ARDSNet (ALTA) Case Report Forms (CRFs)

Table of Contents

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.	Date and time of **randomization:** randomdtm **Make CERTAIN that date is correct before saving.**	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) Req ⌄ : Req ⌄ *24-hour clock*
2.	Study Enrollment: study **Make CERTAIN that selection is correct before saving.**	*[1]* ◯ ALTA Only *[2]* ◯ EDEN/Omega only *[3]* ◯ Coenrolled in both ALTA and EDEN/Omega
3.	Study Patient ID:	A255

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 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)?	[1] ○ Yes [0] ○ No	
2.	Date and time of qualifying CXR: qualdtm	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) Req ⌄ : Req ⌄ 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 ⌄ / Req ⌄ / Req ⌄ (2006-2012) Req ⌄ : Req ⌄ 24-hour clock	
5.	Intent to begin/continue enteral feedings? intfeed	[1] ○ Yes [0] ○ No	
6.	Pa02: 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 ⌄ / Req ⌄ / Req ⌄ (2006-2012) Req ⌄ : Req ⌄ 24-hour clock	
9.	First date that all these criteria exist simultaneously: critdt	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012)	
10.	Gender: gender	[1] ○ Male [2] ○ Female	
11.	Ethnicity: ethnic	[1] ○ Hispanic or Latino [2] ○ Not Hispanic or Latino	
12.	Race (Check all that apply):	[1] ☐ American Indian or Alaskan Native [2] ☐ Asian [5] ☐ White [3] ☐ Black or African American [4] ☐ Native Hawaiian or other Pacific Islander [5] ☐ Not Reported	native asian white afamer island norace
13.	Age as appears on screening form (in years): age	xxx (n >= 13)	
14.	Is patient's true age greater than 89? agegt89	**[1]** ○ Yes, patient is older than 89 years. True age is: agetrue	

table = enroll1

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

table = enroll1

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

table = enroll1

		mdrefaltareas *[1]* ◯ Refusal to use conservative fluid protocol *[2]* ◯ Refusal to use 6ml ventilator protocol **[5]** ◯ Other: 　mdrefaltaoth
		mdrefeoc ☐ MD refusal for EDEN/Omega (specify reason)
		mdrefeoreas *[1]* ◯ Refusal to use conservative fluid protocol *[2]* ◯ Refusal to use 6ml ventilator protocol *[3]* ◯ Unwilling to delay nutrition *[4]* ◯ Unwilling to start nutrition early **[5]** ◯ Other: 　mdrefeooth
		[2] ◯ Not excluded
		[3] ◯ Not excluded and not enrolled, explain: A200 notexenreas

Lung Injury Category

17.	Trauma: trauma	*[0]* ◯ None *[1]* ◯ Primary *[2]* ◯ Secondary
18.	Sepsis: sepsis	*[0]* ◯ None **[1]** ◯ Primary (indicate site): Pulldown List 1 ⌄ sepsite *[2]* ◯ Secondary
19.	Multiple Transfusion: transf	*[0]* ◯ None *[1]* ◯ Primary *[2]* ◯ Secondary
20.	Aspiration: aspir	*[0]* ◯ None *[1]* ◯ Primary *[2]* ◯ Secondary
21.	Pneumonia: pneumo	*[0]* ◯ None *[1]* ◯ Primary *[2]* ◯ Secondary
22.	Other: otherlung	*[0]* ◯ None **[1]** ◯ Primary (describe): 　otherpr **[2]** ◯ Secondary (describe): 　othersec

table = enroll1

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] ⚪ Yes [0] ⚪ No
2. Has informed consent been obtained for the participation in **EDEN/Omega**? eoconsent	[1] ⚪ Yes [0] ⚪ No
3. Has informed consent been obtained for **genetic testing** testing in this study? genconsent	[1] ⚪ Yes [0] ⚪ No
4. Has informed consent been obtained for **future genetic reasearch in ARDS**? futconsenta	[1] ⚪ Yes [0] ⚪ 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] ⚪ Yes [0] ⚪ No
6. Has informed consent been obtained to **CONTACT** subject in the future for other studies? contconsent	[1] ⚪ Yes [0] ⚪ No

oldaltajan08 : Apache III Demographics (Apache Dem) table = apache_demog

1.	Hospital Admission Date: hasddt	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012)
2.	Hospital Admission Type: admtype	[1] ◯ Medical [2] ◯ Surgical scheduled [3] ◯ Surgical unscheduled **[4]** ◯ Other: admother
3.	ICU Admission Date: icudt	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012)
4.	Time of ICU Admission: icutm	Req ⌄ : Req ⌄ *24-hour clock*
5.	Patient Admitted Directly From: admitfrom	[1] ◯ OR [2] ◯ Recovery Room [3] ◯ ER [4] ◯ Floor [5] ◯ Another Special Care Unit [6] ◯ Another Hospital [7] ◯ Direct Admit [8] ◯ Stepdown Unit
6.	What was patient's place of residence prior to hospitalization? reside	[1] ◯ Home Independantly [2] ◯ Home with help (supervision, direction, or personal assistance) [3] ◯ Home with professional help(nursing/nursing service) [4] ◯ Intermediate care or rehabilitation facility [5] ◯ Skilled nursing facility [6] ◯ Another acute hospital **[7]** ◯ Other (Please Specify) resideother
7.	Is patient immediately post-operative from elective surgery? surgel	[1] ◯ Yes [0] ◯ No
8.	ICU Readmit: icureadmit	[1] ◯ Yes [0] ◯ No
9.	ICU Readmit within 24 hours: readmit24	[1] ◯ Yes [0] ◯ No
10.	Is chronic health information available?	[1] ◯ Yes [0] ◯ No healthinfo
11.	Is the patient on chronic dialysis or peritoneal dialysis? chrondial	[1] ◯ Yes [0] ◯ No
12.	AIDS (do not include HIV positive without AIDS criteria): aids	[1] ◯ Yes [0] ◯ No
13.	Leukemia (AML,CML,ALL,multiple myeloma): leuk	[1] ◯ Yes [0] ◯ No
14.	Non-Hodgkin's Lymphoma: lymph	[1] ◯ Yes [0] ◯ No
15.	Solid tumor with metastasis: tumor	[1] ◯ Yes [0] ◯ 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] ◯ Yes [0] ◯ No

table = apache_demog

17.	Hepatic failure with coma or encephalopathy: hepa	[1] ◯ Yes	[0] ◯ No		
18.	Cirrhosis: cirr	[1] ◯ Yes	[0] ◯ No		
19.	Diabetes Mellitus: diab	[1] ◯ Yes	[0] ◯ No		
20.	History of hypertension: hyper	[1] ◯ Yes	[0] ◯ No		
21.	Prior myocardial infarction: myocard	[1] ◯ Yes	[0] ◯ No		
22.	Congestive heart failure: heart	[1] ◯ Yes	[0] ◯ No		
23.	Peripheral Vascular Disease: vascular	[1] ◯ Yes	[0] ◯ No		
24.	Prior stroke with sequelae: aestroke	[1] ◯ Yes	[0] ◯ No		
25.	Dementia: dementia	[1] ◯ Yes	[0] ◯ No		
26.	Chronic pulmonary disease: chrpulm	[1] ◯ Yes	[0] ◯ No		
27.	Arthritis: arthritis	[1] ◯ Yes	[0] ◯ No		
28.	Peptic Ulcer Disease: ulcer	[1] ◯ Yes	[0] ◯ No		
29.	Vasopressors in the 24 hours prior to randomization? vasol24	[1] ◯ Yes	[0] ◯ 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 ○ °C ○ °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] ○ Yes [0] ○ No
7.	Was patient ventilated when the highest resp rate occurred? venth	[1] ○ Yes [0] ○ 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. mm³
13.	Platelets (lowest): plate	Lowest xxx X 1000 /mm³

Chemisty

USE VALUES FROM 24 HOURS PRECEDING RANDOMIZATION

#		
14.	Serum Sodium: sodiumo sodiuml sodiumh	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

table = apache_phys

17.	Serum Creatinine: creato creatl creath	Only xx.x	Lowest xx.x	Highest xx.x mg/dL
18.	Serum Glucose: gluco glucl gluch	Only xxxx	Lowest xxxx	Highest xxxx mg/dL
19.	Serum Albumin: albumo albuml albumh	Only xx.x	Lowest xx.x	Highest 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] ◯ Yes [0] ◯ 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] ◯ Yes [0] ◯ No

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] ⚪ Never [Skip to Q's 9-10] [1] ⚪ Monthly or less [2] ⚪ 2 to 4 times a month [3] ⚪ 2 to 3 times a week [4] ⚪ 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] ⚪ 1 or 2 [1] ⚪ 3 or 4 [2] ⚪ 5 or 6 [3] ⚪ 7, 8, or 9 [4] ⚪ 10 or more
3.*	How often do you have six or more drinks on one occasion? alch6freq	[0] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ 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] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ 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] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ 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] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ Daily or almost daily
7.*	How often during the last year have you had a feeling of guilt or remorse after drinking? alchguilt	[0] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ 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] ⚪ Never [1] ⚪ Less than monthly [2] ⚪ Monthly [3] ⚪ Weekly [4] ⚪ Daily or almost daily

9.	Have you or someone else been injured as a result of your drinking? alchinjury	[0] ◯ No [2] ◯ Yes, but not in the last year [4] ◯ 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] ◯ No [2] ◯ Yes, but not in the last year [4] ◯ Yes, during the last year

Smoking History

11.	Ever smoker (> 100 cigarettes in lifetime)? smoker	[1] ◯ Yes [0] ◯ 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] ◯ Yes smokequitdt [2] ◯ No, when quit: NReq/Unk ⌄ / NReq/Unk ⌄ / NReq ⌄ (1920-2012)

	* Item is not required

oldaltajan08 : Baseline Ventilator Parameters (Base Vent)

MOST RECENT VALUES PRIOR TO RANDOMIZATION

1.	Ventilator Mode (select all that apply): simv	[1] ☐ SIMV
	prvc	[2] ☐ PRVC (pressure regulated volume control) or equivalent
	pressup	**[3]** ☐ Pressure Support xx cm H20 pressupcmh2o
	volassist	[4] ☐ Volume Assist/Control
	presassist	**[5]** ☐ Pressure Assist xxx cm H20 presascmh2o
	pcirv	[6] ☐ PC IRV
	aprv	[7] ☐ Airway Pressure Release Ventilation (APRV)
	ventoth	[8] ☐ Other
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
After initial vent change, if any, on a tidal volume of 6-8 ml/kg PBW		
12.*	Calculated delivered tidal volume: tidalpost	xxxx (n >= 0) ml
13.*	Plateau Pressure: pplatpost	xx (n >= 3) cm H20
14.*	PEEP: peeppost	xx cm H20

* Item is not required

oldaltajan08 : 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	○ °C ○ °F
7. Measured Height: height	xxx.x	○ cm ○ in
8. Measured Weight: weight	xxx	○ kg ○ 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.	[0] ○ No [1] ○ Yes IV Dobutamine Infusion Rate: dobut ○ ug/kg/min ○ ug/min dobutu IV Dopamine Infusion Rate: dopa ○ ug/kg/min ○ ug/min dopau IV Norepinephrine Infusion Rate: norepi ○ ug/kg/min ○ ug/min norepiu IV Epinephrine Infusion Rate: epi ○ ug/kg/min ○ ug/min epiu IV Vasopressin Infusion Rate: vasorate units/min IV Neosynephrine (phenylephrine) Infusion Rate: neosyn ○ ug/kg/min ○ ug/min neosynu If Other Please Specify: vasooth	
10. Beta blockers (IV, PO, PGT) in 24 hours preceding randomization? betablock **ALTA or Co-enrolled only**	[1] ○ Yes [0] ○ No	
* 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 phos EDEN/Omega/Co-Enrolled)**:	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	xxxxxxxxxxxxxx.	mg/dL
11.*	Prothrombin time prothrombin	xxx.x	Seconds
* Item is not required			

oldaltajan08 : On-Study Dosing/Safety (ALTA) (ALTA Dosing)

	Dose	held_other	dose_time	dose_complete	stop_other	HR_pre	HR_post	max_HR	SBP_pre
1.									

RECORD SBP AND HR VALUES CLOSEST IMMEDIATELY BEFORE AND 15 MINUTES AFTER COMPLETION OF ALL STUDY DRUG DOSES ADMINISTERED THIS CALENDAR DATE.

1.a	Dose: altadose	[1] ⚪ Full dose [2] ⚪ Reduced dose [0] ⚪ None, select reason: 　　　Pulldown List 1 ▾　altanodose
1.b*	If "other", indicate reason:	altanodoseoth
1.c*	Time dose initiated:	Req ▾ : Req ▾　24-hour clock　altadosetm
1.d*	Was dose completed?　altadosecomp	[1] ⚪ Yes [2] ⚪ No, select reason: 　　　Pulldown List 2 ▾　altastopreas
1.e*	If "other", indicate reason:	altastopoth
1.f*	HR-pre:　hrpre	xxx
1.g*	HR-post:　hrpost	xxx
1.h*	Maximal heart Rate (from time aerosolization begins to 15 minutes after completion of the aerosol):　hrmax	xxx
1.i*	SBP-pre:　sbppre	xxx
1.j*	SBP-post:　sbppost	xxx

* Item is not required

Pulldown List 1:			
RefName	Display Text	Value	Design Note
Heart Threshhold	Heart Threshhold Reached	1	
Serum potassium lt 3	Serum potassium < 3.0 mEq/L	2	
There is 24 hr hold	There is currently a 24-hour hold on study drug	3	
PVCS during administration	PVCS (>5 new/min) during administration	4	
Receiving non study beta agonist	Receiving non-study beta-agonist therapy	6	
Sustained ventribular or atrial arrhythmias after study entry	Sustained ventricular or atrial arrhythmias after study entry	7	
Development of vtach or vfib	Development of v-tach or v-fib	8	
Study drug discontinued for remainder of trial	Study drug discontinued for remainder of trial	9	
Diabetic ketoacidosis or uncontrolled diabetes	Diabetic ketoacidosis or uncontrolled diabetes	10	

Uncontrolled hypertension	Uncontrolled hypertension	11	
Agitation tremor restlessness	Agitation/tremor/restlessness	12	
All protocol specified doses given this calendar date	All protocol specified doses given this calendar date	13	
OtherDosing	Other	20	

Pulldown List 2:			
RefName	**Display Text**	**Value**	**Design Note**
Heart Threshhold	Heart Threshhold Reached	1	
Serum potassium lt 3	Serum potassium < 3.0 mEq/L	2	
There is 24 hr hold	There is currently a 24-hour hold on study drug	3	
PVCS during administration	PVCS (>5 new/min) during administration	4	
Receiving non study beta agonist	Receiving non-study beta-agonist therapy	6	
Sustained ventribular or atrial arrhythmias after study entry	Sustained ventricular or atrial arrhythmias after study entry	7	
Development of vtach or vfib	Development of v-tach or v-fib	8	
Study drug discontinued for remainder of trial	Study drug discontinued for remainder of trial	9	
Diabetic ketoacidosis or uncontrolled diabetes	Diabetic ketoacidosis or uncontrolled diabetes	10	
Uncontrolled hypertension	Uncontrolled hypertension	11	
Agitation tremor restlessness	Agitation/tremor/restlessness	12	
All protocol specified doses given this calendar date	All protocol specified doses given this calendar date	13	
OtherDosing	Other	20	

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] ◯ Yes [0] ◯ No
2.	Eye Opening Score: eye	[1] ◯ None [2] ◯ To pain [3] ◯ To voice [4] ◯ Spontaneous
3.	Motor Response Score: motor	[1] ◯ Flaccid [2] ◯ Extension abnormal flexion [3] ◯ Abnormal flexion [4] ◯ Flexion withdrawal [5] ◯ Localizes to pain [6] ◯ Obeys commands
4.	Verbal Response Score: verbal	[1] ◯ None, or generally unresponsive if on ventilator [2] ◯ Incomprehensible [3] ◯ Inappropriate, or questionable oriented if on vent [4] ◯ Confused [5] ◯ 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 ˅| / |NReq ˅| / |NReq ˅| (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 ▾ / NReq ▾ / NReq ▾ (2007-2012)
3.	Cytokine and coagulation parameters sample collected (Plasma)? cyto0	*[1]* ◯ Yes *[2]* ◯ No, reason: cytoreas0
4.	Plasma fatty acids sample collected (Plasma)? fattyacid0	*[1]* ◯ Yes *[2]* ◯ No, reason: fattyacidreas0 *[3]* ◯ Not enrolled in EDEN/OMEGA
5.	Plasma epinephrine level sample collected (Plasma)? epi0	*[1]* ◯ Yes *[2]* ◯ No, reason: epireas0 *[3]* ◯ Not enrolled in ALTA
6.	Urine sample collected? urine0	*[1]* ◯ Yes *[2]* ◯ No, reason: urinereas0
7.	Whole blood sample collected (Genetics)? blood0	*[?]* ◯ Yes, date collected: bloodcolldt0 Req ▾ / Req ▾ / Req ▾ (2006-2012) *[2]* ◯ No, reason: bloodreas0

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: colldt1	NReq ▾ / NReq ▾ / NReq ▾ (2007-2012)
10.	Plasma Albuterol level sample collected (Plasma)? alb1	*[1]* ◯ Yes *[2]* ◯ No, reason: albreas1 *[3]* ◯ Not enrolled in ALTA
11.	Plasma epinephrine level sample collected (Plasma)? epi1	*[1]* ◯ Yes *[2]* ◯ No, reason: epireas1

		[3] ◯ 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 A8 [____] A8 [____]
13.*	Cytokine and coagulation parameters sample collected (Plasma)? cyto3	[1] ◯ Yes, date collected: cytocolldt3 Req ▾ / Req ▾ / Req ▾ (2006-2012) [2] ◯ No, reason: cytoreas3n [____]
14.*	Plasma fatty acids sample collected (Plasma)? fattyacid3	[1] ◯ Yes, date collected: fattyaciddt3 Req ▾ / Req ▾ / Req ▾ (2006-2012) [2] ◯ No, reason: fattyacidreas3 [____] [3] ◯ Not enrolled in EDEN/OMEGA
15.*	Urine sample collected? urine3	[1] ◯ Yes, date collected: urinecolldt3 Req ▾ / Req ▾ / Req ▾ (2006-2012) [2] ◯ No, reason: urinereas3 [____]

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 A8 [____] A8 [____]
17.*	Cytokines and coagulation parameters sample collected (Plasma)? cyto6	[1] ◯ Yes, date collected: cytocolldt6 Req ▾ / Req ▾ / Req ▾ (2006-2012) [2] ◯ No, reason: cytoreas6 [____]
18.*	Plasma fatty acids sample collected (Plasma)? fattyacid6	[1] ◯ Yes, date collected: fattyaciddt6 Req ▾ / Req ▾ / Req ▾ (2006-2012) [2] ◯ No, reason: A255 [____] [3] ◯ Not enrolled in EDEN/OMEGA
19.*	Urine sample collected? urine6	[1] ◯ Yes, date collected: urinecolldt6 Req ▾ / Req ▾ / Req ▾ (2006-2012)

table = spec_coll

		[2] ⚪ No, reason: urinereas6
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 A8 A8
21.*	Cytokines and coagulation parameters sample collected (Plasma)? cyto12	**[1]** ⚪ Yes, date collected: cytocolldt12 Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) **[2]** ⚪ No, reason: cytoreas12
22.*	Plasma fatty acids sample collected (Plasma)? fattyacid12	**[1]** ⚪ Yes, date collected: fattyaciddt12 Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) **[2]** ⚪ No, reason: fattyacidreas12 *[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]** ○ Yes, date collected: baldt0 　Req ▼ / Req ▼ / Req ▼ (2006-2012) **[2]** ○ No, reason: 　balnotreas0
2.*	Volume instilled: balvolin0	∣ xx ∣ ml
3.*	Volume returned: balvolout0	∣ xx ∣ ml
4.*	INR value obtained within the 36 hours prior to BAL? balinr0	*[2]* ○ No, BAL contraindicated **[1]** ○ Yes, was value ≤ 2.0? balinrle2_0 　*[1]* ○ Yes 　*[2]* ○ No, BAL contraindicated
5.*	Platelet value obtained in the 36 hours prior to BAL? balplate0	*[2]* ○ No, BAL contraindicated **[1]** ○ Yes, was value ≥ $50 \times 10^3/mm^3$? 　*[1]* ○ Yes balplatege5_0 　*[2]* ○ No, BAL contraindicated

Day 3

6.	Mini-BAL completed? If **NO**, do not complete questions 7-10. 　　　　　bal3	**[1]** ○ Yes, date collected: baldt3 　Req ▼ / Req ▼ / Req ▼ (2006-2012) **[2]** ○ No, reason: 　balnotreas3
7.*	Volume instilled: balvolin3	∣ xx ∣ ml
8.*	Volume returned: balvolout3	∣ xx ∣ ml
9.*	INR value obtained within the 36 hours prior to BAL? balinr3	*[2]* ○ No, BAL contraindicated **[1]** ○ Yes, was value ≤ 2.0? balinrle2_3 　*[1]* ○ Yes 　*[2]* ○ No, BAL contraindicated
10.*	Platelet value obtained in the 36 hours prior to BAL? balplate3	*[2]* ○ No, BAL contraindicated **[1]** ○ Yes, was value ≥ $50 \times 10^3/mm^3$? 　*[1]* ○ Yes balplatege5_3 　*[2]* ○ 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]* ○ Yes *[N]* ○ No	
2.*	Time of Measurement: dsmeasuretm	|Req ▼| : |Req ▼| *24-hour clock*	
3.*	Ventilator Mode (select all that apply): simv_ds prvc_ds pressup_ds volassist_ds presassist_ds pcirv_ds aprv_ds ventoth_ds	*[1]* ☐ SIMV *[2]* ☐ PRVC (pressure regulated volume control) or equivalent **[3]** ☐ Pressure Support |xx| cm H20 pressupcmh2o_ds *[4]* ☐ Volume Assist/Control **[5]** ☐ Pressure Assist |xxx| cm H20 presascmh2o_ds *[6]* ☐ PC IRV *[7]* ☐ Airway Pressure Release Ventilation (APRV) *[8]* ☐ Other	
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 : 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]* ○ No **[1]** ○ 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): simv prvc pressup volassist presassit pcirv aprv ventoth	*[1]* ☐ SIMV *[2]* ☐ PRVC (pressure regulated volume control) or equivalent **[3]** ☐ Pressure Support │ xx │ cm H20 pressupcmh2o *[4]* ☐ Volume Assist/Control **[5]** ☐ Pressure Assist │ xxx │ cm H20 presascmh2o *[6]* ☐ PC IRV *[7]* ☐ Airway Pressure Release Ventilation (APRV) *[8]* ☐ Other
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 wtih 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 ○ °C ○ °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] ○ Yes [0] ○ No
8.	Any vasopressors/inotropes this calendar day? If yes, enter 0800 infusion rates. vaso	[0] ○ No **[1]** ○ Yes dobut IV Dobutamine Infusion Rate: xx.xx ○ ug/kg/min ○ ug/min dobutu dopa IV Dopamine Infusion Rate: xx.xx ○ ug/kg/min ○ ug/min dopau norepi IV Norepinephrine Infusion Rate: xxx.xx ○ ug/kg/min ○ ug/min norepiu epi IV Epinephrine Infusion Rate: xx.xx ○ ug/kg/min ○ ug/min epiu vasorate IV Vasopressin Infusion Rate: x.xx units/min neosyn IV Neosynephrine (phenylephrine) Infusion Rate: xxx.xx ○ ug/kg/min ○ ug/min neosynu If Other Please Specify: vasooth

Complete the following question for ALTA/Co-Enrolled subjects only.		
9.*	Beta Blockers (IV, PO, PGT) this calendar day? betablock	*[1]* ⃝ Yes *[0]* ⃝ No
10.*	Aerosolized or MDI delivered ipatropium this calendar day? ipatro	**[1]** ⃝ Yes: Enter total number of doses this calendar day ipadose │ xx │ *[0]* ⃝ No
11.*	Non-study beta-agonist aerosol given by ICU team this calendar day? nsbetag	**[1]** ⃝ Yes: Enter total dose in mg of non-study beta-agonist aerosol given this calendar day nsbetadose │ xx │ mg *[0]* ⃝ 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:　insulinrt **(Enter "0" if not on continous insulin infusion at time of glucose value)**	xx.x	u/hr
12.*	Total sq insulin given in the 6 hours preceding the glucose value:　insulinsq **(Enter "0" if no sq insulin given in the 6 hrs proceeding the glucose value)**	xxxxx	Units
13.*	Lowest glucose this day:　glucmin	xxxx.	mg/dL
* 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]* ◯ Yes *[N]* ◯ No
2.	In the **12 hours prior** to the random check time, did MAP fall below 60 mmHg? map60	*[Y]* ◯ Yes *[N]* ◯ 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]* ◯ Yes *[N]* ◯ No
4.	In the **4 hours prior** to the random check time, was Lasix given? lasix4	*[Y]* ◯ Yes *[N]* ◯ No
5.	In the **12 hours prior** to the random check time, was fluid bolus (> 15 ml/kg PBW) given? bolus12	*[Y]* ◯ Yes *[N]* ◯ No
6.	Average UOP in the **4 hours prior** to the random check time < 0.5 ml/kg/hr? avuop4	*[Y]* ◯ Yes *[N]* ◯ No
7.	On **this calendar day**, was patient in acute renal failure or receiving renal replacement therapy? renal	*[Y]* ◯ Yes *[N]* ◯ 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]* ◯ No **[1]** ◯ Yes, propofol infusion rate is: | xxxxx | ml propinfate
	ontarget and rate [*hidden*]	

* 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]* ☐ Check this box
Day 1 Random Check Time chktm1	| NReq ⌄ *24-hour clock*
Day 2 Random Check Time chktm2	| NReq ⌄ *24-hour clock*
Day 3 Random Check Time chktm3	| NReq ⌄ *24-hour clock*
Day 4 Random Check Time chktm4	| NReq ⌄ *24-hour clock*
Day 5 Random Check Time chktm5	| NReq ⌄ *24-hour clock*
Day 6 Random Check Time chktm6	| NReq ⌄ *24-hour clock*
Day 7 Random Check Time chktm7	| NReq ⌄ *24-hour clock*

oldaltajan08 : Brussels Table (Brussels)   Collected for days 0-28

		24HR WORST VALUE					
1.*	Date brussdt	Req ⌄ / Req ⌄ / Req ⌄ (2006-2012)					
2.*		Syst BP systbp	PaO2/FiO2 pf	Platelets X1000 plate	Creatinine creat	Bilirubin bili	Vasopressor vaso *[1]* ◯ Yes *[0]* ◯ No

oldaltajan08 : Adverse Event (Ae)

CALL CCC IMMEDIATELY FOR **SERIOUS, UNEXPECTED, STUDY RELATED ADVERSE** EVENTS

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

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

	2012)
	[2] ○ AE present, no treatment
	[3] ○ AE present/being treated
	[4] ○ Residual effect/no treatment
	[5] ○ Residual effect/being treated
	[6] ○ Deceased as a result of this AE

* Item is not required

oldaltajan08 : Atrial Fibrillation (Atrial Fibrillation)

Please complete form <u>one time</u> at ICU discharge.

1.	Does the patient have a history of chronic or recurrent atrial fibrillation? afibhist	[Y] ◯ Yes [N] ◯ No
2.	Was the cardiac rhythm at the time of study hospital admission atrial fibrillation? afibadmit	[Y] ◯ Yes [N] ◯ No
3.	Did the patient develop new atrial fibrillation during the study hospitalization and <u>prior to ICU discharge</u> afibnew	**[1]** ◯ Yes: afibnewc On how many days did atrial fibrillation occur (any duration, midnight to midnight) │ afibdays │ Did atrial fibrillation develop (check only one): afibpre *[1]* ☐ Before first dose of study drug was administered? afibduring *[2]* ☐ During the days on which study drug was administered? atfibpost *[3]* ☐ More than 4 hours after the last dose of study drug was administered? *[0]* ◯ No
4.	Was chronic or new onset atrial fibrillation treated <u>prior to ICU discharge</u>? (check all that apply) afibtreat	**[1]** ◯ Yes: *[1]* ☐ DC cardioversion afibdccard *[2]* ☐ Vasopressor for hypotension that occured after onset of atrial fibrillation afibvaso *[3]* ☐ Beta Blocker afibbeta *[4]* ☐ Amiodarone afibamid *[5]* ☐ Anticoagulation afibantic *[6]* ☐ Digoxin afibdig *[7]* ☐ Diltiazem afibdilt *[0]* ◯ No

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

		[0] ○ No
6.	Did patient TOLERATE SBT? If yes, enter date FIRST tolerated SBT: sbttol	[1] ○ Yes, Date: NReq ▾ / NReq ▾ / NReq ▾ (2007-2012) [0] ○ No sbttoldt
7.	Did patient reach 48 hour UAB before day 29? If yes, enter date FIRST reached 48 hours UAB: uab	[1] ○ Yes, Date: Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No uabdt
8.	Was patient extubated before day 29? If yes, enter date FIRST extubated: extub	[1] ○ Yes, Date: extubdt NReq ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
9.	Did Subject undergo tracheostomy prior to day 29? If yes, enter first date: trach	[1] ○ Yes, Date: NReq ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ 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] ○ Yes, date of ICU DC: Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No dischargedt1
11.*	Readmitted to ICU? readmit1	[1] ○ Yes, date of ICU readmission: readmitdt1 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
12.*	Discharged from ICU? discharge2	[1] ○ Yes, date of ICU DC: dischargedt2 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
13.*	Readmitted to ICU? readmit2	[1] ○ Yes, date of ICU readmission: readmitdt2 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
14.*	Discharged from ICU? discharge3	[1] ○ Yes, date of ICU DC: dischargedt3 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
15.*	Readmitted to ICU? readmit3	[1] ○ Yes, date of ICU readmission: readmitdt3 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
16.*	Discharged from ICU? discharge4	[1] ○ Yes, date of ICU DC: dischargedt4 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No
17.*	Readmitted to ICU? readmit4	[1] ○ Yes, date of ICU readmission: readmitdt4 Req ▾ / Req ▾ / Req ▾ (2006-2012) [0] ○ No

18.*	Discharged from ICU? discharge5	**[1]** ○ Yes, date of ICU DC: dischargedt5 Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No

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	**[1]** ○ Yes, date of first UAB (first date with no AB; midnight to midnight): Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No uabdt1
20.*	Patient returned to assisted breathing? retab1	**[1]** ○ Yes, date of return to AB: Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No retabdt1
21.*	Patient achieved unassisted breathing again? uab2	**[1]** ○ Yes, date of UAB (2nd date with no AB; midnight to midnight): Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No uabdt2
22.*	Patient returned to assisted breathing? retab2	**[1]** ○ Yes, date of return to AB: Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No retabdt2
23.*	Patient achieved unassisted breathing again? uab3	**[1]** ○ Yes, date of UAB (3rd date with no AB; midnight to midnight): Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No uabdt3
24.*	Patient returned to assisted breathing? retab3	**[1]** ○ Yes, date of return to AB: Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No retabdt3
25.*	Patient achieved unassisted breathing again? uab4	**[1]** ○ Yes, date of UAB (4th date with no AB; midnight to midnight): Req ⌄ / Req ⌄ / Req ⌄ (2006-2012) *[0]* ○ No uabdt4
26.*	End of Life Decision-making (for all patients, alive or dead): dnr	*[1]* ○ No DNR decision made *[2]* ○ DNR decision made: withhold only CPR (or CR or PR) *[3]* ○ DNR decision made: withhold life support in addition to CPR *[4]* ○ DNR decision made: withdraw life support *[5]* ○ Diagnosis of brain death *[6]* ○ Unknown/can't tell
27.*	Was written consent obtained from subject during study hospitalization? wconsent	*[1]* ○ Yes **[2]** ○ No, reason: wconsentreas *[1]* ○ Patient died *[2]* ○ Patient never regained decision making

		capacity *[3]* ◯ Patient declined further participation in study **[4]** ◯ Other: 　　wconsentreasoth
28.* (This is an invisible system question for reporting. Please ignore it) [*hidden*]		
29.* (This is an invisible system question for reporting. Please ignore it.) [*hidden*]		
* Item is not required		