ARDSNet03 Annotated CRFs
Table of Contents

Part 01:04 ALI SCREENING ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

COMPLETE FOR PATIENTS MEETING CRITERIA 1-3 IN DESIGNATED ICU'S

1. Acute Onset
2. Within past 24 hrs patient had ALL of the following? 1=Yes, 2=No: SCRE1
   - PaO2/FiO2 less than or equal to 300 mmHg? 1=Yes, 2=No: SCRE2
   - Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph?
   - Receiving positive pressure ventilation via endotracheal tube?
3. No clinical evidence of left Atrial hypertension (if measured pulmonary arterial wedge pressure < or = 18 mmHg)? 1=Yes, 2=No: SCRE3
4. PaO2: PAO2
5. FiO2: FIO2
6. First date that all these criteria exist simultaneously: FDATE

Part 02:04 ALI SCREENING ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

7. Patient Hospital ID #: NOTE: hospid field removed from database HOSPID
8. Gender 1=Male, 2=Female: GENDER
9. Ethnicity 1=White, not of Hispanic Origin, 2=Black, not of Hispanic Origin, 3=Hispanic, 4=Asian/Pacific Islander, 5=American Indian/Alaskan Native, 6=Other: ETHNIC
10. Age: AGE
11. Location 1=MICU, 2=SICU, 3=Cardiac SICU, 4=CCU, 5=Neuro ICU, 6=Burn, 7=Trauma, 8=Cancer Unit, 9=MICU/SICU, 10=Other LOCAT LOCOTH
12. Regularly Screened ICU 1=Yes, 2=No: RSICU

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Part 03:04 ALI SCREENING ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

13. Primary Reason for Exclusion: REASON
0=Not Excluded, 1=MD Refuses, 2=Patient/Family Refuses,
3=Patient Unable/Surrogate Unavailable, 4=Patient < 18 Years,
5=Other Trial 30 days, 6=Inclusion Criteria > 36 hours,
7=Neuromuscular Disease, 8=Patient Pregnant, 9=Increased ICP,
10=Chronic Lung Disease, 11=Burns > 30%, 12=Terminal Illness,
13=Bone/Lung Transplant, 14=Not Committed to Full Support,
17=Chronic Liver Disease, 19=Morbid Obesity,
20=Treated with Methylxanthines within 24 hours,
21=Theophylline level > or = 10mcg/L, 22=Allergy to Methylxanthines

13b. Comments:
COMMENT

NOTE that variable 'COMMENT' is not included in the limited access dataset, in compliance with non-identifiability requirements.

Part 04:04 ALI SCREENING ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

14. Lung Injury Category (0=None, 1=Primary, 2=Secondary)
Trauma: TRAUMA Sepsis: SEPSIS Multiple Transfusion: MULTRAN
Aspiration: ASPIR Pneumonia: PNEUM Other: OTHER
Other Description: OTHTXT

FOLLOWING ITEMS ARE FOR SCREENED PATIENTS ONLY - NOT FOR PATIENTS ENROLLED IN ARDSNET 03

15. Date of unassisted breathing if unassisted breathing sustained for greater than 48 hours UNASSIS
16. Date of Discharge from Study Hospital DISCH
17. Status at Discharge from Study Hospital 1=Alive, 2=Dead: DISSTAT

NOTE that some of the data originally entered into 'OTHTXT' (item 14 Other Description) have been masked, due to the sensitive nature of these data. Please refer to page 2 item 8 of the Change Descriptions document (01-03_changes.pdf) for further detail.

Part 01:01 INCLUSION CRITERIA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No: Date of Randomization: VDATE

INCL1 1. Acute Onset

INCL2 2. Within the past 24 hours did patient have 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?

INCL3 3. No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure < or = 18 mmHg)

IF ANSWERS TO 1-3 YES, CONTINUE TO EXCLUSION CRITERIA

INCLUDE

Part 01:04 EXCLUSION CRITERIA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes, 2=No: Date: VDATE

EXCL1 1. Attending physician unwilling to participate?
EXCL2 2. Patient/Family unwilling to participate?
EXCL3 3. Patient unable and family unavailable to give consent?
EXCL4 4. Is patient less than 18 years old?
EXCL5 5. Has patient participated in other intervention trials in ALI, ARDS or Sepsis within the past 30 days?
EXCL6 6. Has it been > 36 hours since all inclusion criteria were met?
EXCL7 7. Does the patient have neuromuscular disease that impairs the ability to ventilate spontaneously?
EXCL8 8. Is patient pregnant (HCG required for women of reproductive potential)?
EXCL9 9. Does the patient have elevated ICP, tricyclic antidepressant overdose, HGBSS, HGBSC, or other conditions where hypercapnia would be contraindicated?
EXCL10 10. Does patient have severe chronic respiratory disease?

Part 02:04 EXCLUSION CRITERIA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes, 2=No:

EXCL11 11. Does patient have burns greater than or equal to 30% total body surface area?
EXCL12 12. Does patient have a malignancy or other chronic irreversible disease or condition for which 6 month mortality is estimated at greater than 50%?
EXCL13 13. Has the patient had either a bone marrow transplant or lung transplant?
EXCL14 14. Not committed to full support?
EXCLN15 15. Treated with methylxanthines (e.g. pentoxifylline, theophylline, aminophylline) within 4 hours?
EXCLN16 16. If aminophylline or theophylline use within 24 hours, is theophylline level greater than or equal to 10 mg/L?

EXCLUDE

Part 03:04 EXCLUSION CRITERIA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

17. Does patient have suspected chronic liver disease? 1=Yes,2=No: EXCL17
If No, skip to #18. If Yes, answer Child-Pugh A-E; and if this answer is greater than or equal to 10, patient is excluded.

A. Ascites 1=None,2=Present,3=Tense: PUGHA

B. Encephalopathy 1=None,2=Grade I or II,3=Grade III or IV: PUGHB

No Abnormality

Grade I or II - trivial lack of awareness; shortened attention span; lethargy; disorientation in time; clear personality change or inappropriate behavior

Grade II or IV - very drowsy; semicomatose but responsive to stimuli; confused; gross disorientation in time or space; bizarre behavior; coma; unresponsive to painful stimuli with/out abnormal movements

C. Bilirubin (mg/dl) 1=[<2],2=[2-3],3=[>3]: PUGHC

D. Albumin (g/dl) 1=[>3.5],2=[2.8-3.5],3=[<2.8]: PUGHD

E. Prothrombin time (sec. prolonged) 1=[<=4],2=[5-10],3=[>10]: PUGHE

Total: PUGHTOT

Part 04:04 EXCLUSION CRITERIA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No:

EXCLN18 18. Allergy to methylxanthines (including coffee, tea, or chocolate)?

EXCL20 19. Is the patient morbidly obese? (weight(kg)/height(cm)>1)

IF ANY OF THE ABOVE ANSWERS ARE YES PATIENT SHOULD NOT BE ENROLLED

EXCL21 20. Has informed consent been obtained?

If patient is eligible for the study and consent has been obtained, please call for randomization number.

EXCL21B 21. Is patient randomized? (If Yes, system prompts for number)

22. Patient randomized to (1=6 ml/kg,2=12 ml/kg): EXCL22

23. Date/time of initial ventilator change: EXCL23DT EXCL23TM

24. Study drug kit number: EXCLN24

NOTE: question 20 was split into two parts:
- 20a. Has informed consent for the study been obtained? (variable name 'excl21')
- 20b. Has informed consent for genetic testing been obtained? (variable name 'gene')

EXCLUDE

Part 01:02 APACHE III DEMOGRAPHICS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: YDATE

1. Hospital Admission Date: HADMDT
2. ICU Admission Date: ICUDT
3. Time of ICU Admission: ICUTM
4. Patient Admitted Directly From 1=OR,2=Recovery Room, 3=ER, 4=Floor, 5=Another Special Care Unit, 6=Another Hospital, 7=Direct Admit, 8=Stepdown Unit: ADMFRM

1=Yes,2=No:

5. Is patient immediately post-operative from elective surgery?: SURGEL
6. ICU Readmit: ICURE
7. ICU Readmit within 24 hours: ICURE2
8a. Is chronic health information available?: CHRNC
8b. Is the patient on chronic dialysis or peritoneal dialysis?: DIALY
9a. AIDS (do not include HIV positive without AIDS criteria): AIDS
9b. Leukemia (AML,CML,all lymphocytic leuk.,multiple myeloma): LEUK

Part 02:02 APACHE III DEMOGRAPHICS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No:

9c. Non-Hodgkin's Lymphoma: LYMPH
9d. Solid tumor with metastasis: TUMOR
9e. Immune suppression (radiation, chemotherapy or greater than or equal to 0.3 mg/kg/day prednisone or equivalent) within the past 6 months: IMMUNE
9f. Hepatic failure with coma or encephalopathy: HEPA
9g. Cirrhosis: CIRR
9h. Diabetes Mellitus: DIAB

Part 01:02 APACHE III PHYSIOLOGY ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

USE VALUES FROM 24HRS PRECEDING INITIAL VENT CHANGES Date: VDATE

VITAL SIGNS	Lowest	Highest		Lowest	Highest
1. Temperature:	TEMPCL	TEMPCH	C	TEMPFL	TEMPFH F
2. Systolic BP:	SYSBPL	SYSBPH	mmHg		
3. Mean Arterial Pressure:	MEANAPL	MEANAPH	mmHg		
4. Heart Rate:	HRATEL	HRATEH	beats/min		
5. Respiratory Rate:	RESPL	RESPH	breaths/min		

6a. Was patient ventilated when the lowest respiratory rate occured? 1=Yes,2=No: LVENT

6b. Was patient ventilated when the highest respiratory rate occured? 1=Yes,2=No: HVENT

7. Urine Output/24 hours: URINE ml

Part 02:02 APACHE III PHYSIOLOGY ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

USE VALUES FROM 24HRS PRECEDING INITIAL VENT CHANGES

HEMATOLOGY	Lowest	Highest	
*8. Hct:	HCTL	HCTH	%
*9. WBC:	WBCL	WBCH	/mm^3
*10. Platelets (lowest):	PLATE		X1000 /mm^3

CHEMISTRY			
*11. Serum Sodium:	SODIUML	SODIUMH	meq/L
*12. Serum Potassium:	POTASL	POTASH	meq/L
*13. Serum BUN (highest):		BUN	mg/dl
*14. Serum Creatinine:	CREATL	CREATH	mg/dl
*15. Serum Glucose:	GLUCL	GLUCH	mg/dl
*16. Serum Albumin:	ALBUML	ALBUMH	g/dl
*17. Serum Bilirubin (highest):		BILI	mg/dl
*18. Serum Bicarbonate (lowest):	BICAR		meq/L

Part 01:02 APACHE - ABG ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Visit Date: VDATE

REPORT ALL ABG'S IN THE 24HRS PRECEDING INITIAL VENT CHANGE

	FiO2	PaO2 mmHg	PaCO2 mmHg	pH	Intubated when ABG obtained 1=Yes,2=No
1.	FIO21	PAO21	PACO21	PH1	INTUBAT1
2.	FIO22	PAO22	PACO22	PH2	INTUBAT2
3.	FIO23	PAO23	PACO23	PH3	INTUBAT3
4.	FIO24	PAO24	PACO24	PH4	INTUBAT4
5.	FIO25	PAO25	PACO25	PH5	INTUBAT5
6.	FIO26	PAO26	PACO26	PH6	INTUBAT6
7.	FIO27	PAO27	PACO27	PH7	INTUBAT7
8.	FIO28	PAO28	PACO28	PH8	INTUBAT8
9.	FIO29	PAO29	PACO29	PH9	INTUBAT9
10.	FIO210	PAO210	PACO210	PH10	INTUBAT10

NOTE: in the database, the 'copnum' variable represents the rows shown here

Part 02:02 APACHE - ABG ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___

	FiO2	PaO2 mmHg	PaCO2 mmHg	pH	Intubated when ABG obtained 1=Yes,2=No
11.	FIO211	PAO211	PACO211	PH11	INTUBAT11
12.	FIO212	PAO212	PACO212	PH12	INTUBAT12
13.	FIO213	PAO213	PACO213	PH13	INTUBAT13
14.	FIO214	PAO214	PACO214	PH14	INTUBAT14
15.	FIO215	PAO215	PACO215	PH15	INTUBAT15
16.	FIO216	PAO216	PACO216	PH16	INTUBAT16
17.	FIO217	PAO217	PACO217	PH17	INTUBAT17
18.	FIO218	PAO218	PACO218	PH18	INTUBAT18
19.	FIO219	PAO219	PACO219	PH19	INTUBAT19
20.	FIO220	PAO220	PACO220	PH20	INTUBAT20

BABG

NOTE: the original production of the data extract tables combined the above variables into: fio2, pao2, paco2, ph, and intubate, as you can see in the electronic 'babg' table you have received. No data were altered as a result of this restructuring.

Part 01:03 VITAL SIGNS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1. Date and time of current intubation: INTUBDT INTUBTM

ITEMS 2-5 ARE MOST RECENT IN THE 4 HRS PRECEDING INITIAL VENT CHANGE AND BEFORE STUDY DRUG INITIATION

For highest and lowest, use the maximum and minimum values on this calendar date (may include values in the reference period).

	Lowest		Highest		Reference	
2. Heart Rate:	HRATEL bpm		HRATEH bpm		HRATER bpm	
3. Systolic BP:	SYSBPL mmHg		SYSBPH mmHg		SYSBPR mmHg	
4. Diastolic BP:	DIABPL mmHg		DIABPH mmHg		DIABPR mmHg	
5. Temperature:	TEMPCL C	TEMPFL F	TEMPCH C	TEMPFH F	TEMPCR C	TEMPFR F
6. Height	HEIGHTC cm		HEIGHTI in			
7. Gender:	GENDER 1=Male,2=Female					
8. IBW:	IBW kg (computed)					
9. Weight:	WEIGHTK kg		WEIGHTL lbs			

Part 02:03 VITAL SIGNS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

10. Fluid Intake/24 hours: FLUIDI ml
11. Urine Output/24 hours: FLUIDO ml

LABS:

12. Hct:	HCT	%
13. WBC:	WBC	/mm^3
14. Bilirubin:	BILI	mg/dL
15. AST:	AST	Units/L
16. ALT:	ALT	Units/L
17. Alkaline Phosphatase:	ALKAL	Units/L
18. Platelets:	PLATE	X 1000 /mm^3
19. Albumin:	ALBUM	g/dL

VITAL

Part 03:03 VITAL SIGNS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___

LABS (continued):

20. Sodium:	SODIUM	mEq/L
21. Potassium:	POTAS	mEq/L
22. Glucose:	GLUC	mg/dL
23. Creatinine:	CREAT	mg/dL
24. BUN:	BUN	mg/dL
25. Chloride:	CHLOR	mEq/L
26. HCO3:	BICAR	mEq/L
27. HGB:	HGB	g/dL
28. HCG:	HCG	mIU/ml

Collect blood for cytokines prior to initial vent change.

VITAL

NOTE that this baseline 'Vital' form was joined with the on-study 'Vital' form (page 19-20) to create the electronic 'vital' table that you have received.

Part 01:02 VENTILATOR PARAMETERS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

MOST RECENT IN 4HR INTERVAL BEFORE INITIAL VENT CHANGE Date: VDATE
Initial Vent Change Time: VENTICHTM

1. Ventilator Manufacturer and Model: VMODEL
   1=Puritan-Bennett 7200, 2=Servo 9000,
   3=Servo 300, 4=Hammilton Veolar/Amadeus,
   5=Bird 8400, 6=Bear 1000, 7=Other
2. Ventilator Mode
   2.1 SIMV 1=Yes,2=No: SIMV 2.2 Pressure Support 1=Yes,2=No: PSUPP
   2.3 Assist/Control 1=Yes,2=No: A/C 2.4 Pressure Control 1=Yes,2=No: PCON
   2.5 PC IRV 1=Yes,2=No: PCIRV 2.6 Other 1=Yes,2=No: OTHER OTHERSP
3. Calculated Delivered Tidal Volume: TIDAL ml
4. Pressure Control Level: PCONL cm H2O
   (If on Pressure Control Ventilation)
5. Pressure Support: PSUPL cm H2O
   (If on Pressure Support Ventilation)

Part 02:02 VENTILATOR PARAMETERS ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

6. Set Rate:	SRATE	breaths/min.
7. Total Respiratory Rate:	TRESPR	breaths/min.
8. Total Minute Ventilation:	TMNVNT	L/min
9. PEEP:	PEEP	cm H2O
10. Plateau Pressure 0.5 second end-inspiratory pause:	PSTAT1	cm H2O
11. Peak Inspiratory Pressure:	PEAK	cm H2O
12. I:E Ratio: a.Set I:E: IERATIO or b.True I:E: TIERATIO		
13. Mean Airway Pressure:	MAPRES	cm H2O
14. FiO2:	FIO2	
15. PaO2:	PAO2	mmHg
16. PaCO2:	PACO2	mmHg
17. Arterial pH:	ARTPH	
18. SpO2:	SPO2	%

VENT

NOTE that this baseline 'Vent' form was joined with the on-study 'Vent' form (page 33) to create the electronic 'vent' table that you have received.

Part 01:01 CHEST X-RAY ARDSNET 03 Day:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

USE MOST RECENT CXR PRIOR TO TIME OF ENROLLMENT

1. Radiographic Lung Injury Score (# of quadrants 0-4) RADIS

2. Barotrauma:

Pneumothoraces	1=Right, 2=Left, 3=Bilateral, 4=None:	BARO1
Subcutaneous emphysema	1=Yes, 2=No:	BARO2
Pneumomediastinum	1=Yes, 2=No:	BARO3
Pneumatoceles > 2 cm diam	1=Right, 2=Left, 3=Bilateral, 4=None:	BARO4

3. Chest Tube 1=Right, 2=Left, 3=Bilateral, 4=None: CTUBE

OSCHEST

NOTE that this baseline Chest XRay form was joined with the on-study Chest XRay form (page 34) to create the electronic 'oschest' table that you have received.

Part 01:03 MEDICATIONS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

INDICATE 1=YES,2=NO IF ANY OF THE FOLLOWING

Date: VDATE

MEDICATIONS WERE ADMINISTERED WITHIN 24 HOURS
OF INITIAL VENTILATOR CHANGE

CHART2 1. Chart review suggests infection within 72 hours from enrollment?
-If bacteremia, fill out Bacteremia form
-If septic shock, fill out Septic Shock form
-If specific site of infection identified, fill out infection form for that site.

SEDAT 2. Sedative/Tranquilizers
(benzodiazepines,narcotics,barbiturates,propofol)

BLOCKER 3. Neuromuscular Blocking Agents

ANTIF 4. Antifungal Imidazole (e.g. Fluconazole)

AMPHO 5. Amphotericin

Part 02:03 MEDICATIONS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

AMINO1 6. Aminoglycosides
If Yes, list antibiotics for this category: AMINO2 AMINO3
1=Gentamicin,2=Tobramycin,3=Amikacin,4=Other Aminoglycosides

CEPH1 7. Cephalosporins
If Yes, list antibiotics for this category: CEPH2 CEPH3
1=Cefazolin,2=Cefotaxime,3=Cefotetan,4=Ceftazidime,5=Ceftriaxone,
6=Cefuroxime,7=Cefepime,8=Other Cephalosporins

MAC1 8. Macrolides
If Yes, list antibiotics for this category: MAC2 MAC3
1=Azithromycin,2=Clarithromycin,3=Clindamycin,4=Erythromycin

PCN1 9. Penicillins
If Yes, list antibiotics for this category: PCN2 PCN3
1=Ampicillin,2=Ampicillin-Subactam,3=Aztreonam,4=Imipenam-
Cilistatin,5=Nafcillin,6=Penicillin,7=Piperacillin,8=Ticarcillin,
9=Other Penicillins

MM

Part 03:03 MEDICATIONS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

QUIN01 10. Quinolones
If Yes, list antibiotics for this category: QUIN02 QUIN03
1=Ciprofloxacin, 2=Ofloxacin, 3=Other Quinolones
VANCO 11. Vancomycin
OANT 12. Other Antibiotic
APSYC 13. Antipsychotics (e.g. haloperidol, droperidol)
NITRIC 14. Nitric Oxide
PRONE 15. Prone Positioning
AVRLS 16. Antivirals
METH 17. Methylxanthines (e.g. theophylline, pentoxifylline, or aminophylline)

MM

NOTE that this baseline Monitoring and Medications form was joined with the on-study Monitoring and Medications form (page 35-36) to create the electronic 'mm' table that you have received.

Part 01:01 12-LEAD ECG ARDSNET 03 Visit: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date of ECG: ECDT Time of ECG: ECTIME

RECORD ECG FROM THE 24 HOUR INTERVAL PRIOR TO THE FIRST STUDY DRUG INFUSION. IF MORE THAN ONE, USE MOST RECENT.

Heart Rate: ECHRT bpm

Cardiac Cycle Measurements: P-R Interval: ECPR sec
QRS Interval: ECQRS sec
Q-T Interval: ECQT sec

Interpretation: ECINT
1=Within normal limits
2=Abnormal

ECG

NOTE that this baseline 'ECG' form was joined with the on-study 'ECG' form (page 37) to create the electronic 'ecg' table that you have received.

Part 01:02 FIRST DOSE VITAL SIGNS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

Record vital signs just prior to the first study drug dose, at the conclusion of the first dose, and 30 minutes after completion of the first dose.

Prior to initial dose: Time: DOSE1TM

1. Heart Rate: HRATE1 bpm
2. Systolic BP: SYSBP1 mmHg
3. Diastolic BP: DIABP1 mmHg
4. Temperature: TEMPCL1 C/TEMPFL1 F

At conclusion of first dose: Time: DOSE2TM

1. Heart Rate: HRATE2 bpm
2. Systolic BP: SYSBP2 mmHg
3. Diastolic BP: DIABP2 mmHg
4. Temperature: TEMPCL2 C/TEMPFL2 F

Part 02:02 FIRST DOSE VITAL SIGNS ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Thirty minutes after first dose: Time: DOSE3TM

1. Heart Rate: HRATE3 bpm
2. Systolic BP: SYSBP3 mmHg
3. Diastolic BP: DIABP3 mmHg
4. Temperature: TEMPCL3 C/TEMPFL3 F

Part 01:02 DRUG DOSING/SPECIMEN LOG ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1a. Start time of infusion: START1TM
1b. Dosage: DOSE1 mg
2a. Start time of infusion: START2TM
2b. Dosage: DOSE2 mg

3a. Start time of infusion: START3TM
3b. Dosage: DOSE3 mg

4a. Start time of infusion: START4TM
4b. Dosage: DOSE4 mg
5a. Start time of infusion: START5TM
5b. Dosage: DOSE5 mg

Part 02:02 DRUG DOSING/SPECIMEN LOG ARDSNET 03 Visit:0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

IF A PATIENT DEVELOPS A CREATININE > 2.5 OR BILIRUBIN > 3.0, ADDITIONAL STUDY DRUG LEVELS WILL BE DRAWN PRE- AND POST- STUDY DRUG INFUSION DAILY FOR 3 DAYS AND THEN WEEKLY UNTIL DAY 28 OR HOSPITAL DISCHARGE.

Specimen collection (Before and immediately after completion of first study drug infusion.)

Drug Levels:

6a. Pre-infusion blood draw done? 1=Yes,2=No: PREINFDL
6b. If Yes, give time of blood draw: PRETM
7a. Post-infusion blood draw done? 1=Yes,2=No: POSTINF1
7b. If Yes, give time of blood draw: POST1TM
7c. Stop time of infusion: STOP1TM

Surrogate Markers:

8a. Pre-infusion blood draw done? 1=Yes,2=No: PREINFS
8b. If Yes, give time of blood draw: SURTM

FOR DAY 0 CYTOKINES, SEE SPECIMEN COLLECTION IN ALL MENU

NOTE that this baseline 'DDSL' form was joined with two other on-study 'DDSL' forms (pages 38 and 42) to create the electronic 'ddsl' table that you have received.

Part 01:01 GLASGOW COMA ARDSNET 03 Day: 0

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1. Is patient on a sedative or neuromuscular blocker? 1=Yes, 2=No: SEDATE
   If yes, use best estimate
2. Eye Opening Score 4=Spontaneous, 3=To Voice, 2=To Pain, 1=None: EYE
3. Motor Response Score MOTOR
   6=Obeys Commands, 5=Localizes to Pain, 4=Flexor Withdrawal,
   3=Abnormal Flexion, 2=Extension, 1=Flaccid:
4. Verbal Response Score OR On Ventilator VERBAL
   5=Oriented, 5=Appears Oriented,
   4=Confused, 3=Quesionably Oriented,
   3=Inappropriate, 1=Generally Unresponsive
   2=Incomprehensible,
   1=None

Total: TOTAL

GLASGOW

Part 01:02 ON STUDY VITAL SIGNS ARDSNET 03 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

For reference period items, use values between 06:00 to 10:00. If more than one value, use the value closest to 08:00. If not available in reference period, use closest to reference period on same calendar day.
For highest and lowest, use the maximum and minimum values on this calendar date (may include values in the reference period).

	Lowest	Highest	Reference
1. Heart Rate:	HRATEL bpm	HRATEH bpm	HRATER bpm
2. Systolic BP:	SYSBPL mmHg	SYSBPH mmHg	SYSBPR mmHg
3. Diastolic BP:	DIABPL mmHg	DIABPH mmHg	DIABPR mmHg
4. Temperature:	TEMPCL C TEMPFL F	TEMPCH C TEMPFH F	TEMPCR C TEMPFR F
5. Weight:	WEIGHTK kg WEIGHTL lbs		

Part 02:02 ON STUDY VITAL SIGNS ARDSNET 03 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

6. Fluid Intake/24 hours:	FLUIDI	ml
7. Urine Output/24 hours:	FLUIDO	ml
LABS:		
8. Hct:	HCT	%
9. WBC:	WBC	/mm^3
10. AST:	AST	Units/L
11. ALT:	ALT	Units/L
12. Alkaline Phosphatase:	ALKAL	Units/L
13. Platelets:	PLATE	X 1000 /mm^3
14. Bilirubin:	BILI	mg/dL
15. Albumin:	ALBUM	g/dL
16. Sodium:	SODIUM	mEq/L
17. Potassium:	POTAS	mEq/L
18. Glucose:	GLUC	mg/dL

VITAL

Part 01:01 ON STUDY VITAL SIGNS ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

LABS (continued):

19. Creatinine: CREAT mg/dL
20. BUN: BUN mg/dL
21. Chloride: CHLOR mEq/L
22. HCO3: BICAR mEq/L
23. HGB: HGB g/dL

Collect blood for cytokines on Days 1 and 3.

VITAL

NOTE that this on-study 'Vital' form was joined with the baseline 'Vital' form (page 9-10) to create the electronic 'vital' table that you have received.

Part 03:03 STUDY TERMINATION ARDSNET 03 Day:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

4. Was the patient discharged alive from ICU during the first 28 days after enrollment? 1=Yes,2=No: ICU
4a. If Yes, date of discharge: ICUDT
5. Did the patient return to an ICU during the first 28 days? 1=Yes,2=No: RICU
5a. If Yes, number of calendar dates on which the patient received any ICU-care between the date 4a and day 28: RICUDAYS
6. Patient discharged alive from study hospital? 1=Yes,2=No: ALIVE
6a. If Yes, date of discharge alive from hospital: ALIVEDT
6b. If Yes, status at Study Day 28: 1=Alive,2=Dead: STATD28
7. Status at Study Day 60: 1=Alive,2=Dead: STATD60

FILL OUT AN AE FORM FOR ALL SERIOUS ADVERSE EVENTS, REHOSPITALIZATIONS FOR SERIOUS ADVERSE EVENTS, AND ALL UNEXPECTED DEATHS UP TO DAY 60.

TERM

NOTE that the rest of this form is printed on page 32.

Part 01:01 ADDITIONAL COMMENTS ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Form Name: FRMNAME Date: VDATE
Item Number: ITEMNUM
Day Number: DAYNUM

Comment:
COMMENT

COMMENT

NOTE that the data from the 'COMMENT' table have not been included in the limited access dataset, in compliance with non-identifiability requirements.

Part 01:01 EARLY DRUG DISCONTINUATION ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

COMPLETE THIS FORM IF LSF STUDY DRUG WAS DISCONTINUED PRIOR TO THE COMPLETION OF 48 HOURS UNASSISTED BREATHING OR DAY 20, WHICHEVER OCCURRED FIRST.

1. Reason(s) for discontinuation: REASON1 REASON2 REASON3
   1. Unacceptable toxicity
   2. Withdrawal of patient or surrogate consent
   3. Unforseen events
   4. MD withdraws patient
   5. Death
   6. Adverse event
   7. Protocol violation
   8. Other (specify): OTHERTXT

NOTE that variable 'OTHERTXT' is not included in the limited access dataset, in compliance with non-identifiability requirements.

DDC

Part 01:01 DEATH REPORT ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Complete this form for all deaths during study hospitalization to Day 180 and for all deaths to Day 60 regardless of location. All unexpected deaths to day 60 are to be reported to the CCC immediately.

1. Date of Death: DDATE
2. Cause of Death: DCAUSE
2a. If patient died within 28 days of randomization, was death related to infection? DINFEC
1=not related, 2=possibly related,
3=probably related, 4=not applicable
3. Describe event:
DESC

NOTE that variable 'DCAUSE' has been removed from the limited access dataset, to maintain non-identifiability. Variable 'FAILURE' captures similar information, based on WHO codes.

NOTE that variable 'DESC' is not included in the limited access dataset, in compliance with non-identifiability requirements.

DEATH

NOTE that the electronic database 'DEATH' also contains the following variables: system1, system2, failure, and msof. Please refer to the Summary of Changes document (01-03_changes.pdf) for a description of these variables.

Part 01:01 PERITONITIS ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

THIS FORM IS TO BE USED FOR PERITONITIS NOT ASSOCIATED WITH PERITONEAL DIALYSIS. PERITONITIS IS DEFINED AS A POSITIVE GRAM STAIN OR CULTURE OF PERITONEAL FLUID WITH > 250 PMNs/ml IN PERITONEAL FLUID OR FREE PERITONEAL AIR WITH BACTEREMIA.

1. Date of diagnosis: PERTN1

2. Peritoneal Fluid Cultures: PERTN2

1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B. cattarhalis,10=Other Gram Negative cocci,11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus, 17=Other Virus,18=None identified/Not obtained

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.

APT

Part 01:01 WOUND INFECTION ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

THIS FORM IS TO BE USED FOR WOUND INFECTION REQUIRING EXTENSIVE DEBRIDEMENT AND/OR HEALING BY SECONDARY INTENTION.

1. Date of diagnosis: WOUND1
2. Wound Culture: WOUND2

1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B. cattarhalis,10=Other Gram Negative cocci,11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus, 17=Other Virus,18=None identified/Not obtained

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.

AWI

Part 01:01 VIRAL INFECTION ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

THIS FORM IS TO BE USED FOR DISSEMINATED VIRAL INFECTIONS

1. Date of diagnosis: VIRAL1
2. Organism: VIRAL2
   1=Herpes Simplex, 2=Varicella zoster, 3=CMV, 4=Other

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).

AVI

Part 01:01 MENINGITIS ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1. Date of diagnosis: MENGT1
2. Organism recovered from cerebrospinal fluid: MENGT2
   1=Neiseria meningiditis, 2=Strep pneumoniae, 3=Hemophilus influenzae, 4=Other Gram Negative Rods, 5=Staph. Aureus, 6=Other

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.

AMN

Part 01:01 EMPYEMA ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1. Date of diagnosis: EMPYE1
2. Organism: EMPYE2

1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B. cattarhalis,10=Other Gram Negative cocci,11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus, 17=Other Virus,18=None identified/Not obtained

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.

AEM

Part 01:01 DEEP TISSUE ABSCESS ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

THIS FORM IS TO BE USED FOR ABDOMINAL OR OTHER DEEP TISSUE ABSCESS

1. Date of diagnosis: DTISU1

2. Organism: DTISU2

1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B. cattarhalis,10=Other Gram Negative cocci,11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus, 17=Other Virus,18=None identified/Not obtained

3. Site of infection/abscess: DTISU3

1=Hepatic Abscess,2=Splenic Abscess,3=Pericolic Abscess,4=Pancreatic Abscess,5=Cholcystitis,6=Myositis,7=Other

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.

ADT

Part 01:01 OTHER INFECTION ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1a. C. difficile colitis? 1=Yes,2=No OTHRIN1
1b. If Yes, give date: OTHRIN2
2a. Indwelling vascular line infection? 1=Yes,2=No OTHRIN3
2b. If Yes, give date: OTHRIN4
3a. Peritonitis (on Peritoneal Dialysis)? 1=Yes,2=No OTHRIN5
3b. If Yes, give date: OTHRIN6
OTHRIN7
4a. Sinus Infection? 1=Yes,2=No
4b. If Yes, give date: OTHRIN8
OTHRIN9
5a. Skin Infection? 1=Yes,2=No
5b. If Yes, give date: OTHRIN10
6a. Septic arthritis? 1=Yes,2=No OTHRIN11
6b. If Yes, give date: OTHRIN12
7a. Urinary tract infection? UTRACT
7b. If Yes, give date: UDATE
8a. Other infection? 1=Yes,2=No OTHRIN13
8b. If Yes, give date: OTHRIN14

ADI

Part 01:03 STUDY TERMINATION ARDSNET 03 Day:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

Complete this form on study days 28 AND 60. For patients alive after day 60 who have not been discharged home or are on assisted breathing, check on the patient's status at intervals of at most 30 days until the patient: 1) goes home with unassisted breathing or 2) dies or 3) the patient survives 180 days at any location with or without assisted breathing, whichever comes first.

1. Patient Status: STATUS
   1=Home with unassisted breathing
   2=Dead prior to discharge home with unassisted breathing or dead prior to achieving unassisted breathing at home for 48 hrs
   3=Other

1a. If 1, date discharged home on unassisted breathing: ST1DT

1b. If 2, date of death: ST2DT

1c. If 3, date of last patient contact: ST3DT

Part 02:03 STUDY TERMINATION ARDSNET 03 Day:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

2. Patient able to sustain a period of continuous unassisted breathing for at least 48 hrs during first 28 days? 1=Yes,2=No: UNASSIST

2a. If Yes, enter the first calendar date of the first period of unassisted breathing that lasted > or = 48 hours: UNADT

3. Did the patient return to assisted breathing during the first 28 days after achieving > or = 48 hours unassisted breathing? 1=Yes,2=No: ASSIST

3a. If Yes, number of calendar dates on which the patient required assisted breathing between the date 2a and day 28: ASDAYS

3b. If 3a=Yes, was the patient able to sustain another period of unassisted breathing for >= 48 hours without returning to assisted breathing by Day 28? 1=Yes,2=No: SUSTAIN

3c. If 3b=Yes, enter beginning date of the last period of Unassisted Breathing: UNA2DT

NOTE that the rest of this form is printed on page 21.

Part 01:02 ON STUDY VENTILATOR PARAMETERS ARDSNET 03 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

IF ON POSITIVE PRESSURE VENT DURING REFERENCE PERIOD 0600-1000. IF MORE THAN ONE VALUE, USE VALUES CLOSEST TO 0800. IF ABG NOT AVAILABLE IN REFERENCE PERIOD, USE CLOSEST TO REFERENCE PERIOD ON SAME CALENDAR DATE. Date: VDATE

1. Ventilator Manufacturer and Model: VMODEL
   1=Puritan-Bennett 7200, 2=Servo 9000,
   3=Servo 300, 4=Hammilton Veolar/Amadeus,
   5=Bird 8400, 6=Bear 1000, 7=Other
2. Ventilator Mode
   2.1 Assist/Control 1=Yes,2=No: ASSIST
   2.2 Pressure Support 1=Yes,2=No: PSUPP
   2.3 Unassisted Breathing 1=Yes,2=No: UNASIS
3. Calculated Delivered Tidal Volume: TIDALml
   (If on Assist/Control)
4. Pressure Support: PSUPL cm H2O
   (If on Pressure Support Ventilation)

Part 02:02 ON STUDY VENTILATOR PARAMETERS ARDSNET 03 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

5. Set Rate:	SRATE	breaths/min.
6. Total Respiratory Rate:	TRESPR	breaths/min.
7. Total Minute Ventilation:	TMNVNT	L/min
8. PEEP:	PEEP	cm H2O
9. Plateau Pressure 0.5 second end-inspiratory pause:	PSTAT1	cm H2O
10. Peak Inspiratory Pressure:	PEAK	cm H2O
11. I:E Ratio: a.Set I:E IRATIO:ERATIO or b.True I:E	IRATIO:ERATIO	
12. Mean Airway Pressure:	MAPPES	cm H2O
13. FiO2:	FIO2	
14. PaO2:	PAO2	mmHg
15. PaCO2:	PACO2	mmHg
16. Arterial pH:	ARTPH	
17. SpO2:	SPO2	%

Page ID: [202] VENT Print Count: [1]

NOTE that this on-study 'Vent' form was joined with the baseline 'Vent' form (page 11) to create the electronic 'vent' table that you have received.

Part 01:01 CHEST X-RAY ARDSNET 03 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

Use first CXR in the reference period 06:00-10:00. If unavailable in reference period, use first CXR this calendar day.

1. Radiographic Lung Injury Score (# of quadrants 0-4) RADIS
2. Barotrauma:
   - Pneumothoraces 1=Right,2=Left,3=Bilateral,4=None: BARO1
   - Subcutaneous emphysema 1=Yes,2=No: BARO2
   - Pneumomediastinum 1=Yes,2=No: BARO3
   - Pneumatoceles > 2 cm diam 1=Right,2=Left,3=Bilateral,4=None: BARO4
3. Chest Tube 1=Right,2=Left,3=Bilateral,4=None: CTUBE

OSCHEST

NOTE that this on-study Chest XRay form was joined with the baseline Chest XRay form (page 12) to create the electronic 'oschest' table that you have received.

Part 01:03 MONITORING AND MEDICATION ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No Date: VDATE

CHART1. Chart review suggests infection this calendar day?
-If bacteremia, fill out Bacteremia form
-If septic shock, fill out Septic Shock form
-If specific site of infection identified, fill out infection form for that site.

NEWN2. Do clinicians suspect new nosocomial pneumonia?
If yes, fill out Pneumonia form.

INDICATE 1=YES,2=NO IF ANY OF THE FOLLOWING MEDICATIONS WERE ADMINISTERED THIS CALENDAR DAY

SEDAT 3. Sedative/Tranquilizers (benzodiazepines,narcotics,barbiturates,propofol)

BLOCKER 4. Neuromuscular Blocking Agents

ANTIF 5. Antifungal Imidazole (e.g. Fluconazole)

AMPHO 6. Amphotericin

Part 02:03 MONITORING AND MEDICATION ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

AMINO1 7. Aminoglycosides
If Yes, list antibiotics for this category: AMINO2 AMINO3
1=Gentamicin,2=Tobramycin,3=Amikacin,4=Other Aminoglycosides

CEPH1 8. Cephalosporins
If Yes, list antibiotics for this category: CEPH2 CEPH3
1=Cefazolin,2=Cefotaxime,3=Cefotetan,4=Ceftazidime,5=Ceftriaxone, 6=Cefuroxime,7=Cefepime,8=Other Cephalosporins

MAC1 9. Macrolides
If Yes, list antibiotics for this category: MAC2 MAC3
1=Azithromycin,2=Clarithromycin,3=Clindamycin,4=Erythromycin

PCN1 10. Penicillins
If Yes, list antibiotics for this category: PCN2 PCN3
1=Ampicillin,2=Ampicillin-Subactam,3=Aztreonam,4=Imipenam-Cilistatin,5=Nafcillin,6=Penicillin,7=Piperacillin,8=Ticarcillin, 9=Other Penicillins

Part 03:03 MONITORING AND MEDICATION ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

QUINO1 11. Quinolones
If Yes, list antibiotics for this category: QUINO2 QUINO3
1=Ciprofloxacin, 2=Ofloxacin, 3=Other Quinolones

VANCO 12. Vancomycin

OANT 13. Other Antibiotics

APSYC 14. Antipsychotics (e.g. haloperidol, droperidol)

AVRLS 15. Antivirals

EXPT1 16. Experimental therapies
If yes, list experimental therapies: EXPT2 EXPT3 EXPT4
1=Nitric oxide, 2=Surfactant, 3=Partial Liquid Vent., 4=ECMO, 5=IVOX, 6=HFV or HFO, 7=Prone Positioning, 8=Inhaled PGI or PGE, 9=Intravenous PGI or PGE, 10=Prednisone > 15 mg/d

METH 17. Methylxanthines (e.g. theophylline, pentoxifylline, or aminophylline)

MM

NOTE that this on-study Monitoring and Medications form was joined with the baseline Monitoring and Medications form (page 13-14) to create the electronic 'mm' table that you have received.

Part 01:01 12-LEAD ECG ARDSNET 03 Visit: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date of ECG: ECDT Time of ECG: ECTIME

PERFORM ECG WITHIN ONE HOUR OF STUDY DRUG INFUSION
ON THIS CALENDAR DAY.

Heart Rate: ECHRT bpm

Cardiac Cycle Measurements: P-R Interval: ECPR sec
QRS Interval: ECQRS sec
Q-T Interval: ECQT sec

Interpretation: ECINT
1=Within normal limits
2=Abnormal

ECG

NOTE that this on-study 'ECG' form was joined with the baseline 'ECG' form (page 15) to create the electronic 'ecg' table that you have received.

Part 01:02 DRUG DOSING ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1a. Start time of infusion: START1TM
1b. Dosage: DOSE1 mg
2a. Start time of infusion: START2TM
2b. Dosage: DOSE2 mg
3a. Start time of infusion: START3TM
3b. Dosage: DOSE3 mg
4a. Start time of infusion: START4TM
4b. Dosage: DOSE4 mg
5a. Start time of infusion: START5TM
5b. Dosage: DOSE5 mg

Part 02:02 DRUG DOSING ARDSNET 03 Visit:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

IF A PATIENT DEVELOPS A CREATININE > 2.5 OR BILIRUBIN > 3.0, ADDITIONAL STUDY DRUG LEVELS WILL BE DRAWN PRE- AND POST- STUDY DRUG INFUSION DAILY FOR 3 DAYS AND THEN WEEKLY UNTIL DAY 28 OR HOSPITAL DISCHARGE.

Specimen collection

6. Study drug levels required this calendar day? 1=Yes,2=No: DLEVS

Drug Levels:

7a. Pre-infusion blood draw done? 1=Yes,2=No: PREINFDL
7b. If Yes, give time of blood draw: PRETM
7c. Enter Specimen Bar Code Number: BARCODE1
8a. Post-infusion blood draw done? 1=Yes,2=No: POSTINF1
8b. If Yes, give time of blood draw: POST1TM
8c. Enter Specimen Bar Code Number: BARCODE2
8d. Stop time of infusion: STOP1TM

NOTE: variables 'barcode1' and 'barcode2' were removed from the limited-access dataset to protect patient confidentiality.

DDSL

Page ID: [206] Print Count: [1]

NOTE that this on-study 'DDSL' form was joined with two other 'DDSL' forms (pages 17 and 42) to create the electronic 'ddsl' table that you have received.

Part 01:05 WEANING ARDSNET 03 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

DURING THE SAME CALENDAR DAY Date: VDATE

1. Was the patient permanently withdrawn from the vent arm of the protocol? 1=Yes,2=No: VWDRAW
2. Was the patient permanently withdrawn from the study drug arm of the protocol? 1=Yes,2=No: KWDRAW
   If Yes, fill out Drug Discontinuation and Physical Exam forms.
3. At 0600, was patient on: WEA2N
   1=Volume Assist/Control Ventilation 2=Pressure Support Ventilation
   3=Unassisted Breathing 4=Other:
   WEA2NO

1=Yes,2=No
3=Not tried/Evaluated

4. Did patient meet weaning evaluation criteria? WEA3N
4a. If 4 is Yes, did patient pass 5 minute CPAP trial? WEA4N

Part 02:05 WEANING ARDSNET 03 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

5. Were there attempts to wean PS by 5cmH2O? 1=Yes,2=No: WEA5CM
   If No, why not:
   WEA5TXT

NOTE that variable 'WEA5TXT' is not included in the limited access data, in compliance with non-identifiability requirements.

WEANING HISTORY: Record initial and subsequent Pressure Support levels along with their corresponding starting times each time the Pressure Support level is changed.

Pressure Support Level		Time		Pressure Support Level		Time	
5a.	LEVELA	TIMEA		5b.	LEVELB	TIMEB	
5c.	LEVELC	TIMEC		5d.	LEVELD	TIMED	
5e.	LEVELE	TIMEE		5f.	LEVELF	TIMEF	
5g.	LEVELG	TIMEG		5h.	LEVELH	TIMEH	

Part 03:05 WEANING ARDSNET 03 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

6. Did patient tolerate a trial of spontaneous breathing > 2 hours?
1=Yes,2=No,3=Not tried/Evaluated: WEA6N

7. Did patient complete 48 hours of unassisted breathing on this calendar day?
1=Yes,2=No: WEA7N

For items 9 through 13 enter first recorded value in 4 hr interval ON or AFTER time of ventilator check. If no time appears, skip items 8-15.

Selected Time of ventilator check: VENTCKTM

8. Was patient on assist/control continuously during 4 hrs preceding and 4 hrs following selected ventilator check time? 1=Yes,2=No: ASSIST

9. FiO2: FIO2

10a. Calculated Delivered Tidal Volume: TIDAL ml

10b. Tidal volume increased because of severe dyspnea? 1=Yes,2=No: VOLIN

Part 04:05 WEANING ARDSNET 03 Day:1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

11. PEEP PEEP cm H2O

12. Set Rate: SRATE

13. Pplat Mid: PPLAT cm H2O

For items 14-16 enter last value in the four hour interval PRIOR TO (BUT NOT ON) the randomly selected time for ventilator check. If both SpO2 and PaO2 were available during the four hour interval, enter ONLY the SpO2 or PaO2 (but NOT BOTH) used to set or assess the values of FiO2 or PEEP in items 9 and 11.

14a. pH: PH

14b. If pH available, was set rate changed in the interval between measurement and the time set rate (Item 11) recorded? 1=Yes,2=No: SETCHNG

Part 05:05 WEANING ARDSNET 03 Day: 1

Copy ___:___ Investigator: _____ Patient ID: ___ _____

15a. SpO2(enter corrected SpO2 if adjusted using SaO2): SPO2 %
15b. If SpO2 was used, was FiO2 or PEEP changed in the interval between SpO2 measurement and the time FiO2 or PEEP (Items 9 or 11) recorded? 1=Yes,2=No: FIOCHNG

16a. PaO2: PAO2
16b. If PaO2 was used, was FiO2 or PEEP changed in the interval between PaO2 measurement and the time FiO2 or PEEP (Items 9 or 11) recorded? 1=Yes,2=No: PEECHNG

17. If no pH was available for question 14a, then enter most recent: NOPH

WEAN

Part 01:02 DRUG DOSING/SPECIMEN LOG ARDSNET 03 Visit:3

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

1a. Start time of infusion:	START1TM
1b. Dosage:	DOSE1 mg
2a. Start time of infusion:	START2TM
2b. Dosage:	DOSE2 mg
3a. Start time of infusion:	START3TM
3b. Dosage:	DOSE3 mg
4a. Start time of infusion:	START4TM
4b. Dosage:	DOSE4 mg
5a. Start time of infusion:	START5TM
5b. Dosage:	DOSE5 mg

Part 02:02 DRUG DOSING/SPECIMEN LOG ARDSNET 03 Visit:3

Copy ___:___ Investigator: _____ Patient ID: ___ _____

IF A PATIENT DEVELOPS A CREATININE > 2.5 OR BILIRUBIN > 3.0, ADDITIONAL STUDY DRUG LEVELS WILL BE DRAWN PRE- AND POST- STUDY DRUG INFUSION DAILY FOR 3 DAYS AND THEN WEEKLY UNTIL DAY 28 OR HOSPITAL DISCHARGE.

Drug Levels:

6a. Pre-infusion blood draw done? 1=Yes,2=No: PREINFDL
6b. If Yes, give time of blood draw: PREITM
7a. Post-infusion blood draw done? 1=Yes,2=No: POSTINF1
7b. If Yes, give time: POST1TM
7c. Stop time of infusion: STOP1TM

Surrogate Markers:

8a. Pre-infusion blood draw done? 1=Yes,2=No: PREINFS
8b. If Yes, give time: SURTM
9a. Post-infusion blood draw done? 1=Yes,2=No: POSTINF2
9b. If Yes, give time: POST2TM
9c. Stop time of infusion: STOP2TM

FOR DAY 3 CYTOKINES, SEE SPECIMEN COLLECTION IN ALL MENU

DDSL

NOTE that this on-study 'DDSL' form was joined with two other 'DDSL' forms (pages 17 and 38) to create the electronic 'ddsl' table that you have received.

Part 01:02 BRUSSELS TABLE DAYS 0-14 ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE

	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat-inine	Bili-rubin	Vasopressor 1=Y,2=N
Day 0.5	VDATE 0	SYSBP0	PAFI0	PLATE0	CREAT0	BILI0	VASO0
Day 1	1	1	1	1	1	1	1
Day 2	2	2	2	2	2	2	2
Day 3	3	3	3	3	3	3	3
Day 4	4	4	4	4	4	4	4
Day 5	5	5	5	5	5	5	5
Day 6	6	6	6	6	6	6	6
Day 7	7	7	7	7	7	7	7
Day 8	8	8	8	8	8	8	8
Day 9	9	9	9	9	9	9	9
Day 10	10	10	10	10	10	10	10
Day 11	11	11	11	11	11	11	11
Day 12	12	12	12	12	12	12	12

Part 02:02 BRUSSELS TABLE DAYS 0-14 ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE

	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat-inine	Bili-rubin	Vasopressor 1=Y,2=N
Day 13	VDATE 13	SYSBP13	PAFI13	PLATE13	CREAT13	BILI13	VASO13
Day 14	14	14	14	14	14	14	14

BRUSS

Part 01:01 BRUSSELS TABLE DAYS 15-28 ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

24HR WORST VALUE	Date	Syst BP	PaO2/ FiO2	Platelets X 1000	Creat- inine	Bili- rubin	Vasopressor 1=Y,2=N
Day 15	VDATE0	SYSBP0	PAFI0	PLATE0	CREAT0	BILI0	VASO0
Day 16	1	1	1	1	1	1	1
Day 17	2	2	2	2	2	2	2
Day 18	3	3	3	3	3	3	3
Day 19	4	4	4	4	4	4	4
Day 20	5	5	5	5	5	5	5
Day 21	6	6	6	6	6	6	6
Day 22	7	7	7	7	7	7	7
Day 23	8	8	8	8	8	8	8
Day 24	9	9	9	9	9	9	9
Day 25	10	10	10	10	10	10	10
Day 26	11	11	11	11	11	11	11
Day 27	12	12	12	12	12	12	12
Day 28	13	13	13	13	13	13	13

BRUSS

NOTE: the original production of the data extract tables combined the above variables into: vdate, sysbp, pafi, plate, creat, bili, and vaso, as you can see in the electronic 'bruss' table you have received. No data were altered as a result of this restructuring.

Part 01:02 ADVERSE EVENT REPORT ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1. Date of event: EVDATE 2. Time of event: EVTM Date: VDATE
3. Specified event: SPEVNT
   1=Increased ICP 2=GI Bleed 3=Arrhythmia
   5=Other adverse event 6=Nausea/Vomiting
   Other Specify: OTHER
4. Describe event or problem:
   DESC
5. Severity of event (1=mild, 2=moderate, 3=severe): SEVER
6. Did AE require therapeutic intervention to prevent permanent impairment/damage? (1=Yes, 2=No): THERA

NOTE that variables 'OTHER' and 'DESC' are not included in the limited access dataset, in compliance with non-identifiability requirements.

Part 02:02 ADVERSE EVENT REPORT ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes, 2=No
7. Was the patient in immediate risk of death due to the event? RISKDE
8. Did the patient die as a result of the event? DIE
9. Was the event unexpected in ARDS or more severe or frequent than expected in ARDS? (1=yes, 2=no, 3=unknown): EXPECT
10. Causal relationship to study drug: CAUSAL
    1=definitely associated 2=probably associated
    3=possible association 4=probably not associated
    5=definitely not associated 6=uncertain association
11. Was study drug discontinued as a result of this event? DISC
12. Was patient withdrawn from the ventilator because of event? WDRAW
13. Outcome to date: OUTCOME
    1=recovered - date: RECDT 2=AE present, no treatment
    3=AE present/being treated 4=residual effect/no treatment
    5=residual effect/being treated 6=deceased

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NOTE that the electronic database 'AER' also contains the following variables: system1, system2, failure, and msof. Please refer to the Summary of Changes document (01-03_changes.pdf) for a description of these variables.

Part 01:01 SPECIMEN COLLECTION ARDSNET 03 Day: ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

Date: VDATE

	1=Yes,2=No	Date
Day 0		
Blood for cytokine	BLOOD1	BLDT1
Day 1		
Blood for cytokine	BLOOD2	BLDT2
Day 3		
Blood for cytokine	BLOOD3	BLDT3

SPEC

Part 01:02 BACTEREMIA ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

ENTER ALL POSITIVE BLOOD CULTURES. IF PRIMARY SITE OF BACTEREMIA IDENTIFIED(e.g. Pneumonia), FILL OUT INFECTION FOR FOR THAT SITE. IF SEPTIC SHOCK DEVELOPS, FILL OUT SEPTIC SHOCK FORM.

	Date	Time	Organism		Date	Time	Organism
1.	BACT1	BTIME1	BORGN1	2.	BACT2	BTIME2	BORGN2
3.	BACT3	BTIME3	BORGN3	4.	BACT4	BTIME4	BORGN4
5.	BACT5	BTIME5	BORGN5	6.	BACT6	BTIME6	BORGN6
7.	BACT7	BTIME7	BORGN7	8.	BACT8	BTIME8	BORGN8
9.	BACT9	BTIME9	BORGN9	10.	BACT10	BTIME10	BORGN10

Organism:
1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B.cattarhalis,10=Other Gram Negative cocci, 11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus,17=Other Virus

Part 02:02 BACTEREMIA ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

ENTER ALL POSITIVE BLOOD CULTURES. IF PRIMARY SITE OF BACTEREMIA IDENTIFIED(e.g. Pneumonia), FILL OUT INFECTION FOR FOR THAT SITE. IF SEPTIC SHOCK DEVELOPS, FILL OUT SEPTIC SHOCK FORM.

	Date	Time	Organism		Date	Time	Organism
11.	BACT11	BTIME11	BORGN11	12.	BACT12	BTIME12	BORGN12
13.	BACT13	BTIME13	BORGN13	14.	BACT14	BTIME14	BORGN14
15.	BACT15	BTIME15	BORGN15	16.	BACT16	BTIME16	BORGN16
17.	BACT17	BTIME17	BORGN17	18.	BACT18	BTIME18	BORGN18
19.	BACT19	BTIME19	BORGN19	20.	BACT20	BTIME20	BORGN20

Organism:
1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B.cattarhalis,10=Other Gram Negative cocci, 11=Candida Species,12=Torulopsis Species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus,17=Other Virus

BACTR

Page ID: [3005] Print Count: [1]

NOTE: the original production of the data extract tables combined the above variables into: bact, btime, and borgn, as you can see in the electronic 'bactr' table you have received. No data were altered as a result of this restructuring.

Part 01:02 SEPTIC SHOCK ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes,2=No FILL OUT THIS FORM FOR EACH EPISODE OF SEPTIC SHOCK.

SEPTIC1 1a. Were 2 or more of the following SIRS criteria present?
-temperature > 38C or < 36C OR:
-heart rate > 90 beats/min OR:
-respiratory rate > 20 breaths/min or PaCo2 < 32mmHg (if on unassisted breathing) OR:
-WBC > 12,000 or <4000 or >10% immature (bands)

1b. If Yes, date of SIRS onset: SEPTIC2

One or more of the following shock criteria (2a-2c) must be present for >= 2 consecutive hours despite fluid resuscitation to meet shock criteria. Select all that apply:

SEPTIC3 2a. Systolic BP < 90 mmHg?

SEPTIC4 2b. Reduction > = 40 mmHG from baseline?

SEPTIC5 2c. Pressor requirement to maintain BP?

2d. Date first shock criteria met: SEPTIC6

Part 02:02 SEPTIC SHOCK ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

SEPTIC7 3. Primary site of infection identified?
If Yes, list site: SEPTIC8
1=Pneumonia,2=Peritonitis,3=Wound infection,4=Meningitis, 5=Empyema,6=Biliary tract,7=Abdominal abscess,8=C. difficile colitis,9=Urinary tract,10=Vascular line,11=Peritonitis on dialysis,12=Sinusitis,13=Skin infection,14=Septic arthritis, 15=Other

SEPTIC9 4a. Did shock resolve?
-Systolic BP >= 90mmHg AND off pressors for 1 calendar day. SBP may transiently (<= 2 consecutive hours) fall below 90mmHg or pressors may be used transiently (<= 2 consecutive hours) on this calendar day.

4b. If yes, date of resolution: SEPTIC10

Part 01:01 PNEUMONIA ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1. Date of diagnosis: PNEUM1

Within a 48hr period did the patient have: (1=Yes,2=No)

2a. Chest radiograph shows new infiltrate persisted for 48 hrs? PNEUM9

2b. New fever or hypothermia or leukocytosis or leukopenia? PNEUM2

3. Was an endotracheal aspirate sent for gram stain(1=Yes,2=No)? PNEUM3

4. Was an endotracheal aspirate sent for culture(1=Yes,2=No)? PNEUM4

5. Was there bacteriological confirmation of this episode of suspected pneumonia(1=Yes,2=No)? PNEUM5

5b. Organism 1: PNEUM6 5c. Organism 2: PNEUM7 5d. Organism 3: PNEUM8

1=Staph aureus,2=Staph epidermidis,3=Strep pneumoniae,4=Enterococcus, 5=Other Gram Positive,6=Pseudomonas Species,7=Hemophilus influenza, 8=Other Gram Negative rod,9=B.cattarhalis,10=Other Gram Negative cocci, 11=Candida Species,12=Torulopsis species,13=Aspergillus Species, 14=Varicella Zoster,15=Herpes Simplex,16=Cytomegalovirus,17=Other Virus

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).

PNEUM

Part 01:01 FUNGAL INFECTION ARDSNET 03 Visit:ALL

Copy ___:___ Investigator: _____ Patient ID: ___ _____

1=Yes, 2=No

FUNGL1 1a. Blood culture positive for yeast infection?
1b. If Yes, date: FUNGL2
FUNGL3 2a. Evidence of deep tissue infection (endopthalmitis, hepatic/splenic abscesses/cutaneous emboli with fungal elements)?
2b. If Yes, date of diagnosis: FUNGL4
FUNGL5 3a. Unexplained fever with 3 sites of colonization?
3b. If Yes, date of diagnosis: FUNGL6
FUNGL7 4a. Oral or mucosal candiasis?
4b. If Yes, date of diagnosis: FUNGL8
FUNGL9 5. Organism: 1=Candida species, 2=Torulopsis species, 3=Aspergillus species, 4=Other

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).

AFI