Dexamethasone Annotated CRF

Table of Contents

Comprehensive Sickle Cell Centers	**Inclusion Criteria**	**Screening/Baseline** **Page: 01**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

For the subject to be considered eligible for this study, Questions 1 through 6 must be answered Yes.

1. Is the subject ⩾ 5 years of age at the time of consent? ☐ (INCL:INCL1) Yes ☐ (INCL:INCL1) No

2. Has there been a confirmed diagnosis of either sickle cell anemia (Hgb SS) or sickle-β°-thalassemia (Hgb Sβ°)? ☐ (INCL:INCL2) Yes ☐ (INCL:INCL2) No

3. Is the subject currently experiencing ACS defined as a new lobar or segmental pulmonary infiltrate seen on a chest radiograph **and** two or more of the following findings in the 24 hours preceding enrollment (signing consent)? ☐ (INCL:INCL3) Yes ☐ (INCL:INCL3) No

   Which of these symptoms is the subject experiencing in the 24 hours preceding enrollment?

   ☐ **If Inclusion Criteria #3 = Yes,** at least two symptoms must be checked below.

   (Check all that apply)
   - ☐ (INCL:INCL3A) Temperature ⩾ 38.5°C
   - ☐ (INCL:INCL3B) Tachypnea
   - ☐ (INCL:INCL3C) Dyspnea or increased work of breathing
   - ☐ (INCL:INCL3D) Chest wall pain
   - ☐ (INCL:INCL3E) Oxygen saturation of < 90% in room air by pulse oximetry

4. Is the subject experiencing one or more of these findings at the time of enrollment? ☐ (INCL:INCL4NW) Yes ☐ (INCL:INCL4NW) No

   Which of these symptoms is the subject experiencing at the time of enrollment?

   ☐ **If Inclusion Criteria #4 = Yes,** at least one symptom must be checked below.

   (Check all that apply)
   - ☐ (INCL:INCL4A) Temperature ⩾ 38.5°C
   - ☐ (INCL:INCL4B) Tachypnea
   - ☐ (INCL:INCL4C) Dyspnea or increased work of breathing
   - ☐ (INCL:INCL4D) Chest wall pain
   - ☐ (INCL:INCL4E) Oxygen saturation of < 90% in room air by pulse oximetry

5. Is the subject currently experiencing an episode of ACS that was diagnosed within the preceding 24 hours? ☐ (INCL:INCL4) Yes ☐ (INCL:INCL4) No

6. Is the subject able to take medication in capsule form? ☐ (INCL:INCL5) Yes ☐ (INCL:INCL5) No

7. Was written, informed consent provided by the subject and/or parents or guardians before study entry? ☐ (INCL:INCL6) Yes ☐ (INCL:INCL6) No

Date of informed consent: INCL:INFODA / INCL:INFOMO / INCL:INFOYR

DD MMM YYYY

Comments for page:

INCL:COMMENT

Submit Query Cancel Form Completion Help Print

For the subject to be considered eligible for this study, Questions 1 through 11 must be answered No. Question 8 may be N/A.

1.	Has the subject previously participated in this study?	☐ (EXCL:EXCL1)	Yes	☐ (EXCL:EXCL1)	No	
2.	Does the subject have a condition that will likely be exacerbated by corticosteroid therapy, including diabetes mellitus, hypertension, esophageal or gastrointestinal ulceration or bleeding, or known avascular necrosis?	☐ (EXCL:EXCL2)	Yes	☐ (EXCL:EXCL2)	No	
3.	Has the subject been diagnosed with ACS in the 6 months preceding enrollment?	☐ (EXCL:EXCL3)	Yes	☐ (EXCL:EXCL3)	No	
4.	Has the subject been treated with oral or parenteral corticosteroid therapy for any reason within the preceding 14 days?	☐ (EXCL:EXCL4)	Yes	☐ (EXCL:EXCL4)	No	
5.	Has the subject used inhaled corticosteroids or systemic corticosteroids for respiratory illness in the preceding 3 months?	☐ (EXCL:EXCL5)	Yes	☐ (EXCL:EXCL5)	No	
6.	Does the subject have a chronic pulmonary condition that requires treatment with corticosteroids?	☐ (EXCL:EXCL6)	Yes	☐ (EXCL:EXCL6)	No	
7.	Is the subject currently participating in a chronic transfusion program (for the purposes of this study, "current participation" is defined as having received the last transfusion within the 4 months preceding study entry and "chronic transfusion program" is defined as a regimen of serial simple or exchange transfusions given at least every 6 weeks for at least 3 consecutive transfusions for the prevention of SCD-related complications)?	☐ (EXCL:EXCL7)	Yes	☐ (EXCL:EXCL7)	No	
8.	Is the subject pregnant?	☐ (EXCL:EXCL8)	Yes	☐ (EXCL:EXCL8)	No	☐ (EXCL:EXCL8) N/A
9.	Has the subject been treated with any investigational drug in the preceding 90 days?	☐ (EXCL:EXCL9)	Yes	☐ (EXCL:EXCL9)	No	

10. Does the subject have either a history of tuberculosis or a positive skin test for tuberculosis?	☐ (EXCL:EXCL10) Yes	☐ (EXCL:EXCL10) No
11. Is the subject known to be infected with HIV or does the subject have a known current systemic fungal infection?	☐ (EXCL:EXCL11) Yes	☐ (EXCL:EXCL11) No

Comments for page:

EXCL:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Demographics/Study Entry Health History**	**Screening/Baseline** **Page: 03**
Dexamethasone for ACS	Date of assessment: DEMO:ASSDA / DEMO:ASSMO / DEMO:ASSYR (DD / MMM / YYYY)	CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Date of Birth: DEMO:DOBDA / DEMO:DOBMO / DEMO:DOBYR (DD / MMM / YYYY) **Gender:** ☐ (DEMO:GENDER) Male ☐ (DEMO:GENDER) Female

Ethnicity:
☐ (DEMO:ETHNIC) Hispanic or Latino
☐ (DEMO:ETHNIC) Not Hispanic or Latino

Race: *(check all that apply)*
☐ (DEMO:RACE1) American Indian/Alaska Native
☐ (DEMO:RACE2) Asian
☐ (DEMO:RACE3) Black or African-American
☐ (DEMO:RACE4) Native Hawaiian or other Pacific Islander
☐ (DEMO:RACE5) White
☐ (DEMO:RACE6) Other, specify: DEMO:OTHSP

Genotype: ☐ (DEMO:GENOTYP) SS ☐ (DEMO:GENOTYP) Sβo

Date of Study Enrollment: DEMO:ENROLDA / DEMO:ENROLMO / DEMO:ENROLYR (DD / MMM / YYYY) **Time of Study Enrollment*:** DEMO:ENROLHR : DEMO:ENROLMI (24-hour clock) (Hour / Min)

** Study enrollment is defined as the time that informed consent is signed.*

Severity of ACS:
☐ (DEMO:SEVERE) Mild-moderate
☐ (DEMO:SEVERE) Severe

Was a screening/baseline/diagnostic chest radiograph taken per protocol within 24 hours? *(record information on Chest Radiograph form)* ☐ (DEMO:CHESTYN) Yes ☐ (DEMO:CHESTYN) No

Date of Randomization: DEMO:RANDDA / DEMO:RANDMO / DEMO:RANDYR (DD / MMM / YYYY) **Time of Randomization:** DEMO:RANDHR : DEMO:RANDMI (24-hour clock) (Hour / Min)

Randomization #: DEMO:RANDNUM

Weight (kg): DEMO:WEIGHT **Blood Pressure at Enrollment (mm Hg):** DEMO:SYS / DEMO:DIA (Systolic / Diastolic)

How many lifetime episodes, not counting a current episode, of ACS has the patient experienced (best estimate of number)? DEMO:ACS OR ☐ (DEMO:ACSUK) Unknown

Has the patient ever been diagnosed with asthma? ☐ (DEMO:ASTHMA) Yes ☐ (DEMO:ASTHMA) No ☐ (DEMO:ASTHMA) Unknown

Is the subject using supplemental O_2 at study entry? ☐ (DEMO:SUPO2) Yes ☐ (DEMO:SUPO2) No

If Yes, date and time started:

DEMO:SUPO2DA	/	DEMO:SUPO2MO	/	DEMO:SUPO2YR		DEMO:SUPO2HR	:	DEMO:SUPO2MI
DD		MMM		YYYY		Hour		Min

If Yes, O_2 saturation: DEMO:YESO2 %

Did the subject have a fever ≥ 38.5°C at study entry? ☐ (DEMO:FEVER) Yes ☐ (DEMO:FEVER) No

If Yes, date and time started:

DEMO:FEVERDA	/	DEMO:FEVERMO	/	DEMO:FEVERYR		DEMO:FEVERHR	:	DEMO:FEVERMI
DD		MMM		YYYY		Hour		Min

If Yes, temperature at study entry (°C): DEMO:TEMP

Is the subject hypoxemic (O_2 saturation < 92% in room air) at study entry? ☐ (DEMO:HYPOX) Yes ☐ (DEMO:HYPOX) No

If Yes, date and time started:

DEMO:HYPOXDA	/	DEMO:HYPOXMO	/	DEMO:HYPOXYR		DEMO:HYPOXHR	:	DEMO:HYPOXMI
DD		MMM		YYYY		Hour		Min

What is the subject's steady-state value*? DEMO:NOVALUE %

*If steady-state value is not known, enter 92%.

Comments for page:

DEMO:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Pregnancy Test**	Screening/Baseline Page: 04
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Pregnancy Test

☐ (PREG:PREGND) Not done (check reason below)

- ☐ (PREG:REASON) Subject male
- ☐ (PREG:REASON) Subject is too young (not sexually mature)
- ☐ (PREG:REASON) Postmenopausal
- ☐ (PREG:REASON) Hysterectomy
- ☐ (PREG:REASON) Tubal ligation
- ☐ (PREG:REASON) Other, specify: PREG:RSNOTS

Date of Collection: PREG:COLLDA / PREG:COLLMO / PREG:COLLYR
DD MMM YYYY

Type: ☐ (PREG:TYPE)Serum ☐ (PREG:TYPE)Urine

Result: ☐ (PREG:RESULT)Positive ☐ (PREG:RESULT)Negative

Comments for page:
PREG:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**ACS Assessment**	Screening/Baseline Page: 05
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form immediately prior to first dose of study drug.

Date of Assessment: ACSA:ASSDA (DD) / ACSA:ASSMO (MMM) / ACSA:ASSYR (YYYY) **Time of Assessment:** ACSA:ASSHR (Hour) : ACSA:ASSMI (Min) (24-hour clock)

Element of Index **Value**

1. Respiratory Rate

A. Current Rate (breaths per minute): ACSA:RESPRAT

2. Work of breathing

A. Retractions	☐ (ACSA:RETRAC) Yes	☐ (ACSA:RETRAC) No
B. Nasal flaring	☐ (ACSA:NASAL) Yes	☐ (ACSA:NASAL) No
C. Use of accessory muscles	☐ (ACSA:MUSC) Yes	☐ (ACSA:MUSC) No

3. Pain

A. Current thoracic pain scale[2] ACSA:THORAC

B. Non-thoracic body pain ACSA:OVERALL

Pain scale: ☐ (ACSA:SCALE) Oucher Scale ☐ (ACSA:SCALE) Numeric Rating Scale

Location of pain: (check all that apply)
☐ (ACSA:PAIN1) Lower Back ☐ (ACSA:PAIN2) Upper Extremities ☐ (ACSA:PAIN3) Head & Neck
☐ (ACSA:PAIN4) Abdomen ☐ (ACSA:PAIN5) Lower Extremities

4. SpO_2 (off oxygen = 1 minute)[1]

A. Current Value (%):
(in room air)

ACSA:SPO2VAL **or** ☐ (ACSA:SPO2NA) N/A

5. Medical intervention

A. Supplemental O_2 ☐ (ACSA:SUPO2) Yes ☐ (ACSA:SUPO2) No

B. Invasive or noninvasive ventilatory support ☐ (ACSA:VENTSUP) Yes ☐ (ACSA:VENTSUP) No

[1] If subject is ventilated or if it is deemed unsafe to trial subject off O_2, check 'N/A' for "Current Value (%)".

[2] Enter value of 10 point numeric rating scale or the Oucher.

Comments for page:

ACSA:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Hematology Labs**	Screening/Baseline Page: 06
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Collection Date: HEMA:COLLDA / HEMA:COLLMO / HEMA:COLLYR (DD / MMM / YYYY)

Collection Time: HEMA:COLLHR : HEMA:COLLMI (24-hour clock) (Hour / Min)

☐ Labs not done (provide a comment) (HEMA:NOTDO)

Test	Value
WBC ($x10^3/mm^3$)	HEMA:WBC
RBC ($x10^6/mm^3$)	HEMA:RBC
HGB (g/dL)	HEMA:HGB
HCT (%)	HEMA:HCT
MCV (fL)	HEMA:MCV
Platelets ($x10^3/mm^3$)	HEMA:PLATE
Abs. reticulocyte count ($x10^3/mm^3$)	HEMA:ABRETIC
OR % Reticulocyte	HEMA:RETICPT

Comments for page:

HEMA:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**ACS Assessment**	Hospitalization Page: 07
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form **every 4 hours and at Hospital Discharge even if the assessment is missed**. Do **not** add the discharge assessment unless the subject is discharged.

Hospitalization day number: ACSD:DAYNUM (Key the leading "0".)

HOUR ACSD:HOUR

Date of Assessment: ACSD:ASSDA / ACSD:ASSMO / ACSD:ASSYR (DD / MMM / YYYY) **Time of Assessment:** ACSD:ASSHR : ACSD:ASSMI (24-hour clock) (Hour / Min)

Check one of the following to indicate if and when this assessment was completed: ☐ (ACSD:COMPLET) Assessment missed[1] ☐ (ACSD:COMPLET) on schedule ☐ (ACSD:COMPLET) > 30 minutes early ☐ (ACSD:COMPLET) > 30 minutes late

Element of Index	Value
1. Respiratory Rate	
A. Current Rate (breaths per minute):	ACSD:RESPRAT
2. Work of breathing	
A. Retractions	☐ (ACSD:RETRAC) Yes ☐ (ACSD:RETRAC) No
B. Nasal flaring	☐ (ACSD:NASAL) Yes ☐ (ACSD:NASAL) No
C. Use of accessory muscles	☐ (ACSD:MUSC) Yes ☐ (ACSD:MUSC) No
3. Pain	
A. Current thoracic pain scale[3]	ACSD:THORAC
B. Non-thoracic body pain	ACSD:OVERALL

Pain scale: ☐ (ACSD:SCALE) Oucher Scale ☐ (ACSD:SCALE) Numeric Rating Scale

Location Lower Upper Head

of pain: (check all that apply)

☐ (ACSD:PAIN1) Back ☐ (ACSD:PAIN2) Extremities ☐ (ACSD:PAIN3) & Neck

☐ (ACSD:PAIN4) Abdomen ☐ (ACSD:PAIN5) Lower Extremities

4. SpO_2 (off oxygen = 1 minute)[1]

A. Current Value (%): (in room air) ACSD:SPO2VAL **or** ☐ (ACSD:SPO2NA) N/A

5. Medical intervention

A. Supplemental O_2 ☐ (ACSD:SUPO2) Yes ☐ (ACSD:SUPO2) No

B. Invasive or noninvasive ventilatory support ☐ (ACSD:VENTSUP) Yes ☐ (ACSD:VENTSUP) No

[1] Provide a comment to explain why the assessment was missed.

[2] If subject is ventilated or if it is deemed unsafe to trial subject off O_2, check 'N/A' for "Current Value (%)".

[3] Enter value of 10 point numeric rating scale or the Oucher.

Comments for page:

ACSD:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Hematology Labs**	**Hospitalization** **Page: 08**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form once per day while the subject is admitted in the hospital.

Hospitalization day number: HEMD:DAYNUM (Key the leading "0".)

Collection Date: HEMD:COLLDA / HEMD:COLLMO / HEMD:COLLYR (DD / MMM / YYYY)

Collection Time: HEMD:COLLHR : HEMD:COLLMI (24-hour clock) (Hour : Min)

☐ Labs not done (provide a comment) (HEMD:NOTDO)

Test	Value
WBC ($x10^3/mm^3$)	HEMD:WBC
RBC ($x10^6/mm^3$)	HEMD:RBC
HGB (g/dL)	HEMD:HGB
HCT (%)	HEMD:HCT
MCV (fL)	HEMD:MCV
Platelets ($x10^3/mm^3$)	HEMD:PLATE
Abs. reticulocyte count ($x10^3/mm^3$)	HEMD:ABRETIC
OR % Reticulocyte	HEMD:RETICPT

Comments for page:

HEMD:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Daily Assessments**	**Hospitalization** **Page: 09**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form once per day while the subject is admitted in the hospital.

Hospitalization day number: DASS:DAYNUM (Key the leading "0".)

Date of assessment: DASS:ASSDA / DASS:ASSMO / DASS:ASSYR
DD MMM YYYY

Vitals and Pulse Oximetry

Maximum Temperature (°C) DASS:TEMP

Maximum Heart Rate (BPM) DASS:RATE

Maximum Respiration Rate (RR) DASS:RESP

Maximum Systolic Blood Pressure (mm Hg)
with corresponding diastolic
DASS:SYS1 (Systolic) / DASS:DIA1 (Diastolic)

Maximum Diastolic Blood Pressure (mm Hg)
with corresponding systolic
DASS:SYS2 (Systolic) / DASS:DIA2 (Diastolic)

Minimum O_2 Saturation (SpO_2)
(in room air)
DASS:O2SAT %

Per protocol, hypertension indicated by the following results should be reported as Adverse Events:

- A single blood pressure in which the systolic pressure is ≥ 140 mmHg ***and*** the diastolic pressure is ≥ 90 mmHg;
- A systolic pressure ≥ 140 mmHg on 2 more occasions in a rolling 24 hour period regardless of diastolic pressure;
- A diastolic pressure ≥ 90 mmHg on 2 more occasions in a rolling 24 hour period regardless of systolic pressure.

Does the subject have new onset hypertension (per protocol)? ☐ (DASS:HYPER) Yes ☐ (DASS:HYPER) No

If Yes, enter this on AE form.

If Yes, what is the suspected reason?

☐ (DASS:REASON) Crying or irritated
☐ (DASS:REASON) Severe pain
☐ (DASS:REASON) Fluid overload
☐ (DASS:REASON) Unknown
☐ (DASS:REASON) Other, specify DASS:OTHSP

If Yes, did this require treatment? ☐ (DASS:TREAT) Yes ☐ (DASS:TREAT) No

Does the subject have fluid overload? ☐ (DASS:FLUID) Yes ☐ (DASS:FLUID) No

Did the subject receive any blood transfusions in this 24 hour period? ☐ (DASS:TRAN) Yes ☐ (DASS:TRAN) No

If Yes, which type (mark all that apply)? ☐ (DASS:TRANTYP) Simple ☐ (DASS:TRANTYP) Exchange

If Simple is marked, how many simple transfusions? DASS:NUMSIMP

Did the subject start using supplemental O_2 in this 24 hour period? ☐ (DASS:SUPO2) Yes ☐ (DASS:SUPO2) No

If Yes, time started: DASS:SUPO2HR (Hour) : DASS:SUPO2MI (Min)

Did the subject start a fever ≥ 38.5°C in this 24 hour period? ☐ (DASS:FEVER) Yes ☐ (DASS:FEVER) No

If Yes, time started: DASS:FEVERHR (Hour) : DASS:FEVERMI (Min)

Did the subject become hypoxemic (O_2 saturation < 92% in room air) in this 24 hour period? ☐ (DASS:HYPOX) Yes ☐ (DASS:HYPOX) No

If Yes, time started: DASS:HYPOXHR (Hour) : DASS:HYPOXMI (Min)

Comments for page:

DASS:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Hospital Discharge**	**Discharge** **Page: 10**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form **at hospital discharge**.

Date of Discharge: HDIS:DISCDA / HDIS:DISCMO / HDIS:DISCYR (DD / MMM / YYYY) **Time of Discharge:** HDIS:DISCHR : HDIS:DISCMI (24-hour clock) (Hour : Min)

Is the subject using supplemental O_2 at hospital discharge? ☐ (HDIS:SUPO2) Yes ☐ (HDIS:SUPO2) No

If No, date and time that supplemental O_2 was discontinued: HDIS:SUPO2DA / HDIS:SUPO2MO / HDIS:SUPO2YR (DD / MMM / YYYY) HDIS:SUPO2HR : HDIS:SUPO2MI (Hour : Min)

OR ☐ (HDIS:NOSUPO2) Subject did not use supplemental O_2 between study enrollment and hospital discharge

Does the subject have a temperature = 38.5 °C at hospital discharge? ☐ (HDIS:FEVER) Yes ☐ (HDIS:FEVER) No

If No, date and time that fever stopped: HDIS:FEVERDA / HDIS:FEVERMO / HDIS:FEVERYR (DD / MMM / YYYY) HDIS:FEVERHR : HDIS:FEVERMI (Hour : Min)

OR ☐ (HDIS:NOFEVER) Subject did not have a fever between study enrollment and hospital discharge

Reminder: Be sure to also complete the ACS Assessment at Hospital Discharge.

Comments for page:

HDIS:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Complete this form at the **first follow-up visit,** if the subject was discharged from the hospital.

Was the assessment completed? ☐ (ACF1:COMPLET) Yes ☐ (ACF1:COMPLET) No

If No, indicate the reason (check one):

☐ (ACF1:REASON) Subject is still an in-patient at the hospital
☐ (ACF1:REASON) Subject or parent/guardian decision
☐ (ACF1:REASON) Serious Adverse Event
☐ (ACF1:REASON) Other, specify ACF1:OTHSP

Date of Assessment: ACF1:ASSDA / ACF1:ASSMO / ACF1:ASSYR (DD / MMM / YYYY)

Time of Assessment: ACF1:ASSHR : ACF1:ASSMI (24-hour clock) (Hour : Min)

Element of Index	Value
1. Respiratory Rate	
A. Current Rate (breaths per minute):	ACF1:RESPRAT
2. Work of breathing	
A. Retractions	☐ (ACF1:RETRAC) Yes ☐ (ACF1:RETRAC) No
B. Nasal flaring	☐ (ACF1:NASAL) Yes ☐ (ACF1:NASAL) No
C. Use of accessory muscles	☐ (ACF1:MUSC) Yes ☐ (ACF1:MUSC) No
3. Pain	
A. Current thoracic pain scale[2]	ACF1:THORAC
B. Non-thoracic body pain	ACF1:OVERALL

Pain scale: ☐ (ACF1:SCALE) Oucher Scale ☐ (ACF1:SCALE) Numeric Rating Scale

Location: Lower Upper Head &

of pain: (check all that apply)

☐ (ACF1:PAIN1) Back ☐ (ACF1:PAIN2) Extremities ☐ (ACF1:PAIN3) Neck

☐ (ACF1:PAIN4) Abdomen ☐ (ACF1:PAIN5) Lower Extremities

4. SpO_2 (off oxygen = 1 minute)[1]

A. Current Value (%): (in room air) ACF1:SPO2VAL **or** ☐ (ACF1:SPO2NA) N/A

5. Medical intervention

A. Supplemental O_2 ☐ (ACF1:SUPO2) Yes ☐ (ACF1:SUPO2) No

B. Invasive or noninvasive ventilatory support ☐ (ACF1:VENTSUP) Yes ☐ (ACF1:VENTSUP) No

[1] If subject is ventilated or if it is deemed unsafe to trial subject off O_2, check 'N/A' for "Current Value (%)".

[2] Enter value of 10 point numeric rating scale or the Oucher.

Comments for page:

ACF1:COMMENT

Submit Query Cancel Form Completion Help Print

Complete this form at the **first follow-up visit,** if the subject was discharged from the hospital.

Was the assessment completed? ☐ (VTL1:COMPLET) Yes ☐ (VTL1:COMPLET) No

If No, indicate the reason **(check one):**

☐ (VTL1:REASON) Subject is still an in-patient at the hospital
☐ (VTL1:REASON) Lost to follow-up
☐ (VTL1:REASON) Serious Adverse Event
☐ (VTL1:REASON) Other, specify VTL1:OTHSP
☐ (VTL1:REASON) Subject or parent/guardian decision

Date of Assessment: VTL1:ASSDA / VTL1:ASSMO / VTL1:ASSYR (DD / MMM / YYYY)

Time of Assessment: VTL1:ASSHR : VTL1:ASSMI (24-hour clock) (Hour : Min)

Vitals

Temperature (°C) VTL1:TEMP

Heart Rate (BPM) VTL1:RATE

Respirations (RR) VTL1:RESP

Blood Pressure (mm Hg) VTL1:SYS (Systolic) / VTL1:DIA (Diastolic)

Per protocol, hypertension indicated by the following results should be reported as Adverse Events:

- A single blood pressure in which the systolic pressure is ≥ 140 mmHg ***and*** the diastolic pressure is ≥ 90 mmHg;
- A systolic pressure ≥ 140 mmHg on 2 more occasions in a rolling 24 hour period regardless of diastolic pressure;
- A diastolic pressure ≥ 90 mmHg on 2 more occasions in a rolling 24 hour period regardless of systolic pressure.

Does the subject have new onset hypertension (per protocol)? ☐ (VTL1:HYPER) Yes ☐ (VTL1:HYPER) No

If Yes, enter this on AE form.

If Yes, what is the suspected reason?

- ☐ (VTL1:REASON2) Crying or irritated
- ☐ (VTL1:REASON2) Severe pain
- ☐ (VTL1:REASON2) Fluid overload
- ☐ (VTL1:REASON2) Unknown
- ☐ (VTL1:REASON2) Other, specify VTL1:OTHSP2

If Yes, did this require treatment? ☐ (VTL1:TREAT) Yes ☐ (VTL1:TREAT) No

Reminder: Do not forget to enter data on the Study Drug Home Record.

Comments for page:

VTL1:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Complete this form at the **first follow-up visit.** All questions relate to events that have occurred **since hospital discharge.**

Was the assessment completed? ☐ (FLU1:COMPLET) Yes ☐ (FLU1:COMPLET) No

If No, indicate the reason (check one):

☐ (FLU1:REASON) Subject is still an in-patient at the hospital

☐ (FLU1:REASON) Lost to follow-up

☐ (FLU1:REASON) Serious Adverse Event

☐ (FLU1:REASON) Other, specify FLU1:OTHSP

☐ (FLU1:REASON) Subject or parent/guardian decision

Has the subject experienced:

1. Acute Painful Episode? ☐ (FLU1:PAIN) Yes ☐ (FLU1:PAIN) No

If Yes, record number of events below. Record only the **final** location if a single pain crises was treated at multiple locations.

Since discharge, how many pain crises:

1. Were treated at home? FLU1:HOME *(enter 0 for none)*
2. Were treated in a clinic or doctor's office, not hospital? FLU1:CLINIC *(enter 0 for none)*

2. Hospitalization? ☐ (FLU1:HSPVST) Yes ☐ (FLU1:HSPVST) No

If Yes, press the "Add Event " button to record details for each hospitalization.

Delete Event

Primary Reason: HOSP:REASON1

Other, specify: HOSP:REAS1S

Date admitted: HOSP:ADMITDA (DD) / HOSP:ADMITMO (MMM) / HOSP:ADMITYR (YYYY)

Secondary Reason: HOSP:REASON2

Other, specify: HOSP:REAS2S

Date discharged: HOSP:DISCDA (DD) / HOSP:DISCMO (MMM) / HOSP:DISCYR (YYYY)

Add Event

3. Emergency Room Visit Not Resulting in Hospitalization? ☐ (FLU1:ERVISIT) Yes ☐ (FLU1:ERVISIT) No

If Yes, press the "Add Event " button to record details for each emergency room visit.

Delete Event

Primary Reason: EMER:EREASN1

Other, specify: EMER:ERV1S

Date admitted: EMER:ERVADDA / EMER:ERVADMO / EMER:ERVADYR
DD MMM YYYY

Secondary Reason: EMER:EREASN2

Other, specify: EMER:ERV2S

Date discharged: EMER:ERVDSDA / EMER:ERVDSMO / EMER:ERVDSYR
DD MMM YYYY

Add Event

Comments for page:
FLU1:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Complete this form at the **first follow-up visit.**

Was the assessment completed? ☐ (HEM1:COMPLET) Yes ☐ (HEM1:COMPLET) No

If No, indicate the reason (check one):

☐ (HEM1:REASON) Subject is still an in-patient at the hospital

☐ (HEM1:REASON) Lost to follow-up

☐ (HEM1:REASON) Serious Adverse Event

☐ (HEM1:REASON) Other, specify HEM1:OTHSP

☐ (HEM1:REASON) Subject or parent/guardian decision

Collection Date: HEM1:COLLDA / HEM1:COLLMO / HEM1:COLLYR (DD / MMM / YYYY)

Collection Time: HEM1:COLLHR : HEM1:COLLMI (24-hour clock) (Hour / Min)

Test	Value
WBC ($x10^3/mm^3$)	HEM1:WBC
RBC ($x10^6/mm^3$)	HEM1:RBC
HGB (g/dL)	HEM1:HGB
HCT (%)	HEM1:HCT
MCV (fL)	HEM1:MCV
Platelets ($x10^3/mm^3$)	HEM1:PLATE
Abs. reticulocyte count ($x10^3/mm^3$)	HEM1:ABRETIC
OR % Reticulocyte	HEM1:RETICPT

Comments for page:

HEM1:COMMENT

Complete this form at the **second follow-up visit.**

Was the assessment completed? ☐ (ACF2:COMPLET) Yes ☐ (ACF2:COMPLET) No

If No, indicate the reason (check one):

☐ (ACF2:REASON) Subject was readmitted to the hospital
☐ (ACF2:REASON) Lost to follow-up
☐ (ACF2:REASON) Serious Adverse Event
☐ (ACF2:REASON) Other, specify ACF2:OTHSP
☐ (ACF2:REASON) Subject or parent/guardian decision

Date of Assessment: ACF2:ASSDA / ACF2:ASSMO / ACF2:ASSYR (DD / MMM / YYYY)

Time of Assessment: ACF2:ASSHR : ACF2:ASSMI (24-hour clock) (Hour : Min)

Element of Index	**Value**
1. Respiratory Rate	
A. Current Rate (breaths per minute):	ACF2:RESPRAT
2. Work of breathing	
A. Retractions	☐ (ACF2:RETRAC) Yes ☐ (ACF2:RETRAC) No
B. Nasal flaring	☐ (ACF2:NASAL) Yes ☐ (ACF2:NASAL) No
C. Use of accessory muscles	☐ (ACF2:MUSC) Yes ☐ (ACF2:MUSC) No
3. Pain	
A. Current thoracic pain scale[1]	ACF2:THORAC
B. Non-thoracic body pain	ACF2:OVERALL

Pain scale: ☐ (ACF2:SCALE) Oucher Scale ☐ (ACF2:SCALE) Numeric Rating Scale

Location of pain: (check all that apply)	☐ (ACF2:PAIN1)	Lower Back	☐ (ACF2:PAIN2)	Upper Extremities	☐ (ACF2:PAIN3)	Head & Neck	
	☐ (ACF2:PAIN4)	Abdomen	☐ (ACF2:PAIN5)	Lower Extremities			

4. SpO_2 (off oxygen = 1 minute)[1]

A. Current Value (%): (in room air) ACF2:SPO2VAL **or** ☐ (ACF2:SPO2ND) Not Done

5. Medical intervention

A. Supplemental O_2	☐ (ACF2:SUPO2)	Yes	☐ (ACF2:SUPO2)	No
B. Invasive or noninvasive ventilatory support	☐ (ACF2:VENTSUP)	Yes	☐ (ACF2:VENTSUP)	No

[1] Enter value of 10 point numeric rating scale or the Oucher.

Comments for page:

ACF2:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Complete this form at the **second follow-up visit.**

Was the assessment completed? ☐ (VTL2:COMPLET) Yes ☐ (VTL2:COMPLET) No

If No, indicate the reason (check one):

☐ (VTL2:REASON) Subject is still an in-patient at the hospital
☐ (VTL2:REASON) Lost to follow-up
☐ (VTL2:REASON) Serious Adverse Event
☐ (VTL2:REASON) Other, specify VTL2:OTHSP
☐ (VTL2:REASON) Subject or parent/guardian decision

Date of Assessment: VTL2:ASSDA / VTL2:ASSMO / VTL2:ASSYR (DD / MMM / YYYY)

Time of Assessment: VTL2:ASSHR : VTL2:ASSMI (24-hour clock) (Hour : Min)

Vitals

Temperature (°C) VTL2:TEMP

Heart Rate (BPM) VTL2:RATE

Respirations (RR) VTL2:RESP

Blood Pressure (mm Hg) VTL2:SYS (Systolic) / VTL2:DIA (Diastolic)

Per protocol, hypertension indicated by the following results should be reported as Adverse Events:

- A single blood pressure in which the systolic pressure is ≥ 140 mmHg ***and*** the diastolic pressure is ≥ 90 mmHg;
- A systolic pressure ≥ 140 mmHg on 2 more occasions in a rolling 24 hour period regardless of diastolic pressure;
- A diastolic pressure ≥ 90 mmHg on 2 more occasions in a rolling 24 hour period regardless of systolic pressure.

Does the subject have new onset hypertension (per protocol)? ☐ (VTL2:HYPER) Yes ☐ (VTL2:HYPER) No

If Yes, enter this on AE form.

If Yes, what is the suspected reason?

- ☐ (VTL2:REASON2) Crying or irritated
- ☐ (VTL2:REASON2) Severe pain
- ☐ (VTL2:REASON2) Fluid overload
- ☐ (VTL2:REASON2) Unknown
- ☐ (VTL2:REASON2) Other, specify VTL2:OTHSP2

If Yes, did this require treatment? ☐ (VTL2:TREAT) Yes ☐ (VTL2:TREAT) No

Weight (kg): VTL2:WEIGHT

Comments for page:

VTL2:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Interval Health History**	**Follow-up II** **Page: 17**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form at the **second follow-up visit.** All questions relate to events that have occurred **since the first follow-up visit.**

Was the assessment completed? ☐ (FLU2:COMPLET) Yes ☐ (FLU2:COMPLET) No

If No, indicate the reason (check one):

☐ (FLU2:REASON) Subject is still an in-patient at the hospital

☐ (FLU2:REASON) Lost to follow-up

☐ (FLU2:REASON) Serious Adverse Event

☐ (FLU2:REASON) Other, specify FLU2:OTHSP

☐ (FLU2:REASON) Subject or parent/guardian decision

Has the subject experienced:

1. Acute Painful Episode ☐ (FLU2:PAIN) Yes ☐ (FLU2:PAIN) No

If Yes, record number of events below. Record only the **final** location if a single pain crises was treated at multiple locations.

Since the first follow-up visit, how many pain crises:

1. Were treated at home? FLU2:HOME *(enter 0 for none)*
2. Were treated in a clinic or doctor's office, not hospital? FLU2:CLINIC *(enter 0 for none)*

2. Hospitalization? ☐ (FLU2:HSPVST) Yes ☐ (FLU2:HSPVST) No

If Yes, press the "Add Event " button to record details for each hospitalization.

Primary and Secondary Reason: Delete Event

HOSP:REASON1

Other, specify: HOSP:REAS1S

Date admitted: HOSP:ADMITDA (DD) / HOSP:ADMITMO (MMM) / HOSP:ADMITYR (YYYY)

HOSP:REASON2

Other, specify: HOSP:REAS2S

Date discharged: HOSP:DISCDA (DD) / HOSP:DISCMO (MMM) / HOSP:DISCYR (YYYY)

Add Event

3. Emergency Room Visit (if not hospitalized)? ☐ (FLU2:ERVISIT) Yes ☐ (FLU2:ERVISIT) No

If Yes, press the "Add Event " button to record details for each emergency room visit.

Primary and Secondary Reason:

Delete Event

EMER:EREASN1

Other, specify: EMER:ERV1S

Date admitted: EMER:ERVADDA / EMER:ERVADMO / EMER:ERVADYR
DD MMM YYYY

EMER:EREASN2

Other, specify: EMER:ERV2S

Date discharged: EMER:ERVDSDA / EMER:ERVDSMO / EMER:ERVDSYR
DD MMM YYYY

Add Event

Comments for page:

FLU2:COMMENT

Submit Query Cancel Form Completion Help Print

Comprehensive Sickle Cell Centers	**Respiratory Assessments**	**Follow-up II** **Page: 18**
Dexamethasone for ACS	Date of assessment: RESP:ASMTDA / RESP:ASMTMO / RESP:ASMTYR DD MMM YYYY	CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form at the **second follow-up visit.**

Was the assessment completed? ☐ (RESP:COMPLET) Yes ☐ (RESP:COMPLET) No

If No, indicate the reason (check one):

☐ (RESP:REASON) Subject is still an in-patient at the hospital
☐ (RESP:REASON) Lost to follow-up
☐ (RESP:REASON) Serious Adverse Event
☐ (RESP:REASON) Other, specify RESP:OTHSP
☐ (RESP:REASON) Subject or parent/guardian decision

Was a 30-day chest radiograph taken? ☐ (RESP:CHEST) Yes ☐ (RESP:CHEST) No
(record information on "Chest Radiograph", CRF p. 24)

Pulmonary Function

Test	Value	Predicted Value
FVC:	RESP:FVC1 L	RESP:FVC2 L
FEV_1:	RESP:FEV1 L	RESP:FEV2 L
(FEV_1/FVC):	RESP:FEVFVC1 %	RESP:FEVFVC2 %
($FEF_{25-75\%}$):	RESP:FEF1 %	RESP:FEF2 %
PEFR:	RESP:PEFR1 L/s	RESP:PEFR2 L/s
DLCO:	RESP:DLCO1	RESP:DLCO2
	☐ (RESP:CORHGB1) Corrected for HGB	☐ (RESP:CORHGB2) Corrected for HGB
	☐ (RESP:CORHGB1) Not corrected for HGB	☐ (RESP:CORHGB2) Not corrected for HGB
	☐ (RESP:ND1) Not Done	☐ (RESP:ND2) Not Done

Reminder: Fax the pulmonologist's report to the Protocol Chair, Charles Quinn, MD at 214-648-3122. Remove all subject identification except for the CSCC ID#. This is a confidential fax #.

Comments for page:

RESP:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form at the **second follow-up visit.**

Was the assessment completed? ☐ (HEM2:COMPLET) Yes ☐ (HEM2:COMPLET) No

If No, indicate the reason (check one):

☐ (HEM2:REASON) Subject is still an in-patient at the hospital

☐ (HEM2:REASON) Lost to follow-up

☐ (HEM2:REASON) Serious Adverse Event

☐ (HEM2:REASON) Other, specify HEM2:OTHSP

☐ (HEM2:REASON) Subject or parent/guardian decision

Collection Date: HEM2:COLLDA / HEM2:COLLMO / HEM2:COLLYR (DD / MMM / YYYY)

Collection Time: HEM2:COLLHR : HEM2:COLLMI (24-hour clock) (Hour / Min)

Test	Value
WBC ($x10^3/mm^3$)	HEM2:WBC
RBC ($x10^6/mm^3$)	HEM2:RBC
HGB (g/dL)	HEM2:HGB
HCT (%)	HEM2:HCT
MCV (fL)	HEM2:MCV
Platelets ($x10^3/mm^3$)	HEM2:PLATE
Abs. reticulocyte count ($x10^3/mm^3$)	HEM2:ABRETIC
OR % Reticulocyte	HEM2:RETICPT

Comments for page:

HEM2:COMMENT

Did subject complete the study? ☐ (COMP:CMPYN) Yes ☐ (COMP:CMPYN) No

Date of last contact: COMP:LASTDA / COMP:LASTMO / COMP:LASTYR
DD MMM YYYY

If no, record the date of last contact and select the **primary** reason for early withdrawal from below.

☐ (COMP:REASON) Screen failure (consented, was randomized, but did not receive study drug)

☐ (COMP:REASON) Subject failed to satisfy enrollment criteria ***Specify:*** COMP:SP1

☐ (COMP:REASON) Subject lost to follow-up

☐ (COMP:REASON) Subject or subject's legal representative requested to withdraw ***Specify:*** COMP:SP3

☐ (COMP:REASON) Discontinuation *(Check all that apply)*

- ☐ (COMP:DISCON1) New hypertension (not pre-existing) that requires treatment with anti-hypertensive medications
- ☐ (COMP:DISCON2) Stroke
- ☐ (COMP:DISCON3) Gastrointestinal hemorrhage
- ☐ (COMP:DISCON4) Pregnancy
- ☐ (COMP:DISCON5) In the doctor's opinion the subject's health, safety and/or well-being was threatened by continued participation in the study.

☐ (COMP:REASON) Other adverse event or significant concurrent illness ***Specify:*** COMP:SP4

☐ (COMP:REASON) Death

☐ (COMP:REASON) Other ***Specify:*** COMP:SP5

Investigator:

In your opinion, into which arm was this subject randomized?

☐ (COMP:INVEST) Dexamethasone

☐ (COMP:INVEST) Placebo

☐ (COMP:INVEST) No opinion

Study Coordinator:

In your opinion, into which arm was this subject randomized?

- ☐ (COMP:SCOORD) Dexamethasone
- ☐ (COMP:SCOORD) Placebo
- ☐ (COMP:SCOORD) No opinion

Subject:

In your opinion, into which arm were you randomized?

- ☐ (COMP:SUBJ) Dexamethasone
- ☐ (COMP:SUBJ) Placebo
- ☐ (COMP:SUBJ) No opinion

Investigator's or Treating Physician's Statement: *I have reviewed the data entries within this CRF and, to the best of my knowledge, the data represent a complete and accurate record of the subject's participation in the study.*

PI signature: ☐ (COMP:PISIG) Signature Date: COMP:SIGDA / COMP:SIGMO / COMP:SIGYR

DD MMM YYYY

Comments for page:

COMP:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Study Drug Hospital Log**	**Ongoing** **Page: 21a**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

For each scheduled dose of study drug, **from study entry to hospital discharge,** record the date, time, and dose of study drug. Please be sure information is recorded for **each dose** (even if missed), to ensure accurate and complete information. If a dose was missed, record the date and time that the dose should have been taken.

Date	Time (24-hour clock)	Dose	Route	Comments	
HPSD:DOSEDA / HPSD:DOSEMO / HPSD:DOSEYR DD MMM YYYY	HPSD:DOSEHR : HPSD:DOSEMI Hour Min	HPSD:DOSE mg OR (HPSD:MISSED) Missed dose	HPSD:ROUTE	HPSD:COMM	Delete Event

Add Event

Comments for page:

HPCM:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Comprehensive Sickle Cell Centers	**Study Drug Home Record**	**Ongoing** **Page: 21b**
Dexamethasone for ACS		CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete this form for every scheduled dose (even if dose was missed) **from hospital discharge through the end of study drug therapy**. If a dose was missed, record the date and time that the dose should have been taken.

Delete Event

Date	**Time** (24 -hour clock)	**Dose**	**Comments**
HMSD:DOSEDA / HMSD:DOSEMO / HMSD:DOSEYR DD MMM YYYY	HMSD:DOSEHR : HMSD:DOSEMI Hour Min	☐ (HMSD:DOSE) Dose taken OR ☐ (HMSD:DOSE) Missed dose	HMSD:COMM

Add Event

Comments for page:

HMCM:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Record all transfusions administered during the Pre-enrollment and Follow-up periods.

Record all medications, other than opioid analgesics, from study entry to termination of study (Follow-up II visit). Include start dates prior to the study **only** if the medication continues to be taken at study entry visit. If the start date is unknown because it occurred prior to the start of the study, mark 'Preexisting'.

Delete Medication

Medication	CMED:MEDICAT	
Indication	CMED:INDICAT	
Dose	CMED:DOSE	
Unit[1]	CMED:UNIT Other unit, specify: CMED:UNITSP Simple transfusion, specify number of episodes: CMED:STRANSP	
Route[2]	CMED:ROUTE Other, specify: CMED:ROUTSP	
Pre-existing	☐ (CMED:PREXIST)	
Start Date and TIme	CMED:STARTDA / CMED:STARTMO / CMED:STARTYR DD MMM YYYY	CMED:STARTHR : CMED:STARTMI Hour Min (24-hour clock)
Ongoing	☐ (CMED:ONGOING)	
Stop Date and Time	CMED:STOPDA / CMED:STOPMO / CMED:STOPYR DD MMM YYYY	CMED:STOPHR : CMED:STOPMI Hour Min (24-hour clock)

[1] Unit

1 = CAP	6 = ML	
2 = G	7 = TAB	
3 = GTT	8 = Other unit, specify	
4 = MG	9 = Exchange Transfusion	
5 = MCG	10 = Simple Transfusion, specify	

[2] Route

1 = IA	5 = IS	9 = SC
2 = IM	6 = IV	10 = SQ
3 = INH	7 = PO	11 = TOP
4 = INTRA	8 = PR	12 = Other, specify

Add Medication

Comments for page:

CMYN:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Did the subject experience any Adverse Events? ☐ (AEYN:AEYN) Yes ☐ (AEYN:AEYN) No

Delete Event

Adverse Event/Diagnosis	AEXP:ADVEXP
Sickle Cell Related?	☐ (AEXP:SICKLE) Yes ☐ (AEXP:SICKLE) No
AE Start Date:	AEXP:ONSETDA / AEXP:ONSETMO / AEXP:ONSETYR DD MMM YYYY
AE Stop Date:	AEXP:STOPDA / AEXP:STOPMO / AEXP:STOPYR DD MMM YYYY
Serious? **if Yes, complete SAE Form**	☐ (AEXP:SAE) Yes ☐ (AEXP:SAE) No
Outcome	AEXP:OUTCOME
Severity	AEXP:SEVERE
Relationship to Study Drug	AEXP:RELAT
Action Taken **Record all that apply**	☐ (AEXP:ACTION1) None ☐ (AEXP:ACTION2) Study treatment interrupted/modified ☐ (AEXP:ACTION3) Study treatment discontinued ☐ (AEXP:ACTION4) Concomitant medication given/changed ☐ (AEXP:ACTION5) Hospitalization ☐ (AEXP:ACTION6) ER/Day hospital ☐ (AEXP:ACTION7) Other, specify AEXP:ACT7SP

Add Event

Comments for page:

AEYN:COMMENT

DIAGNOSTIC X-RAY

Record information for the subject's **diagnostic** x-ray.

Date of X-Ray	Time of X-Ray	Pulmonary Infiltrate?	If Yes,	Comments
XRAY:XRAYDA / XRAY:XRAYMO / XRAY:XRAYYR DD MMM YYYY	XRAY:XRAYHR : XRAY:XRAYMI Hour Min (24-hour clock)	☐ (XRAY:PULYN) Yes ☐ (XRAY:PULYN) No	☐ (XRAY:IFYES) New ☐ (XRAY:IFYES) Existing	XRAY:COMM

CLINICALLY INDICATED

Press the "Add" button to record information for each **clinically indicated** x-ray performed while subject is admitted in hospital.

Delete Clinically Indicated X-Ray

Date of X-Ray	Time of X-Ray	Pulmonary Infiltrate?	If Yes,	Comments
CIXR:CRAYDA / CIXR:CRAYMO / CIXR:CRAYYR DD MMM YYYY	CIXR:CRAYHR : CIXR:CRAYMI Hour Min (24-hour clock)	☐ (CIXR:CPULYN) Yes ☐ (CIXR:CPULYN) No	☐ (CIXR:CIFYES) New ☐ (CIXR:CIFYES) Existing	CIXR:CCOMM

Add Clinically Indicated X-Ray

FOLLOW-UP II

Record information for the subject's **Follow-up II** visit x-ray.

Delete Follow-up II X-Ray

Date of X-Ray	Time of X-Ray	Pulmonary Infiltrate?	If Yes,	Comments
FXRA:XRAY2DA / FXRA:XRAY2MO / FXRA:XRAY2YR DD MMM YYYY **or** ☐ (FXRA:XRAY2ND) Not Done	FXRA:XRAY2HR : FXRA:XRAY2MI Hour Min (24-hour clock)	☐ (FXRA:PULYN2) Yes ☐ (FXRA:PULYN2) No	☐ (FXRA:IFYES2) New ☐ (FXRA:IFYES2) Existing	FXRA:COMM2

Add Follow-up II X-Ray

Comments for page:

XRAY:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Study Enrollment Blood Culture

☐ (BCUL:BCND) Subject does not have a fever, baseline blood culture was not performed.

Record **all** bacterial pathogens. If 'Other' is chosen for organism identification, be sure to specify genus and species if known.

Date Obtained	Culture Results	Presumed Contaminant?	Organism identification for all bacterial pathogens	Antimicrobial therapy initiated*?
BCUL:BACDA / BCUL:BACMO / BCUL:BACYR DD MMM YYYY	☐ (BCUL:RESULT) Positive ☐ (BCUL:RESULT) Negative *(If negative, no organism identification required.)*	☐ (BCUL:CONTAM) Yes ☐ (BCUL:CONTAM) No	☐ (BCUL:ORG1) *Streptococcus pneumoniae* ☐ (BCUL:ORG2) *Chlamydia pneumoniae* ☐ (BCUL:ORG3) *Mycoplasma pneumoniae* ☐ (BCUL:ORG4) *Mycoplasma hominis* ☐ (BCUL:ORG5) *Staphylococcus aureus* ☐ (BCUL:ORG6) Other *Staphylococcus* species ☐ (BCUL:ORG7) *E. coli* ☐ (BCUL:ORG8) *Salmonella* species ☐ (BCUL:ORG9) *Other, specify:* BCUL:ORGSP	☐ (BCUL:THERAPY) Yes ☐ (BCUL:THERAPY) No ** (If 'Yes', record antimicrobial therapy on the Concomitant Medications CRF, page 36.)*

Clinically Indicated Blood Culture

Press the 'Add Culture Results' button to enter results for a clinically indicated blood culture.

Record **all** bacterial pathogens. If 'Other' is chosen for organism identification, be sure to specify genus and species if known.

Delete Culture Results

CIBC:CBACDA / CIBC:CBACMO / CIBC:CBACYR DD MMM YYYY	☐ (CIBC:CRESULT) Positive ☐ (CIBC:CRESULT) Negative *(If negative, no organism identification required.)*	☐ (CIBC:CCONTAM) Yes ☐ (CIBC:CCONTAM) No	☐ (CIBC:CORG1) *Streptococcus pneumoniae* ☐ (CIBC:CORG2) *Chlamydia pneumoniae* ☐ (CIBC:CORG3) *Mycoplasma pneumoniae* ☐ (CIBC:CORG4) *Mycoplasma hominis* ☐ (CIBC:CORG5) *Staphylococcus aureus* ☐ (CIBC:CORG6) Other *Staphylococcus* species ☐ (CIBC:CORG7) *E. coli* ☐ (CIBC:CORG8) *Salmonella* species ☐ (CIBC:CORG9) *Other, specify:* CIBC:CORGSP	☐ (CIBC:CTHERAP) Yes ☐ (CIBC:CTHERAP) No ** (If 'Yes', record antimicrobial therapy on the Concomitant Medications CRF, page 36.)*

Add Culture Results

Comments for page:

BCUL:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Record all opioid analgesics administered, from study entry to termination of study (Follow-up II visit).

Non-PCA

Study Day	Opioid Name	Total Dose per 24 hr period	Unit	Route
OPI1:DAY	OPI1:OPIOID Other, specify: OPI1:OPSP	OPI1:DOSE	OPI1:UNIT Other, specify: OPI1:UNITSP	OPI1:ROUTE Other, specify: OPI1:ROUTESP

Delete Non-PCA Medication

Comments
OPI1:COMM

Add Non-PCA Medication

PCA

Study Day	Opioid Name	Total continuous infusion (mg)	Total PCA doses (mg)	Total other boluses (mg)
OPI2:DAY	OPI2:OPIOID2 Other, specify: OPI2:OPSP2	OPI2:INFU	OPI2:DOSE	OPI2:BOLUS

Delete PCA Medication

Comments
OPI2:COMM2

Add PCA Medication

Comments for page:

OPYN:COMMENT

Submit Query | Cancel | Form Completion Help | Print

Dexamethasone for ACS	Date Form Completed: DEVI:COMPDA (DD) / DEVI:COMPMO (MMM) / DEVI:COMPYR (YYYY) Form Completed by: DEVI:COMPINT	CSCC ID: {subject.name} Center Code: {center.name} Hospital Code: {center.hospital.name}

Complete a separate form for each deviation from the protocol.

Date of protocol deviation: DEVI:DEVIDA (DD) / DEVI:DEVIMO (MMM) / DEVI:DEVIYR (YYYY)

Was the subject Randomized? ☐ (DEVI:RANDOMZ) No ☐ (DEVI:RANDOMZ) Yes

Type of Deviation:

☐ (DEVI:DEVITYP) **1. Randomization or Masking Error, Specify:** DEVI:RANDSP

☐ (DEVI:DEVITYP) **2. Dosing Error, Specify:** DEVI:DOSERSP

Did this lead to an overdose? ☐ (DEVI:OVERDOS) No ☐ (DEVI:OVERDOS) Yes

☐ (DEVI:DEVITYP) **3. Missed Visit:**

Which visit was missed? ☐ (DEVI:MISSVIS) Screening/Baseline ☐ (DEVI:MISSVIS) Study Enrollment ☐ (DEVI:MISSVIS) Day, Number: DEVI:DAYMISS
☐ (DEVI:MISSVIS) Discharge ☐ (DEVI:MISSVIS) Follow-up I ☐ (DEVI:MISSVIS) Follow-up II

☐ (DEVI:DEVITYP) **4. Mistimed Visit:**

At which visit? ☐ (DEVI:MISTIME) Screening/Baseline ☐ (DEVI:MISTIME) Study Enrollment ☐ (DEVI:MISTIME) Day, Number: DEVI:DAYTIME
☐ (DEVI:MISTIME) Discharge ☐ (DEVI:MISTIME) Follow-up I ☐ (DEVI:MISTIME) Follow-up II

How far outside the visit window was the missed visit? DEVI:OUTWIND

☐ (DEVI:DEVITYP) **5. Missed Procedure or Laboratory Measure**

For which visit was the assessment missed? ☐ (DEVI:MISPROC) Screening/Baseline ☐ (DEVI:MISPROC) Study Enrollment ☐ (DEVI:MISPROC) Day, Number: DEVI:DAYPROC
☐ (DEVI:MISPROC) Discharge ☐ (DEVI:MISPROC) Follow-up I ☐ (DEVI:MISPROC) Follow-up II

Was the entire assessment missed?

☐ (DEVI:PARTALL) No: Which part of the assessment was missed? DEVI:MISPART

☐ (DEVI:PARTALL) Yes: Which assessment was missed? DEVI:MISSALL

If other, specify: DEVI:OTHASMT

☐ (DEVI:DEVITYP) **6. Inclusion Criteria Not Met**

Inclusion Number(s) DEVI:INCL1 DEVI:INCL2 DEVI:INCL3

☐ (DEVI:DEVITYP) **7. Exclusion Criteria Not Met**

Exclusion Number(s) DEVI:EXCL1 DEVI:EXCL2 DEVI:EXCL3

☐ (DEVI:DEVITYP) **8. Informed Consent, Explain:** DEVI:INFORSP

☐ (DEVI:DEVITYP) **9. Other, Specify:** DEVI:OTHERSP

Reason for Deviation: DEVI:DEVIRES

Steps Taken to Resolve and Prevent Recurrence of Deviation: DEVI:DEVIPRV

Did this deviation result in an adverse experience? ☐ (DEVI:DEVIAE) No ☐ (DEVI:DEVIAE) Yes *(If yes, complete AE form.)*

If yes, was the AE serious? ☐ (DEVI:DEVISAE) No ☐ (DEVI:DEVISAE) Yes
(If yes, complete AE form.)

Will the subject continue with the study? ☐ (DEVI:CONTINU) No ☐ (DEVI:CONTINU) Yes *(If no, complete dicontinuation form.)*

Is report to IRB required for this deviation? ☐ (DEVI:DEVIIRB) No ☐ (DEVI:DEVIIRB) Yes

If yes, Date Reported: DEVI:REPODA / DEVI:REPOMO / DEVI:REPOYR
DD MMM YYYY

If further action is required, describe it: DEVI:OTHACTN

Additional Comments:

DEVI:ADDCOMM

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