

Dexamethasone for ACS

Date Form Completed: / /
 DD MMM YYYY

Form Completed by:

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: / /
 DD MMM YYYY

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

Type of Deviation:

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

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

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: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:MISTIME) Discharge

(DEVI:MISTIME) Follow-up I

(DEVI:MISTIME) Follow-up II

How far outside the visit window was the missed visit?

(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: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:DEVIRE

Steps Taken to Resolve and Prevent Recurrence of Deviation:

DEVI:DEVIPRV

Did this deviation result in an adverse experience?

(DEVI:DEVAE) No (DEVI:DEVAE) 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 discontinuation 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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