

Blood and Marrow Transplant Clinical
Trials Network

SCD Events of Special Interest Form (ESI)

Web Version: 1.0; 4.00; 06-05-17

Segment (PROTSEG): A

Visit Number (VISNO):

Date of last contact: (ESICNTDT) (mm/dd/yyyy)

A single event occurrence is defined as a new onset of any of the below listed Sickle Cell Disease Events of Special Interest (SCD-EOSI) after screening evaluations are completed. A single occurrence resolves once the SCD-EOSI returns to the patient's baseline. Therefore, multiple occurrences of the same or several SCD-EOSIs may be reported in one assessment period.

Since the date of the last study visit indicate if any of the following have occurred:

1. Did the patient experience pulmonary hypertension during this assessment period? (ESIPULM) 1 - Yes 2 - No
2. Was this a new episode of pulmonary hypertension during this assessment period? (ESINPULM) 1 - Yes 2 - No
3. Date of new episode of pulmonary hypertension: (ESINPUDT) (mm/dd/yyyy)
4. How was pulmonary hypertension diagnosed? (ESIPDIAG) 1 - Right Heart Catheterization 2 - Echocardiogram
5. Was an intervention required to treat pulmonary hypertension? (ESINTREQ) 1 - Yes 2 - No
6. Select treatment initiated: (ESIPUTRM)

1 - Sildenafil
2 - Bosentan
3 - Oxygen with RBC Transfusions
9 - Other
- Other, specify: (ESITRMSP)
7. Did the patient experience a new onset of a significant cerebrovascular event (stroke, transient ischemic attack, or seizure) during this assessment period? (ESICEREB) 1 - Yes 2 - No
8. How many times did the patient experience a new onset of stroke during this assessment period? (ESIS TRKT) (xx) time(s)
9. How many times did the patient experience a new onset of transient ischemic attack (TIA) during this assessment period? (ESITIAT) (xx) time(s)
10. How many times did the patient experience a new onset of seizure during this assessment period? (ESIS EIZT) (xx) time(s)
11. Date of first occurrence of any significant cerebrovascular event during this assessment period: (ESICERDT) (mm/dd/yyyy)
12. Did the patient experience renal function compromise (proteinuria or increased creatinine grades ≥ 2 per CTCAE version 4.0) during this assessment period? (ESIRENL) 1 - Yes 2 - No
13. Did the patient experience a new onset of proteinuria during this assessment period? (ESIPROT) 1 - Yes 2 - No
14. Date of new onset of proteinuria: (ESIPRODT) (mm/dd/yyyy)
15. Did the patient experience a new onset of increased creatinine (grades ≥ 2 per CTCAE version 4.0) during this assessment period? (ESINCREA) 1 - Yes 2 - No
16. Date of new onset of increased creatinine: (ESICREDT) (mm/dd/yyyy)
17. Did the patient experience a new onset of avascular necrosis of the hip or shoulder during this assessment period? (ESINECR) 1 - Yes 2 - No

18. Did the patient experience a new onset of leg ulceration during this assessment period? 1 - Yes 2 - No
(ESIULCR)

19. Did the patient experience a new onset of acute chest syndrome requiring hospitalization during this assessment period?(ESIACS) 1 - Yes 2 - No

20. How many times was the patient hospitalized for acute chest syndrome during this assessment period?(ESIACT) (xx) time(s)

21. Date of first occurrence of acute chest syndrome requiring hospitalization during this assessment period:(ESIACTDT) (mm/dd/yyyy)

22. Did the patient experience a new onset of painful vaso-occlusive crisis requiring hospitalization OR parenteral opioid drugs in the outpatient setting during this assessment period?(ESIVOC) 1 - Yes 2 - No

23. How many times was the patient hospitalized for painful vaso-occlusive crisis during this assessment period?(ESIVOCHT) (xx) time(s)

24. How many times were parenteral opioid drugs required for the painful vaso-occlusive crisis in the outpatient setting during this assessment period?(ESIVOCOT) (xx) time(s)

25. Date of first occurrence of painful vaso-occlusive crisis requiring hospitalization OR parenteral opioid drugs in the outpatient setting during this assessment period:(ESIVOCDT) (mm/dd/yyyy)

26. Did any of the events reported above lead to an advanced care intervention or Intensive Care Unit admission/transfer as outlined in the AE reporting section of chapter 4 of the protocol? (ESIAEICU) 1 - Yes 2 - No 3 - Not Applicable

Specify event(s):(ESIAESP)

Comments:(ESICOMM)