to full support chronliv <input type="checkbox"/> Severe chronic liver disease (Child-Pugh Score of 11-15) alvhem <input type="checkbox"/> Diffuse alveolar hemorrhage from vasculitis obese <input type="checkbox"/> Morbid obesity (> 1kg/cm body weight) nocons <input type="checkbox"/> No consent/inability to obtain consent inabvent <input type="checkbox"/> Contraindications to (inability to utilize) the ARDS network 6ml /kg PBW ventilation protocol (e.g. high frequency ventilation) moribund <input type="checkbox"/> Moribund patient not expected to survive 24 hours nocvacc <input type="checkbox"/> No intent to obtain central venous access for monitoring intravascular pressures ptrefalta <input type="checkbox"/> Patient/surrogate refusal to ALTA ptrefeo <input type="checkbox"/> Patient/surrogate refusal to EDEN/Omega gt72grvent <input type="checkbox"/> Greater than 72 hours since mechanical ventilation initiated

- | | | |
|-----------|--------------------------|--|
| refshock | <input type="checkbox"/> | Refractory shock (defined in protocol) |
| noentacc | <input type="checkbox"/> | Unable to obtain enteral access |
| hoentfist | <input type="checkbox"/> | Presence of high-output (>500 cc/day) enterocutaneous fistula |
| curtpn | <input type="checkbox"/> | Current TPN use or intent to use TPN within 7 days |
| malnutr | <input type="checkbox"/> | Severe malnutrition with BMI < 18.5 or loss of > 30% total body weight in the previous 6 months |
| lap | <input type="checkbox"/> | Laparotomy expected within 7 days |
| raisehead | <input type="checkbox"/> | Unable to raise head of bed 30-45 degrees |
| shbowel | <input type="checkbox"/> | Short-bowel syndrome or absence of gastrointestinal tract |
| hoentfist | <input type="checkbox"/> | Presence of high-output (>500 cc/day) enterocutaneous fistula |
| inrgt5 | <input type="checkbox"/> | INR > 5.0 or platelet count < 30,000/mm ³ or history of bleeding disorder |
| ichem | <input type="checkbox"/> | Intracranial hemorrhage within the previous month |
| allergy | <input type="checkbox"/> | Allergy to enteral formula, n-3 fatty acids, gamma-linolenic acid, vitamin E, vitamin C, beta-carotene, taurine, or L-carnitine |
| reqsub | <input type="checkbox"/> | Requirement for, or physician insistence on, enteral formula supplemented with omega-3 fatty acids (ex: Oxepa®, Impact®) or providing omega-3 fatty acid, GLA, or anti-oxidant supplementation |
| contralb | <input type="checkbox"/> | Contraindication to aerosolized albuterol (Appendix A.8) |
| dailyba | <input type="checkbox"/> | Daily use of inhaled beta agonist, corticosteroid, or oral leukotriene modifier or, acute need for inhaled beta agonist therapy for acute and chronic airway obstruction |
| acutemi | <input type="checkbox"/> | Acute myocardial infarction or acute coronary syndrome within 30 days |
| heartfail | <input type="checkbox"/> | Congestive heart failure |
| othstud | <input type="checkbox"/> | Participation in other experimental medication trial within 30 days with the exception of the ARDSNet nutrition trial |
| hrgt85 | <input type="checkbox"/> | Heart rate greater than 85% of maximal predicted heart rate (MGR85) as calculated by $MHR85 - 0.85 \times (220 - \text{age})$ |
| gt5pvcs | <input type="checkbox"/> | Greater than 5 PVCs/min in the 4 hours prior to randomization |
| newafib | <input type="checkbox"/> | New onset (since hospital admission) of a-fib requiring anticoagulation |
| mdrefalta | <input type="checkbox"/> | MD refusal for ALTA (specify reason) |

		<p>[1] <input type="radio"/> Refusal to use conservative fluid protocol</p> <p>mdrefaltareas [2] <input type="radio"/> Refusal to use 6ml ventilator protocol</p> <p>[5] <input type="radio"/> Other: mdrefaltaoth </p> <p>mdrefeoc <input type="checkbox"/> MD refusal for EDEN/Omega (specify reason)</p> <p>[1] <input type="radio"/> Refusal to use conservative fluid protocol</p> <p>mdrefeoreas [2] <input type="radio"/> Refusal to use 6ml ventilator protocol</p> <p>[3] <input type="radio"/> Unwilling to delay nutrition</p> <p>[4] <input type="radio"/> Unwilling to start nutrition early</p> <p>[5] <input type="radio"/> Other: mdrefeooth </p> <p>[2] <input type="radio"/> Not excluded</p> <p>[3] <input type="radio"/> Not excluded and not enrolled, explain: A200 notexenreas</p>
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Lung Injury Category		
17.	Trauma: trauma	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary</p> <p>[2] <input type="radio"/> Secondary</p>
18.	Sepsis: sepsis	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary (indicate site): Pulldown List 1 <input type="button" value="v"/> sepsite </p> <p>[2] <input type="radio"/> Secondary</p>
19.	Multiple Transfusion: transf	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary</p> <p>[2] <input type="radio"/> Secondary</p>
20.	Aspiration: aspir	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary</p> <p>[2] <input type="radio"/> Secondary</p>
21.	Pneumonia: pneumo	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary</p> <p>[2] <input type="radio"/> Secondary</p>
22.	Other: otherlung	<p>[0] <input type="radio"/> None</p> <p>[1] <input type="radio"/> Primary (describe): otherpr </p> <p>[2] <input type="radio"/> Secondary (describe): othersec </p>

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Pulldown List 1:			
RefName	Display Text	Value	Design Note
Bacteremia	Bacteremia, site unknown	9	
CNS	CNS	13	
Female Gu tract	Female GU tract	7	
GI biliary tract	GI/biliary tract	5	
Lung pleura	Lung/pleura	3	
Peritoneum	Peritoneum	4	
Sepsis site unknown	Sepsis site unknown	10	
Skin soft tissue	Skin/soft tissue	1	
Urinary tract	Urinary tract	6	
Vascular line infection	Vascular line infection	8	

oldaltajan08 : Enrollment Form II (Enroll 2) table = enroll2	
1.	Has informed consent been obtained for the participation in ALTA ? altaconsent [1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.	Has informed consent been obtained for the participation in EDEN/Omega ? eoconsent [1] <input type="radio"/> Yes [0] <input type="radio"/> No
3.	Has informed consent been obtained for genetic testing testing in this study? genconsent [1] <input type="radio"/> Yes [0] <input type="radio"/> No
4.	Has informed consent been obtained for future genetic research in ARDS ? futconsenta [1] <input type="radio"/> Yes [0] <input type="radio"/> No
5.	Has informed consent been obtained for Future Genetic Research involved with other medical conditions (for example, obesity, diabetes, cancer, heart disease, Alzheimers disease, etc.) futconsento [1] <input type="radio"/> Yes [0] <input type="radio"/> No
6.	Has informed consent been obtained to CONTACT subject in the future for other studies? contconsent [1] <input type="radio"/> Yes [0] <input type="radio"/> No

oldaltajan08 : Apache III Demographics (Apache Dem) table = apache_demog		
1.	Hospital Admission Date: hasddt	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)
2.	Hospital Admission Type: admtype	[1] <input type="radio"/> Medical [2] <input type="radio"/> Surgical scheduled [3] <input type="radio"/> Surgical unscheduled [4] <input type="radio"/> Other: admother
3.	ICU Admission Date: icudt	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)
4.	Time of ICU Admission: icutm	Req <input type="text"/> : Req <input type="text"/> 24-hour clock
5.	Patient Admitted Directly From: admitfrom	[1] <input type="radio"/> OR [2] <input type="radio"/> Recovery Room [3] <input type="radio"/> ER [4] <input type="radio"/> Floor [5] <input type="radio"/> Another Special Care Unit [6] <input type="radio"/> Another Hospital [7] <input type="radio"/> Direct Admit [8] <input type="radio"/> Stepdown Unit
6.	What was patient's place of residence prior to hospitalization? reside	[1] <input type="radio"/> Home Independantly [2] <input type="radio"/> Home with help (supervision, direction, or personal assistance) [3] <input type="radio"/> Home with professional help(nursing/nursing service) [4] <input type="radio"/> Intermediate care or rehabilitation facility [5] <input type="radio"/> Skilled nursing facility [6] <input type="radio"/> Another acute hospital [7] <input type="radio"/> Other (Please Specify) resideother
7.	Is patient immediately post-operative from elective surgery? surgel	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
8.	ICU Readmit: icureadmit	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
9.	ICU Readmit within 24 hours: readmit24	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
10.	Is chronic health information available? healthinfo	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
11.	Is the patient on chronic dialysis or peritoneal dialysis? chrodial	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
12.	AIDS (do not include HIV positive without AIDS criteria): aids	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
13.	Leukemia (AML,CML,ALL,multiple myeloma): leuk	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
14.	Non-Hodgkin's Lymphoma: lymph	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
15.	Solid tumor with metastasis: tumor	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
16.	Immune suppression (radiation, chemotherapy or greater than or equal to 0.3 mg/kg/day prednisone or equivalent) within the past 6 months: immune	[1] <input type="radio"/> Yes [0] <input type="radio"/> No

17.	Hepatic failure with coma or encephalopathy: hepa	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
18.	Cirrhosis: cirr	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
19.	Diabetes Mellitus: diab	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
20.	History of hypertension: hyper	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
21.	Prior myocardial infarction: myocard	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
22.	Congestive heart failure: heart	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
23.	Peripheral Vascular Disease: vascular	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
24.	Prior stroke with sequelae: aestroke	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
25.	Dementia: dementia	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
26.	Chronic pulmonary disease: chrpulm	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
27.	Arthritis: arthritis	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
28.	Peptic Ulcer Disease: ulcer	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
29.	Vasopressors in the 24 hours prior to randomization? vasol24	[1] <input type="radio"/> Yes [0] <input type="radio"/> No

oldaltajan08 : Apache III Physiology (Apache Phys) table = apache_phys		
Vital signs		
USE VALUES FROM 24 HRS PRECEDING RANDOMIZATION		
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) before initiating study procedures.		
1.	Temperature:	Lowest Highest templ temph <input type="radio"/> °C <input type="radio"/> °F
2.	Systolic BP: sysbpl sysbph	Lowest Highest xxx xxx mmHg
3.	Mean Arterial Pressure: mapl maph	Lowest Highest xxx xxx mmHg
4.	Heart Rate: hratel hrateh	Lowest Highest xxx xxx beats/min
5.	Respiratory Rate: respl resph	Lowest Highest xx xx breaths/min
6.	Was patient ventilated when the lowest resp rate occurred? ventl	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
7.	Was patient ventilated when the highest resp rate occurred? venth	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
8.	Urine output for 24 hours preceding randomization: urineout	xxxxx ml
9.	Total fluid output last 24 hours fluidout	xxxxx ml
10.	Total fluid intake for the 24 hours preceding randomization: fluidin	xxxxx ml
Hematology		
USE VALUES FROM 24 HOURS PRECEDING RANDOMIZATION		
11.	Hct: hcto hctl hcth	Only Lowest Highest xx xx xx %
12.	WBC: wbco wbcl wbch	Only Lowest Highest xxxxx. xxxxx. xxxxx. mm ³
13.	Platelets (lowest): plate	Lowest xxx X 1000 /mm ³
Chemistry		
USE VALUES FROM 24 HOURS PRECEDING RANDOMIZATION		
14.	Serum Sodium: sodiuomo sodiuoml sodiuomh	Only Lowest Highest xxx xxx xxx mEq/L
15.	Serum Potassium: potaso potasl potash	Only Lowest Highest xx.x xx.x xx.x mEq/L
16.	Serum BUN (highest): bun	Highest xxx mg/dL

17.	Serum Creatinine: creato creatl creath	Only	Lowest	Highest
		xx.x	xx.x	xx.x mg/dL
18.	Serum Glucose: gluco glucl gluch	Only	Lowest	Highest
		xxxx	xxxx	xxxx mg/dL
19.	Serum Albumin: albumo albuml albumh	Only	Lowest	Highest
		xx.x	xx.x	xx.x g/dL
20.	Serum Bilirubin (highest): bilih			Highest
				xx.x mg/dL
21.	Serum Bicarbonate (lowest): bicarbl		Lowest	
			xx	mEq/L

oldaltajan08 : Apache-ABG (Apache_abg)

1.	Were any ABG's completed in the 24 hours preceding randomization?	[1] <input type="radio"/> Yes [0] <input type="radio"/> No abg24			
	FiO2_a	PaO2_a	PaCO2_a	pH_a	ABG_intub
2.					

REPORT ALL ABG'S IN THE 24 HRS PRECEDING RANDOMIZATION

2.a	FiO2: fio2abg	x.xx (0.21 =< n <= 1.0)
2.b	PaO2: paco2abg	xxx mmHg
2.c	PaCO2: pao2abg	xxx mmHg
2.d	pH: phabg	x.xx
2.e	Intubated when ABG obtained: intubat	[1] <input type="radio"/> Yes [0] <input type="radio"/> No

table = apache_abg

table = apache_abg2

oldaltajan08 : Day Zero Enteral Feeding Procedures (Feeding)		
1.	Enter Propofol infusion rate at time of randomization: proprate	xxxxx mg/hr
2.	Enteral Feeding Group feedgrp	[1] <input type="radio"/> Trophic [2] <input type="radio"/> Full-calorie
3.	In the 12 hours prior to enrollment, did patient receive any enteral feedings? prebasefeed	[0] <input type="radio"/> No [1] <input type="radio"/> Yes, enter total volume of enteral feeds in 12 hours prior to enrollment xxxx (n >= 0) cc prebasevol
4.	Date and time of initiation of protocol specified enteral feeds: feedinitdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
The following data should be taken from the time of randomization through the end of day 0.		
5.	Did patient receive enteral tube feedings for any part of this 24 hour period? recfeed	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
6.*	Tube feeding goal rate as determined by EDEN protocol required dietary evaluation if available (If on trophic, enter patient's planned full-calorie goal rate). Use the protocol specified goal rate of 25-35 kcal/kg PBW/day until nutrition evaluation complete. goalrate	xxxx cc/hr
7.*	Did the goal rate change during the 24 hour period? goalchange	[1] <input type="radio"/> Yes, new goal rate: xxxx cc/hr [0] <input type="radio"/> No
8.*	Enteral Feeding Formula Brand #1 for this 24 hour period: brand1	A40
9.*	Total volume of enteral formula #1 infused for 24 hour period: brand1vol	xxxxx cc
10.*	Enteral Feeding Formula Brand #2 for this 24 hour period: brand2	A40
11.*	Total volume of enteral formula #2 infused for 24 hour period: brand2vol	xxxxx cc
12.*	# of hours enteral tube feeds on for this 24 hour period: feedhrs	xx hrs
13.*	Were tube feeds turned off for greater than 30 minutes for any part of this 24 hour period or held for the day? feedoff	[1] <input type="radio"/> Yes, Indicate reason for interruption (check all that apply): [1] <input type="checkbox"/> Planned Extubation planext [2] <input type="checkbox"/> GI Intolerance giint [3] <input type="checkbox"/> Invasive bedside procedure invbside [4] <input type="checkbox"/> Surgery surgery [5] <input type="checkbox"/> Patient left the floor left floor care [6] <input type="checkbox"/> Nursing Care(ie bathing, HOB down) [7] <input type="checkbox"/> Medical Administration medadm [8] <input type="checkbox"/> Other A255 feedoffoth [0] <input type="radio"/> No
14.*	Did the patient have any GI intolerances (as	[1] <input type="radio"/> Yes, Indicate type of GI Intolerances (check

	defined by EDEN protocol) for the 24 hour period? giintoleden	<p>all that apply):</p> <p>[1] <input type="checkbox"/> Diarrhea diarrhea</p> <p>[2] <input type="checkbox"/> Vomiting vomiting</p> <p>[3] <input type="checkbox"/> Aspiration aspiration</p> <p>[4] <input type="checkbox"/> Elevated Residuals elevresid</p> <p>[5] <input type="checkbox"/> Regurgitation regurg</p> <p>[6] <input type="checkbox"/> Constipation constipation</p> <p>[7] <input type="checkbox"/> Abdominal distention or cramping cramping</p> <p>[0] <input type="radio"/> No</p>
15.*	Insertion site of feeding tube: feedsite	<p>[1] <input type="radio"/> Nose</p> <p>[2] <input type="radio"/> Mouth</p> <p>[3] <input type="radio"/> Percutaneous</p>
16.*	Feeding tube size: tubesize	<p>[1] <input type="radio"/> Small bore [2] <input type="radio"/> Large bore</p>
17.*	Distal position of feeding tube: distalpos	<p>[1] <input type="radio"/> Gastric [2] <input type="radio"/> Post-pyloric</p>
18.*	Was distal position confirmed during this 24 hour period? distalconf	<p>[1] <input type="radio"/> Yes, how confirmed: distalhow</p> <p>[1] <input type="radio"/> X-Ray</p> <p>[2] <input type="radio"/> Auscultation</p> <p>[3] <input type="radio"/> Other, specify: A40 </p> <p>distaloth</p> <p>[0] <input type="radio"/> No</p>
19.*	Was rate advanced to full-calorie rate during this calendar day? fullcal	<p>[1] <input type="radio"/> Yes, time full calorie reached: fullcaltm</p> <p> Req <input type="text"/> : Req <input type="text"/> 24-hour clock</p> <p>[0] <input type="radio"/> No</p>
* Item is not required		

oldaltajan08 : Alcohol and Smoking Assessment (Alcohol and Smoking)		
The Alcohol Use Disorders Identification Test (AUDIT) Questionnaire		
1.	How often do you have a drink containing alcohol? alchfreq	[0] <input type="radio"/> Never [Skip to Q's 9-10] [1] <input type="radio"/> Monthly or less [2] <input type="radio"/> 2 to 4 times a month [3] <input type="radio"/> 2 to 3 times a week [4] <input type="radio"/> 4 or more times a week
2.*	How many drinks containing alcohol do you have on a typical day when you are drinking? alchnum	[0] <input type="radio"/> 1 or 2 [1] <input type="radio"/> 3 or 4 [2] <input type="radio"/> 5 or 6 [3] <input type="radio"/> 7, 8, or 9 [4] <input type="radio"/> 10 or more
3.*	How often do you have six or more drinks on one occasion? alch6freq	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily
Skip to Question 9 if question 2 is '1 to 2 drinks' and Question 3 is 'never'.		
4.*	How often during the last year have you found you were not able to stop drinking once you had started? alchstop	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily
5.*	How often during the last year have you failed to do what was normally expected from you because of drinking? alchfail	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily
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? alchmorn	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily
7.*	How often during the last year have you had a feeling of guilt or remorse after drinking? alchguilt	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily
8.*	How often during the last year have you been unable to remember what happened the night before because you had been drinking? alchmemory	[0] <input type="radio"/> Never [1] <input type="radio"/> Less than monthly [2] <input type="radio"/> Monthly [3] <input type="radio"/> Weekly [4] <input type="radio"/> Daily or almost daily

9.	Have you or someone else been injured as a result of your drinking? alchinjury	[0] <input type="radio"/> No [2] <input type="radio"/> Yes, but not in the last year [4] <input type="radio"/> Yes, during the last year
10.	Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down? alchconcern	[0] <input type="radio"/> No [2] <input type="radio"/> Yes, but not in the last year [4] <input type="radio"/> Yes, during the last year
Smoking History		
11.	Ever smoker (> 100 cigarettes in lifetime)? smoker	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
If you answered yes then fill out the next 2 questions		
12.*	If ever smoker, estimate pack years: (Pack years = [# packs per day] x [# years smoked])	xxxxx packyr
13.*	Current Smoker? cursmoker	[1] <input type="radio"/> Yes smokequitdt [2] <input type="radio"/> No, when quit: NReq/Unk <input type="button" value="v"/> / NReq/Unk <input type="button" value="v"/> / NReq <input type="button" value="v"/> (1920-2012)
* Item is not required		

oldeden : Baseline Ventilator Parameters (Base Vent)		
MOST RECENT VALUES PRIOR TO RANDOMIZATION		
1.	Ventilator Mode (select all that apply):	[1] <input type="checkbox"/> SIMV simv [2] <input type="checkbox"/> PRVC (pressure regulated volume control) or equivalent prvc [3] <input type="checkbox"/> Pressure Support xx cm H20 pressup pressupcmh2o [4] <input type="checkbox"/> Volume Assist/Control volassist [5] <input type="checkbox"/> Pressure Assist xxx cm H20 presassist presascmh2o [6] <input type="checkbox"/> PC IRV pcirv [7] <input type="checkbox"/> Airway Pressure Release Ventilation (APRV) aprv [8] <input type="checkbox"/> Other ventoth
2.*	Calculated Delivered Tidal Volume (based on volume loss due to gas compression/tube expansion--see CRF Instructions): tidal	xxxxx ml
3.*	Set Rate: setrate	xx (n >= 0) breaths/min
4.	Total Respiratory Rate: resp	xx breaths/min
5.	Total Minute Ventilation: minvent	xx.x (n >= 1.0) L/min
6.	PEEP: peep	xx (n >= 0) cm H20
7.	FiO2 prior to randomization: fio2	x.xx
8.	SpO2 prior to randomization: spo2	xxx %
9.*	Plateau Pressure: (Measurement should be made with a 0.5 second end-inspiratory pause) pplat	xx cm H20
10.*	Peak Inspiratory Pressure: pip	xxx cm H20
11.	Mean airway pressure: meanair	xx cm H20
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: fio2abg	x.xx
13.*	PaO2: pao2abg	xxx mmHg
14.*	PaCO2: paco2abg	xxx mmHg
15.*	Arterial pH: phabg	x.xx
16.*	SpO2 at time of ABG: spo2abg	xxx %
After initial vent change, if any, on a tidal volume of 6-8 ml/kg PBW		
17.*	Calculated delivered tidal volume: tidalpost	xxxx (n >= 0) ml
18.*	Plateau Pressure: pplatpost	xx (n >= 3) cm H20
19.*	PEEP: peeppost	xx cm H20
* Item is not required		

oldeden : Baseline Vital Signs (Base Vitals)		
RECORD VALUES CLOSEST TO THE TIME PRECEDING RANDOMIZATION		
1.	Heart Rate: hrate	xxx beats/min
2.	Systolic BP: sysbp	xxx mmHg
3.	Diastolic BP: diabp	xxx mmHg
4.*	CVP: cvp	xx mmHg
5.*	Mean Arterial Pressure: map (MAP only required if arterial line present)	xxx mmHg
6.	Temperature: temp	xxx.x <input type="radio"/> °C <input type="radio"/> °F
7.	Measured Height: height	xxx.x <input type="radio"/> cm <input type="radio"/> in
8.	Measured Weight: weight	xxx <input type="radio"/> kg <input type="radio"/> lbs
	Predicted Body Weight: pbw	kg
9.	Intravenous Vasopressor or inotrope in 24hrs preceding randomization? vaso If Yes, enter infusion rates at time of randomization for items to the right.	<p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes</p> <p>dobut IV Dobutamine Infusion Rate: dobutu xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min</p> <p>dopa IV Dopamine Infusion Rate: dopau xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min</p> <p>norepi IV Norepinephrine Infusion Rate: norepiu xxx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min</p> <p>epi IV Epinephrine Infusion Rate: epiu xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min</p> <p>vasorate IV Vasopressin Infusion Rate: x.xx units/min</p> <p>neosyn IV Neosynephrine (phenylephrine) Infusion Rate: neosynu xxx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min</p> <p>vasooth If Other Please Specify: A50 </p>
* Item is not required		

oldeden : Baseline Labs (Base Labs)		
OBTAIN VALUES CLOSEST TO THE TIME PRECEDING RANDOMIZATION		
If value not clinically available, it must be drawn prior to first dose of study drug/treatment.		
1.	Hgb: hgb	xx.x g/dL
2.	Sodium: sodium	xxx mEq/L
3.	Potassium: potas	xx.x mEq/L
4.	Glucose: gluc	xxxx mg/dL
5.	Serum Bicarb: bicarb	xx mEq/L
6.*	Serum Phosphorous (Required for EDEN/Omega/Co-Enrolled): phos	xx.x mg/dL
7.*	Serum Magnesium (Required for EDEN/Omega/Co-Enrolled): mg	xx.x mEq/L
8.*	Total Protein (Required for EDEN/Omega/Co-Enrolled): protein	xx g/dL
9.*	Albumin (Required for EDEN/Omega/Co-Enrolled): album	xx.x g/dL
10.*	Lowest glucose this day: glucmin	xxxxxxxxxxxxxxxx. mg/dL
11.*	Prothrombin time prothrombin	xxx.x Seconds
* Item is not required		

oldaltajan08 : Omega Dosing Form (Omega Dose)		
NUTRITION Study Solution Dosing: If not given because of an adverse event, fill out AE form.		
1.	How many of today's SCHEDULED doses of study emulsion were given? omegadose	<input type="radio"/> [0] 0 <input type="radio"/> [1] 1 <input type="radio"/> [2] 2
If any of today's SCHEDULED doses of study emulsion were HELD, please indicate reasons:		
2.*	Reason 1: omegaheld1	<input type="radio"/> [1] Pulldown List 1 <input type="button" value="v"/> omegaheldrs1 <input type="radio"/> [2] Other: omegaheld1oth A255
3.*	Reason 2: omegaheld2	<input type="radio"/> [1] Pulldown List 2 <input type="button" value="v"/> omegaheldrs2 <input type="radio"/> [2] Other: omegaheld2oth A255
4.	How many of these administered doses were tolerated (tolerated = no vomiting, aspiration or residual check in the 2 hours following the dose)?	<input type="radio"/> [0] 0 omegatol <input type="radio"/> [1] 1 <input type="radio"/> [2] 2
* Item is not required		

Pulldown List 1:			
RefName	Display Text	Value	Design Note
Vomiting	Vomiting	1	
Intracranial hemmorrhage	Intracranial hemmorrhage	2	
INR gt 5	INR>5.0	3	
No enteral access	No enteral access	4	

Pulldown List 2:			
RefName	Display Text	Value	Design Note
Vomiting	Vomiting	1	
Intracranial hemmorrhage	Intracranial hemmorrhage	2	
INR gt 5	INR>5.0	3	
No enteral access	No enteral access	4	

oldaltajan08 : Glasgow Coma Scale (Glasgow)		
Enter values for the WORST GCS of the day		
1.	Is patient on a sedative or neuromuscular blocker? sedative	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.	Eye Opening Score: eye	[1] <input type="radio"/> None [2] <input type="radio"/> To pain [3] <input type="radio"/> To voice [4] <input type="radio"/> Spontaneous
3.	Motor Response Score: motor	[1] <input type="radio"/> Flaccid [2] <input type="radio"/> Extension abnormal flexion [3] <input type="radio"/> Abnormal flexion [4] <input type="radio"/> Flexion withdrawal [5] <input type="radio"/> Localizes to pain [6] <input type="radio"/> Obeys commands
4.	Verbal Response Score: verbal	[1] <input type="radio"/> None, or generally unresponsive if on ventilator [2] <input type="radio"/> Incomprehensible [3] <input type="radio"/> Inappropriate, or questionable oriented if on vent [4] <input type="radio"/> Confused [5] <input type="radio"/> Oriented, or appears oriented if on ventilator
	Total: gcs	
5.*	If this form is NOT being filed out on day 0 (baseline), 7 or 28, please specify the date here	NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2007-2012) gcsdt
* Item is not required		

oldaltajan08 : Specimen Collection (Specimen)		
Day 0		
1.	SeraCare Day 0 Accession Number: accession0 This is 2 letters followed by 6 digits	Please enter the accession number twice to verify it A8 A8
2.	Date Baseline Specimens Collected: plasmacolldt0	NReq <input type="button" value="v"/> / NReq <input type="button" value="v"/> / NReq <input type="button" value="v"/> (2007-2012)
3.	Cytokine and coagulation parameters sample collected (Plasma)? cyto0	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: cytoreas0 <input type="text" value="A255"/>
4.	Plasma fatty acids sample collected (Plasma)? fattyacid0	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: fattyacid0 <input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in EDEN/OMEGA
5.	Plasma epinephrine level sample collected (Plasma)? epi0	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: epireas0 <input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in ALTA
6.	Urine sample collected? urine0	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: urinereas0 <input type="text" value="A255"/>
7.	Whole blood sample collected (Genetics)? blood0	[?] <input type="radio"/> Yes, date collected: bloodcolltd0 Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2006-2012) [2] <input type="radio"/> No, reason: bloodreas0 <input type="text" value="A255"/>
Day 1		
8.	SeraCare Day 1 Accession Number: accession1 This is 2 letters followed by 6 digits	Please enter the accession number twice to verify it A8 A8
9.	Date Day 1 Specimens Collected: colltd1	NReq <input type="button" value="v"/> / NReq <input type="button" value="v"/> / NReq <input type="button" value="v"/> (2007-2012)
10.	Plasma Albuterol level sample collected (Plasma)? alb1	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: albreas1 <input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in ALTA
11.	Plasma epinephrine level sample collected (Plasma)? epi1	[1] <input type="radio"/> Yes [2] <input type="radio"/> No, reason: epireas1 <input type="text" value=""/>

		<input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in ALTA
Day 3		
12.*	SeraCare Day 3 Accession Number: accession3 This is 2 letters followed by 6 digits	Please enter the accession number twice to verify it <input type="text" value="A8"/> <input type="text" value="A8"/>
13.*	Cytokine and coagulation parameters sample collected (Plasma)? cyto3	[1] <input type="radio"/> Yes, date collected: cytocolldt3 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) [2] <input type="radio"/> No, reason: cytoreas3n <input type="text" value="A255"/>
14.*	Plasma fatty acids sample collected (Plasma)? fattyacid3	[1] <input type="radio"/> Yes, date collected: fattyaciddt3 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) [2] <input type="radio"/> No, reason: fattyacidreas3 <input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in EDEN/OMEGA
15.*	Urine sample collected? urine3	[1] <input type="radio"/> Yes, date collected: urinecolldt3 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) [2] <input type="radio"/> No, reason: urinereas3 <input type="text" value="A255"/>
Day 6		
16.*	SeraCare Day 6 Accession Number: accession6 This is 2 letters followed by 6 digits	Please enter the accession number twice to verify it <input type="text" value="A8"/> <input type="text" value="A8"/>
17.*	Cytokines and coagulation parameters sample collected (Plasma)? cyto6	[1] <input type="radio"/> Yes, date collected: cytocolldt6 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) [2] <input type="radio"/> No, reason: cytoreas6 <input type="text" value="A255"/>
18.*	Plasma fatty acids sample collected (Plasma)? fattyacid6	[1] <input type="radio"/> Yes, date collected: <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) [2] <input type="radio"/> No, reason: fattyaciddt6 <input type="text" value="A255"/> [3] <input type="radio"/> Not enrolled in EDEN/OMEGA
19.*	Urine sample collected? urine6	[1] <input type="radio"/> Yes, date collected: urinecolldt6 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012)

		<input type="radio"/> [2] No, reason: urinereas6 <input type="text" value="A255"/>
Day 12		
20.*	SeraCare Day 12 Accession Number: accession12 This is 2 letters followed by 6 digits	Please enter the accession number twice to verify it <input type="text" value="A8"/> <input type="text" value="A8"/>
21.*	Cytokines and coagulation parameters sample collected (Plasma)? cyto12	<input type="radio"/> [1] Yes, date collected: cytocolltd12 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) <input type="radio"/> [2] No, reason: cytoreas12 <input type="text" value="A255"/>
22.*	Plasma fatty acids sample collected (Plasma)? fattyacid12	<input type="radio"/> [1] Yes, date collected: fattyacidtd12 <input type="text" value="Req"/> / <input type="text" value="Req"/> / <input type="text" value="Req"/> (2006-2012) <input type="radio"/> [2] No, reason: fattyacidreas12 <input type="text" value="A255"/> <input type="radio"/> [3] Not enrolled in EDEN/OMEGA
* Item is not required		

oldaltajan08 : Mini-BAL (BAL)		
Day 0		
1.	Mini-BAL completed? bal0 If NO , do not complete questions 2-5.	[1] <input type="radio"/> Yes, date collected: baldt0 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [2] <input type="radio"/> No, reason: balnotreas0 <input type="text" value="A255"/>
2.*	Volume instilled: balvolin0	<input type="text" value="xx"/> ml
3.*	Volume returned: balvolout0	<input type="text" value="xx"/> ml
4.*	INR value obtained within the 36 hours prior to BAL? balinr0	[2] <input type="radio"/> No, BAL contraindicated [1] <input type="radio"/> Yes, was value ≤ 2.0 ? balinrle2_0 [1] <input type="radio"/> Yes [2] <input type="radio"/> No, BAL contraindicated
5.*	Platelet value obtained in the 36 hours prior to BAL? balplate0	[2] <input type="radio"/> No, BAL contraindicated [1] <input type="radio"/> Yes, was value $\geq 50 \times 10^3 / \text{mm}^3$? balplatege5_0 [1] <input type="radio"/> Yes [2] <input type="radio"/> No, BAL contraindicated
Day 3		
6.	Mini-BAL completed? bal3 If NO , do not complete questions 7-10.	[1] <input type="radio"/> Yes, date collected: baldt3 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [2] <input type="radio"/> No, reason: balnotreas3 <input type="text" value="A255"/>
7.*	Volume instilled: balvolin3	<input type="text" value="xx"/> ml
8.*	Volume returned: balvolout3	<input type="text" value="xx"/> ml
9.*	INR value obtained within the 36 hours prior to BAL? balinr3	[2] <input type="radio"/> No, BAL contraindicated [1] <input type="radio"/> Yes, was value ≤ 2.0 ? balinrle2_3 [1] <input type="radio"/> Yes [2] <input type="radio"/> No, BAL contraindicated
10.*	Platelet value obtained in the 36 hours prior to BAL? balplate3	[2] <input type="radio"/> No, BAL contraindicated [1] <input type="radio"/> Yes, was value $\geq 50 \times 10^3 / \text{mm}^3$? balplatege5_3 [1] <input type="radio"/> Yes [2] <input type="radio"/> No, BAL contraindicated
* Item is not required		

oldaltajan08 : Dead-Space Measurements (DeadSpace)		
All data except for ventilator mode and arterial blood gas data and FiO2 can be obtained from the NICO monitor on the Tabular Data, Volumetric CO2 or Numerics Screens		
1.	Was the deadspace measurement conducted? dsmeasure	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
2.*	Time of Measurement: dsmeasuretm	Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.*	Ventilator Mode (select all that apply): pressup_ds presassist_ds	[1] <input type="checkbox"/> SIMV simv_ds [2] <input type="checkbox"/> PRVC (pressure regulated volume control) or equivalent prvc_ds [3] <input type="checkbox"/> Pressure Support xx cm H2O pressupcmh2o_ds [4] <input type="checkbox"/> Volume Assist/Control volassist_ds [5] <input type="checkbox"/> Pressure Assist xxx cm H2O presascmh2o_ds [6] <input type="checkbox"/> PC IRV pcirv_ds [7] <input type="checkbox"/> Airway Pressure Release Ventilation apr_v_ds (APRV) [8] <input type="checkbox"/> Other ventoth_ds
4.*	FiO2: fio2_ds	x.xx
5.*	PEEP: peep_ds	xx cm H20
6.*	Total Respiratory Rate: resprate_ds	xx
7.*	Plateau Pressure platpress_ds	xxx cm H20
8.*	Mean Airway Pressure meanair_ds	xxxxx cm H20
9.*	Expired Mechanical Tidal Volume (Vte-m):	xxxx ml tidalvol_ds
10.*	Dead-Space Fraction (Vd/Vt): dsfraction	x.xx
11.*	Alveolar Dead Space (Vtalv): alveolards	xxx ml
12.*	Airway Dead Space (VdAW): airwayds	xxx ml
13.*	Mixed Expired CO2 (PeCO2): peco2_ds	xxx mmHg
14.*	End-Tidal CO2 (ETCO2): etco2_ds	xxx mmHg
15.*	CO2 Excretion (VCO2): vco2_ds	xxx ml
16.*	Arterial pH: ph_ds	x.xx
17.*	Arterial PCO2: pco2_ds	xxx mmHg
18.*	Arterial PO2: po2_ds	xxx mmHg
* Item is not required		

oldaltajan08 : Concomitant Medications (Con Meds)	
FOR THIS CALENDAR DATE	
1. Did patient receive any narcotics this calendar date? (i.e. fentanyl, morphine, narcotics oxycodone=percocet=Roxicet=oxucontin, dilaudid=hydromorphone, mereperidine=Demerol, codeine, Vicodin=hydrocodone=lortab=lorcet)	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
2. Did patient receive any paralytics this calendar date? (i.e. succinylcholine, vecuronium=norcuron, paralytics rocuronium=zemuron, atracurium=tracrium, cis- atracurium=nimbex, pancuronium=pavulon)	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
3. Did patient receive any prokinetics this calendar date? (i.e. erythromycin, metoclopramide=Reglan) prokinetics	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
4. Did patient receive any anti-emetics this calendar date? (i.e. promethazine=phenergan, prochlorperazine=compazine, thiethylperazine=torecan, dolasetron=anzemet, antiemetics ondansetron=zofran)	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
5. Did patient receive any anti-diarrheals this calendar date? antidiarrheals (i.e. diphenoxylate+ atropine = lomotil, loperamide = immodium, bismuth subsalicylate=pepto bismol, fiber)	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
6. Did patient receive any laxatives this calendar date? (i.e. bisacodyl=dulcolax, sorbitol, lactulose, magnesium citrate, polyethylene glycol= go-lytely+nu-lytely=miralax, Metamucil, colace, senna=senokot, milk of magnesium)	[1] <input type="radio"/> Yes [0] <input type="radio"/> No laxatives

oldaltajan08 : I and O (I and O)

Daily fluid totals should capture the total for the previous day.

Example: When completing the day 3 fluid form, enter the fluid totals for day 2.

1.	Total Fluid Intake in last 24h: fluidin	xxxxx (n >= 0) ml
2.*	PRBC given in last 24 hours: prbc24	xx (n >= 0) Units
3.*	FFP given in last 24 hours: ffp24	xx (n >= 0) Units
4.	Total fluid out last 24 hours: fluidout	xxxxx (n >= 0) ml
5.	Total urine output in the last 24 hours: urineout	xxxxx ml
6.	Is the subject enrolled ONLY in the ALTA trial? If so, please enter total volume of enteral feedings in the last 24 hours notedenpt	[0] <input type="radio"/> No [1] <input type="radio"/> Yes, the enteral feedings volume for the last 24 hours is: entfeedvol xxxx ml
* Item is not required		

oldaltajan08 : On Study Ventilator Parameters (On Study Vent)

COMPLETE IF ON ASSISTED BREATHING DURING REFERENCE PERIOD 0600-1000. USE VALUES CLOSEST TO 8 AM.

1.	Ventilator Mode (select all that apply):	<input type="checkbox"/> [1] SIMV simv <input type="checkbox"/> [2] PRVC (pressure regulated volume control) or equivalent prvc pressup <input type="checkbox"/> [3] Pressure Support xx cm H20 pressupcmh2o <input type="checkbox"/> [4] Volume Assist/Control volassist <input type="checkbox"/> [5] Pressure Assist xxx cm H20 presassit presascmh2o <input type="checkbox"/> [6] PC IRV pcirv <input type="checkbox"/> [7] Airway Pressure Release Ventilation (APRV) aprv <input type="checkbox"/> [8] Other ventoth
2.	Calculated Delivered Tidal Volume: tidal	xxxxx ml
3.*	Set Rate: setrate	xx breaths/min
4.	Total Respiratory Rate: resp	xx breaths/min
5.	Total Minute Ventilation: minvent	xx.x L/min
6.	PEEP: peep	xx cm H20
7.	FiO2 at 0800: fio2	x.xx
8.	SpO2 at 0800: spo2	xxx %
9.*	Plateau Pressure: (Measurement should be made with a 0.5 second end-inspiratory pause): pplat	xx cm H20
10.	Peak Inspiratory Pressure: pip	xxx cm H20
11.	Mean airway pressure: meanair	xx cm H20
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: fio2abg	x.xx
13.*	PaO2: pao2abg	xxx mmHg
14.*	PaCO2: paco2abg	xxx mmHg
15.*	Arterial pH: phabg	x.xx
16.*	SpO2 at time of ABG: spo2abg	xxx %
* Item is not required		

oldeden : On Study Vital Signs (On Study Vitals)		
RECORD VALUES CLOSEST TO 8AM (until day 10 or until 48 hours UAB).		
1.	Heart Rate: hrate	xxx beats/min
2.	Systolic BP: sysbp	xxx mmHg
3.	Diastolic BP: diabp	xxx mmHg
4.	Temperature: temp	xxx.x <input type="radio"/> °C <input type="radio"/> °F
5.*	CVP: cvp	xx mmHg
6.*	CXR: cxrquads Enter the number of quadrants with infiltrates if CXR clinically available this calendar day.	x (0 = < n <= 4) (0-4)
7.*	IV or PO corticosteroids totaling more than 20 mg methylprednisolone equivalents given this calendar date? cort20 20 mg methylprednisolone equivalents: ≥3.75 mg dexamethasone ≥20 mg methylprednisolone ≥25 mg prednisone ≥100mg hydrocortisone	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
8.	Any vasopressors/inotropes this calendar day? If yes, enter 0800 infusion rates. vaso	[0] <input type="radio"/> No [1] <input type="radio"/> Yes dobut IV Dobutamine Infusion Rate: xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min dobutu dopa IV Dopamine Infusion Rate: xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min dopau norepi IV Norepinephrine Infusion Rate: xxx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min norepiu epi IV Epinephrine Infusion Rate: xx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min epiu vasorate IV Vasopressin Infusion Rate: x.xx units/min neosyn IV Neosynephrine (phenylephrine) Infusion Rate: xxx.xx <input type="radio"/> ug/kg/min <input type="radio"/> ug/min neosynu vasooth If Other Please Specify: A50

Complete the following question for ALTA/Co-Enrolled subjects only.		
9.*	Beta Blockers (IV, PO, PGT) this calendar day? betablock	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
10.*	Aerosolized or MDI delivered ipatropium this calendar day? ipatro	[1] <input type="radio"/> Yes: Enter total number of doses this calendar day ipadose xx [0] <input type="radio"/> No
11.*	Non-study beta-agonist aerosol given by ICU team this calendar day? nsbetag	[1] <input type="radio"/> Yes: Enter total dose in mg of non-study beta-agonist aerosol given this calendar day xx mg nsbetadose [0] <input type="radio"/> No
* Item is not required		

oldeden : On Study Labs (On-study Labs)		
LABS: Record if clinically available unless otherwise indicated. Use value closest to 0800 on this calendar date.		
1.*	Hgb: hgb	xx.x g/dL
2.*	Sodium: sodium	xxx mEq/L
3.*	Potassium: potas	xx.x mEq/L
4.*	Glucose: gluc	xxxx mg/dL
5.*	Serum Bicarb: bicarb	xx mEq/L
6.*	Serum Phosphorus:(Required on days 1,3,8 for EDEN/Omega) phos	xx.x mEq/L
7.*	Serum Magnesium:(Required on days 1,3,8 for EDEN/Omega) mg	xx.x mg/dL
8.*	Total Protein:(Required on days 1,7,12 for EDEN/Omega) protein	xx g/dL
9.*	Albumin:(Required on days 1,7,12 for EDEN/Omega) album	xx.x g/dL
10.*	Prothrombin time prothrombin	xxx.x Seconds
11.*	Insulin drip rate at time of glucose value: (Enter "0" if not on continous insulin infusion at time of glucose value) insulinrt	xx.x u/hr
12.*	Total sq insulin given in the 6 hours preceding the glucose value: (Enter "0" if no sq insulin given in the 6 hrs preceding the glucose value) insulinsq	xxxxx Units
13.*	Lowest glucose this day: glucmin	xxxx. mg/dL
* Item is not required		

oldaltajan08 : On Study Enteral Feeding Procedures (Feeding)		
1.	Did patient receive enteral tube feedings for any part of this 24 hour period? reccfeed	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
2.*	Tube feeding goal rate as determined by EDEN protocol required dietary evaluation if available (If on trophic, enter patient's planned full-calorie goal rate). Use the protocol specified goal rate of 25-35 kcal/kg PBW/day until nutrition evaluation complete. goalrate	xxxx cc/hr
3.*	Did the goal rate change during the 24 hour period? goalchange	[1] <input type="radio"/> Yes, new goal rate: newgoal xxxx cc/hr [0] <input type="radio"/> No
4.*	Enteral Feeding Formula Brand #1 for this 24 hour period: brand1	A40
5.*	Total volume of enteral formula #1 infused for 24 hour period: brand1vol	xxxxx cc
6.*	Enteral Feeding Formula Brand #2 for this 24 hour period: brand2	A40
7.*	Total volume of enteral formula #2 infused for 24 hour period: brand2vol	xxxxx cc
8.*	# of hours enteral tube feeds on for this 24 hour period: feedhrs	xx hrs
9.*	Were tube feeds turned off for greater than 30 minutes for any part of this 24 hour period or held for the day? feedoff	[1] <input type="radio"/> Yes, Indicate reason for interruption (check all that apply): [1] <input type="checkbox"/> Planned Extubation planext [2] <input type="checkbox"/> GI Intolerance giint [3] <input type="checkbox"/> Invasive bedside procedure invbside [4] <input type="checkbox"/> Surgery surg [5] <input type="checkbox"/> Patient left the floor leftfloor care [6] <input type="checkbox"/> Nursing Care(ie bathing, HOB down) [7] <input type="checkbox"/> Medical Administration medadm [8] <input type="checkbox"/> Other A255 feedoffoth [0] <input type="radio"/> No
10.*	Did the patient have any GI intolerances (as defined by EDEN protocol) for the 24 hour period? giintoleden	[1] <input type="radio"/> Yes, Indicate type of GI Intolerances (check all that apply): [1] <input type="checkbox"/> Diarrhea diarrhea [2] <input type="checkbox"/> Vomiting vomiting [3] <input type="checkbox"/> Aspiration aspiration [4] <input type="checkbox"/> Elevated Residuals residual [5] <input type="checkbox"/> Regurgitation regurg [6] <input type="checkbox"/> Constipation const [7] <input type="checkbox"/> Abdominal distention or cramping cramp [0] <input type="radio"/> No
11.*	Insertion site of feeding tube: feedsite	[1] <input type="radio"/> Nose [2] <input type="radio"/> Mouth

		[3] <input type="radio"/> Percutaneous
12.*	Feeding tube size: tubesize	[1] <input type="radio"/> Small bore [2] <input type="radio"/> Large bore
13.*	Distal position of feeding tube: distalpos	[1] <input type="radio"/> Gastric [2] <input type="radio"/> Post-pyloric
14.*	Was distal position confirmed during this 24 hour period? distalconf	[1] <input type="radio"/> Yes, how confirmed: distalhow [1] <input type="radio"/> X-Ray [2] <input type="radio"/> Auscultation [3] <input type="radio"/> Other, specify: A40 distaloth [0] <input type="radio"/> No
15.*	Was rate advanced to full-calorie rate during this calendar day? fullcal	[1] <input type="radio"/> Yes, time full calorie reached: fullcaltm Req <input type="text"/> : Req <input type="text"/> 24-hour clock [0] <input type="radio"/> No
* Item is not required		

oldeden : Random Check Form (RandomCheck)

Complete on days 1-7

The random check time for each day should be obtained from the Random Check Time Form in the unscheduled section.

1.	In the 12 hours prior to the random check time, did patient receive vasopressors? vaso12prior	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
2.	In the 12 hours prior to the random check time, did MAP fall below 60 mmHg? map60	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
3.	In the 4 hours prior to the random check time, were IV maintenance fluids running? maintflu (Defined as an IV with no medication running at > than your institutions KVO standard).	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
4.	In the 4 hours prior to the random check time, was Lasix given? lasix4	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
5.	In the 12 hours prior to the random check time, was fluid bolus (> 15 ml/kg PBW) given? bolus12	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
6.	Average UOP in the 4 hours prior to the random check time < 0.5 ml/kg/hr? avuop4	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
7.	On this calendar day , was patient in acute renal failure or receiving renal replacement therapy? renal	[Y] <input type="radio"/> Yes [N] <input type="radio"/> No
8.	CVP or PAOP (most recent value in the 4 hours PRIOR to but not on the random check time). Example: if random time is 1200, and you have values at 1100, 1200 and 1300, you should enter the value from 1100.	xxx mmHg CVP cvp_rp xxx mmHg PAOP paop_rc

Complete the following question on days 1, 2 and 3 only

9.*	Is subject enrolled in EDEN/OMEGA or Co-Enrolled? edenptrc If so, enter propofol infusion rate at time of random check?	[0] <input type="radio"/> No [1] <input type="radio"/> Yes, propofol infusion rate is: xxxxx ml propinfate
	ontarget and rate [hidden]	No maintenance fluids A255 Lasix for intravascular pressure A255 Lasix for oliguria A255 Lasix given within 12 hours of shock resolution A255

* Item is not required

oldaltajan08 : Random Check Times (RandCheckTimes)	
1. Check this box and submit the form to compute random check times up to the previous day.	[0] <input type="checkbox"/> Check this box
Day 1 Random Check Time chktm1	NReq <input type="button" value="v"/> 24-hour clock
Day 2 Random Check Time chktm2	NReq <input type="button" value="v"/> 24-hour clock
Day 3 Random Check Time chktm3	NReq <input type="button" value="v"/> 24-hour clock
Day 4 Random Check Time chktm4	NReq <input type="button" value="v"/> 24-hour clock
Day 5 Random Check Time chktm5	NReq <input type="button" value="v"/> 24-hour clock
Day 6 Random Check Time chktm6	NReq <input type="button" value="v"/> 24-hour clock
Day 7 Random Check Time chktm7	NReq <input type="button" value="v"/> 24-hour clock

oldaltajan08 : Brussels Table (Brussels) Collected for days 0-28							
24HR WORST VALUE							
1.*	Date brussdt	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)					
2.*		Syst BP xxx systbp	PaO2/FiO2 xxx pf	Platelets X1000 xxxx plate	Creatinine xx.x creat	Bilirubin xx.x bili	Vasopressor vaso [1] <input type="radio"/> Yes [0] <input type="radio"/> No

oldaltajan08 : Ventilator Associated Pneumonia (VAP)

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.

1.	Date of VAP diagnosis: vapdt	Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2006-2012)
<p>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.</p> <p>Within a period of 48 hours did the patient have:</p>		
2.	Chest radiograph shows new infiltrate that persisted for 48 hours? infiltrate	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
3.	New fever or hypothermia or leukocytosis or leukopenia? feverleuk	[1] <input type="radio"/> Yes [0] <input type="radio"/> No
4.	<p>Bacteriological confirmation of pulmonary infection? pulminf</p> <p>Number 4 includes any of the following:</p> <p>1) Quantitative culture of tracheal secretions with $> 10^6$ cfu/mm³</p> <p>2) Quantitative culture of bronchoalveolar lavage with $> 10^4$ cfu/mm³</p> <p>3) Quantitative culture of protected specimen brush with $> 10^3$ cfu/mm³</p> <p>4) Positive Gram stain with $\geq 3+$ of at least one type of bacteria</p> <p>5) Positive semi-quantitative sputum culture with $\geq 3+$ growth of at least one type of potentially pathogenic bacteria</p> <p>6) Positive blood culture for bacterial pathogen also identified in sputum or other respiratory specimens</p> <p>7) Positive Gram stain or culture of pleural fluid for bacterial pathogen</p>	[1] <input type="radio"/> Yes [0] <input type="radio"/> No

oldaltajan08 : Adverse Event (Ae)		
CALL CCC IMMEDIATELY FOR SERIOUS, UNEXPECTED, STUDY RELATED ADVERSE EVENTS		
1.	Date of the event: aedt	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)
2.	Time of event: aetm	Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.	Protocol Specified EDEN/Omega AE (Contraindications to enteral feeds/omega-3)? protedom	<p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Pick one Contraindication: prottypeedom</p> <p>[1] <input type="radio"/> Hypersensitivity to enteral feeds</p> <p>[2] <input type="radio"/> Hypersensitivity to omega-3 fatty acids</p> <p>[3] <input type="radio"/> Intestinal Ischemia or infarction</p> <p>[4] <input type="radio"/> Increased bleeding</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>
4.	Protocol Specified ALTA AE (ALTA appendix A8)? protalta	<p>[0] <input type="radio"/> No</p> <p>[1] <input type="radio"/> Yes, pick one: prottypealta</p> <p>[1] <input type="radio"/> Hypersensitivity to albuterol</p> <p>[2] <input type="radio"/> Paradoxical bronchospasm</p> <p>[3] <input type="radio"/> Arrhythmias (clinically important)</p> <p>[4] <input type="radio"/> Hypokalemia</p> <p>[5] <input type="radio"/> Diabetic Ketoacidosis or uncontrolled hyperglycemia (2 or more glucose values \geq 300 mg/dl in 24 hours)</p> <p>[6] <input type="radio"/> Uncontrolled hypertension (MAP consistently $>$ 110 for 2 hours, or two recorded values $>$ 120 in 8 hours)</p> <p>[7] <input type="radio"/> Hyperthyroidism</p> <p>[3] <input type="radio"/> Not enrolled in ALTA</p>
5.*	Name of event if not a protocol specified event (COSTART term): costart	A255
6.	Describe events leading to and following the event: aedesc	A500
7.	Severity of event: aesever	<p>[1] <input type="radio"/> Mild</p> <p>[2] <input type="radio"/> Moderate</p> <p>[3] <input type="radio"/> Serious</p>
8.	Was the event unexpected or more severe than expected for ALI patients receiving aerosolized beta-agonist therapy? expectalta	<p>[1] <input type="radio"/> Yes</p> <p>[0] <input type="radio"/> No</p> <p>[4] <input type="radio"/> Unknown</p> <p>[3] <input type="radio"/> Not enrolled in ALTA</p>
9.	Was the event unexpected or more severe than expected for EDEN/Omega therapy managed ALI/ARDS? expectedom	<p>[1] <input type="radio"/> Yes</p> <p>[0] <input type="radio"/> No</p> <p>[4] <input type="radio"/> Unknown</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>

10.	Causal relationship to ALTA study drug? causealta	<p>[1] <input type="radio"/> Definitely associated</p> <p>[2] <input type="radio"/> Probably associated</p> <p>[9] <input type="radio"/> Possible association</p> <p>[4] <input type="radio"/> Probably not associated</p> <p>[5] <input type="radio"/> Definitely not associated</p> <p>[6] <input type="radio"/> Uncertain association</p> <p>[3] <input type="radio"/> Not enrolled in ALTA</p>
11.	Causal relationship to EDEN/Omega procedures? causeedom	<p>[1] <input type="radio"/> Definitely associated</p> <p>[2] <input type="radio"/> Probably associated</p> <p>[9] <input type="radio"/> Possible association</p> <p>[4] <input type="radio"/> Probably not associated</p> <p>[5] <input type="radio"/> Definitely not associated</p> <p>[6] <input type="radio"/> Uncertain association</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>
12.	Causal relationship to study procedures? (mini-BAL, deadspace measurement, fluid conservative management) causestudy	<p>[1] <input type="radio"/> Definitely associated</p> <p>[2] <input type="radio"/> Probably associated</p> <p>[9] <input type="radio"/> Possible association</p> <p>[4] <input type="radio"/> Probably not associated</p> <p>[5] <input type="radio"/> Definitely not associated</p> <p>[6] <input type="radio"/> Uncertain association</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>
13.	Was the ALTA study drug permanently discontinued because of this event? withdrawalta	<p>[1] <input type="radio"/> Yes, date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) wdrawaltadt</p> <p>[0] <input type="radio"/> No</p> <p>[3] <input type="radio"/> Not enrolled in ALTA</p>
14.	Were the EDEN study procedures permanently discontinued because of this event? wdraweden	<p>[1] <input type="radio"/> Yes, date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) wdrawedendt</p> <p>[0] <input type="radio"/> No</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>
15.	Was the Omega study drug permanently discontinued because of this event? wdrawomega	<p>[1] <input type="radio"/> Yes, date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) wdrawomegadt</p> <p>[0] <input type="radio"/> No</p> <p>[3] <input type="radio"/> Not enrolled in EDEN/OMEGA</p>
16.	Status of this adverse event at the time of initial AE report: aestatus	<p>[1] <input type="radio"/> Recovered, date: aerecdt Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[2] <input type="radio"/> AE present, no treatment</p> <p>[3] <input type="radio"/> AE present/being treated</p> <p>[4] <input type="radio"/> Residual effect/no treatment</p> <p>[5] <input type="radio"/> Residual effect/being treated</p> <p>[6] <input type="radio"/> Deceased as a result of this AE</p>
17.*	Final outcome of this adverse event (until resolution or 48h UAB): aeoutcome	<p>[1] <input type="radio"/> Recovered, date: aefinrecdt Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-</p>

		2012)
		[2] <input type="radio"/> AE present, no treatment
		[3] <input type="radio"/> AE present/being treated
		[4] <input type="radio"/> Residual effect/no treatment
		[5] <input type="radio"/> Residual effect/being treated
		[6] <input type="radio"/> Deceased as a result of this AE
* Item is not required		

oldaltajan08 : Clostridium Dificile (C. Dif Culture)		
	dt_c_dif	
1.		
<p>Patients with more than 3 liquid stools totaling more than an estimated 500ml of stool per day, or those with systemic inflammatory response syndrome unexplained by other infection, may have up to three daily stool samples sent for <i>C. difficile</i> investigation (either cytotoxin assay or enzyme immunoassay).</p> <p>Enter all new positive <i>C. difficile</i> cultures after enrollment</p>		
1.a	Date and time of new positive <i>C. difficile</i> culture after enrollment. cdifdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock

oldaltajan08 : Blood Cultures (Blood Cultures)		
	dt_blood_cx	Organism
1.		
Enter all new positive blood cultures after enrollment		
1.a	Date and time of new positive blood culture after enrollment: bcdtm	Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
1.b	Organism bcorg	[1] <input type="radio"/> Staph aureus [2] <input type="radio"/> Coagulase negative staph [3] <input type="radio"/> Strep pneumoniae [4] <input type="radio"/> Enterococcus [5] <input type="radio"/> Other gram positive coccus [6] <input type="radio"/> Pseudomonas species [7] <input type="radio"/> Hemophilus influenza [8] <input type="radio"/> Other gram negative rod [9] <input type="radio"/> Candida or Torulopsis species [10] <input type="radio"/> Aspergillus species [11] <input type="radio"/> Other: bcorgoth A255

oldeden : Cardiac Arrhythmia (Cardiac)	
1.	<p>From the time of enrollment until ICU discharge (or study day 21, whichever occurs first) did subject experience any of the following arrhythmias?</p>
	<p>Check all that apply:</p> <p>[0] <input type="checkbox"/> None nocardiac</p> <p>[1] <input type="checkbox"/> Ventricular fibrillation vfib</p> <p>[2] <input type="checkbox"/> Ventricular tachycardia requiring DC cardioversion vtachdc</p> <p>[4] <input type="checkbox"/> Ventricular tachycardia requiring medical intervention vtachmi</p> <p>[5] <input type="checkbox"/> SVT requiring DC cardioversion svtDC</p> <p>[6] <input type="checkbox"/> SVT requiring medical intervention svtmi</p> <p>[6] <input type="checkbox"/> New onset atrial fibrillation (no treatment required) afibnt</p> <p>[7] <input type="checkbox"/> New onset atrial fibrillation requiring DC cardioversion afibdc</p> <p>[8] <input type="checkbox"/> New onset atrial fibrillation requiring medical intervention afibmi</p>

oldaltajan08 : Study Termination (Study Term)

Begin completion of this form by Day 28. Patients not yet home with unassisted breathing (UAB) should be followed through day 90.

1.	Patient status (through Day 90): <p style="text-align: center;">status</p>	<p>[1] <input type="radio"/> Home with UAB, date: homedt Req [v] / Req [v] / Req [v] (2006-2012)</p> <p>[2] <input type="radio"/> Dead prior to home with UAB, date: deathdt Req [v] / Req [v] / Req [v] (2006-2012)</p> <p>[3] <input type="radio"/> Other, date of last known patient status if not home with UAB or dead: othstatedt Req [v] / Req [v] / Req [v] (2006-2012)</p>
2.	Was this patient permanently withdrawn from the trial (through Day 28)? Study completion does NOT qualify as withdrawn from study. Select all applicable.	<p>[1] <input type="checkbox"/> ALTA Patient altapt [0] <input type="radio"/> Not Withdrawn [1] <input type="radio"/> Withdrawn: altawdraw altawdrawdt Withdrawl date: Req [v] / Req [v] / Req [v] (2006-2012) Reason for withdrawl from ALTA A255 altawdrawreas</p> <p>[1] <input type="checkbox"/> EDEN/OMEGA Patient eopt [0] <input type="radio"/> Not Withdrawn [1] <input type="radio"/> Withdrawn: eowdraw eowdrawdt Withdrawl date: Req [v] / Req [v] / Req [v] (2006-2012) Reason for withdrawl from EDEN/Omega: A255 eowdrawreas</p>
3.	If the patient was enrolled in EDEN/OMEGA study or Co-Enrolled: eo enroll Did patient reach full-calorie enteral feeding rate? eofullcal	<p>[0] <input type="radio"/> Not an EDEN/OMEGA Patient [1] <input type="radio"/> EDEN/OMEGA Patient eopt [1] <input type="radio"/> Yes, first date and time full-calorie rate reached: eofullcaldtm Req [v] / Req [v] / Req [v] (2006-2012) Req [v] : Req [v] 24-hour clock [0] <input type="radio"/> No</p>
4.*	Was patient discharged alive from study hospital (through Day 90)? hospcdct	<p>[1] <input type="radio"/> Yes, date: hospcdct Req [v] / Req [v] / Req [v] (2006-2012) [0] <input type="radio"/> No</p>
5.	Did patient meet criteria for spontaneous breathing trial (SBT) before day 29? If yes, enter date FIRST met criteria: sbtcrit	<p>[1] <input type="radio"/> Yes, date: Req [v] / Req [v] / Req [v] (2006-2012) sbtcritdt</p>

		[0] <input type="radio"/> No
6.	Did patient TOLERATE SBT? If yes, enter date FIRST tolerated SBT: sbttol	[1] <input type="radio"/> Yes, Date: NReq <input type="text"/> / NReq <input type="text"/> / NReq <input type="text"/> (2007-2012) [0] <input type="radio"/> No sbttoldt
7.	Did patient reach 48 hour UAB before day 29? If yes, enter date FIRST reached 48 hours UAB: uab	[1] <input type="radio"/> Yes, Date: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No uabdt
8.	Was patient extubated before day 29? If yes, enter date FIRST extubated: extub	[1] <input type="radio"/> Yes, Date: extubdt NReq <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
9.	Did Subject undergo tracheostomy prior to day 29? If yes, enter first date: trach	[1] <input type="radio"/> Yes, Date: NReq <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No trachdt
ICU HISTORY		
ICU days during study hospitalization to day 90 (days in which patient spent any time in an ICU during study hospitalization).		
10.	Discharged from ICU? discharge1	[1] <input type="radio"/> Yes, date of ICU DC: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No dischargedt1
11.*	Readmitted to ICU? readmit1	[1] <input type="radio"/> Yes, date of ICU readmission: readmitdt1 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
12.*	Discharged from ICU? discharge2	[1] <input type="radio"/> Yes, date of ICU DC: dischargedt2 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
13.*	Readmitted to ICU? readmit2	[1] <input type="radio"/> Yes, date of ICU readmission: readmitdt2 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
14.*	Discharged from ICU? discharge3	[1] <input type="radio"/> Yes, date of ICU DC: dischargedt3 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
15.*	Readmitted to ICU? readmit3	[1] <input type="radio"/> Yes, date of ICU readmission: readmitdt3 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
16.*	Discharged from ICU? discharge4	[1] <input type="radio"/> Yes, date of ICU DC: dischargedt4 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No
17.*	Readmitted to ICU? readmit4	[1] <input type="radio"/> Yes, date of ICU readmission: readmitdt4 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012) [0] <input type="radio"/> No

18.*	Discharged from ICU? discharge5	<p>[1] <input type="radio"/> Yes, date of ICU DC: dischargedt5 Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No</p>
HISTORY ON VENTILATOR		
Ventilator days until UAB at home, death, or day 90 (A ventilator day is any day in which the patient received assisted breathing (AB), except for AB for < 24 hours for a procedure or surgery)		
19.	Patient achieved unassisted breathing? uab1	<p>[1] <input type="radio"/> Yes, date of first UAB (first date with no AB; midnight to midnight): Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No uabdt1</p>
20.*	Patient returned to assisted breathing? retab1	<p>[1] <input type="radio"/> Yes, date of return to AB: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No retabdt1</p>
21.*	Patient achieved unassisted breathing again? uab2	<p>[1] <input type="radio"/> Yes, date of UAB (2nd date with no AB; midnight to midnight): Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No uabdt2</p>
22.*	Patient returned to assisted breathing? retab2	<p>[1] <input type="radio"/> Yes, date of return to AB: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No retabdt2</p>
23.*	Patient achieved unassisted breathing again? uab3	<p>[1] <input type="radio"/> Yes, date of UAB (3rd date with no AB; midnight to midnight): Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No uabdt3</p>
24.*	Patient returned to assisted breathing? retab3	<p>[1] <input type="radio"/> Yes, date of return to AB: Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No retabdt3</p>
25.*	Patient achieved unassisted breathing again? uab4	<p>[1] <input type="radio"/> Yes, date of UAB (4th date with no AB; midnight to midnight): Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2006-2012)</p> <p>[0] <input type="radio"/> No uabdt4</p>
26.*	End of Life Decision-making (for all patients, alive or dead): dnr	<p>[1] <input type="radio"/> No DNR decision made</p> <p>[2] <input type="radio"/> DNR decision made: withhold only CPR (or CR or PR)</p> <p>[3] <input type="radio"/> DNR decision made: withhold life support in addition to CPR</p> <p>[4] <input type="radio"/> DNR decision made: withdraw life support</p> <p>[5] <input type="radio"/> Diagnosis of brain death</p> <p>[6] <input type="radio"/> Unknown/can't tell</p>
27.*	Was written consent obtained from subject during study hospitalization? wconsent	<p>[1] <input type="radio"/> Yes</p> <p>[2] <input type="radio"/> No, reason: wconsentreas</p> <p>[1] <input type="radio"/> Patient died</p> <p>[2] <input type="radio"/> Patient never regained decision making</p>

		<p>capacity</p> <p>[3] <input type="radio"/> Patient declined further participation in study wconsentreasonsoth</p> <p>[4] <input type="radio"/> Other: A255</p>
28.*	<p>Was the Study Completed</p> <p>(This is an invisible system question for reporting. Please ignore it) [hidden]</p>	<p>[1] <input type="radio"/> Patient completed study</p> <p>[0] <input type="radio"/> Patient did not complete study</p>
29.*	<p>Why was the Study Stopped?</p> <p>(This is an invisible system question for reporting. Please ignore it.) [hidden]</p>	<p>[1] <input type="radio"/> Yes</p>
<p>* Item is not required</p>		