Medical Record Abstraction Form – v1.0

Subject ID

This form should be completed using data abstracted from the medical record. This should be completed going back to the **date the last abstraction form was completed**.

DATE THIS FORM COMPLETED: |___|___|-|___|___|-|___|___|___|___|
Month Day Year

1. Confirmed enrollment diagnosis: (CHECK ONLY ONE). DIAGNOSIS MUST BE SUPPORTED BY SOURCE DOCUMENTATION.

Diagnosis	
a. Hb SS or sickle cell anemia	☐
b. Hb SC disease	☐
c. Hb S beta^0 thalassemia	☐
d. Hb S beta$^+$ thalassemia	☐

Diagnosis	
e. Hb S hereditary persistence of fetal Hb (S/HPFH)	☐
f. Hb SE	☐
g. Hb SD	☐
h. Hb SO	☐

a. What was the basis for diagnosis?
- ☐ Newborn screening
- ☐ Hemoglobin fractionation
- ☐ Hemoglobin electrophoresis
- ☐ DNA sequencing

2. Approximate age of first diagnosis (physician confirmed): _____ AGE In YEARS **OR** ☐ NEWBORN SCREENING **OR** ☐ UNKNOWN

3. Has the subject ever been evaluated for curative gene therapy? ☐ Yes ☐ No

4. Most recent test results for alpha-thalassemia?
- ☐ Yes—single alpha globin gene deleted
- ☐ Yes—two alpha globin genes deleted
- ☐ Yes––negative
- ☐ No—not evaluated
- ☐ Unknown

Basic Measurements (most recent)	Not in Record	Measurements	Date (mm/yyyy)	Steady state?
5. Height	☐	|___|___|___| CM		Y N
6. Weight	☐	|___|___|___|.|___| KG		Y N
7. Temperature	☐	|___|___|.|___| Celsius		Y N
8. Heart Rate	☐	|___|___|___| BEATS/MINUTE		Y N
9. Respiration Rate	☐	|___|___|___| BREATHS/MINUTE		Y N
10. Oxygen saturation (SpO_2)	☐	|___|___|___| %		Y N
11. Blood Pressure	☐	|___|___|___| / |___|___|___| ON ANTI-HYPERTENSIVE MEDS? ☐ Yes ☐ No		Y N

12. Has the subject ever used hydroxyurea? YES NO (if NO skip to Endari question)

13. Is the subject currently taking hydroxyurea? ☐ Yes ☐ No
   a. Start date (mm/yyyy) |__|__|-|__|__|__|__|
   b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

14. Has the subject ever taken Endari ☐ Yes ☐ No ➔ **GO TO Q16**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ Mg/kg or _ Mg

15. Has the subject ever taken Adakveo? ☐ Yes ☐ No ➔ **GO TO Q18**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ __ Mg/kg or __ Mg

16. Has the subject ever taken Oxbryta? ☐ Yes ☐ No ➔ **GO TO Q20**

a. Start date (mm/yyyy) |__|__|-|__|__|__|__|

b. Stop/last date (mm/yyyy) |__|__|-|__|__|__|__| ☐ Currently using

c. Total duration of use _____ ☐ Months or ☐ Years ☐ Unknown

d. Current dose _____ Mg/kg or _ Mg

20. Please list all medications the subject is **currently** taking. ☐ NONE CURRENTLY BEING USED

Name of Medication	**Name of Medication**
a.	k.
b.	l.
c.	m.
d.	n.
e.	o.
f.	p.
g.	q.
h.	r.
i.	s.
j.	t.

SCD Complications **Indicate whether the subject has ever had a diagnosis of each condition and the date of the most recently diagnosed episode**	NO	YES	Most recent dx (age or date)		Condition currently under treatment
			Age	Date mm/yyyy	
Musculoskeletal					
24. Avascular necrosis *(check all that apply)*	☐	☐			
a. Hip	☐	☐			
b. Shoulder	☐	☐			
c. Knee	☐	☐			
d. Other location, specify _____	☐	☐			
Genitourinary					
25. Chronic kidney disease	☐	☐			
26. End stage renal disease *(if yes, complete Renal form)*	☐	☐			
a. Kidney transplant	☐	☐			
b. Kidney transplant rejection	☐	☐			
27. Priapism	☐	☐			
Nervous system					
28. Stroke (*check all that apply*)	☐	☐			
a. Ischemic	☐	☐			
b. Hemorrhagic	☐	☐			
c. Transient ischemic attack (TIA)	☐	☐			
d. Silent	☐	☐			
29. Intracranial bleeding	☐	☐			
Cardiovascular					
30. Pulmonary arterial hypertension	☐	☐			
a. Mean pulmonary artery pressure > or = to 25 mm Hg	☐	☐			
b. Tricuspid regurgitation velocity (TRV) > or = to 3.0 m/sec	☐	☐			
31. Left ventricular dysfunction	☐	☐			
Respiratory					
32. Acute chest syndrome	☐	☐			
33. Asthma	☐	☐			
Digestive					
34. Gallstones/cholelithiasis, cholecystitis	☐	☐			
35. Splenomegaly *(check all that apply)*	☐	☐			
a. PRBC transfusion given for splenomegaly? ☐ Yes ☐ No					
b. Splenic sequestration	☐	☐			
# sequestration episodes in past 12 months _____					
c. Splenic infarcts, symptomatic	☐	☐			
d. Hypersplenism	☐	☐			
e. Splenectomy	☐	☐			
Other Autoimmune/Inflammatory					
36. Deep vein thrombosis (DVT)	☐	☐			
a. Pulmonary embolism	☐	☐			
b. Venous thromboembolism (VTE)	☐	☐			

37. Lupus	☐	☐			
38. Rheumatoid arthritis	☐	☐			
39. Gout	☐	☐			
40. Sarcoidosis	☐	☐			
Other Conditions					
41. Multi-organ failure *(check all that apply)*	☐	☐			
a. ICU	☐	☐			
b. Intubation	☐	☐			
c. Simple transfusion	☐	☐			
d. Exchange transfusion	☐	☐			
e. Hemodialysis	☐	☐			
f. Peritoneal dialysis	☐	☐			
42. Pneumococcal sepsis	☐	☐			
43. Skin ulcers	☐	☐			
44. Retinopathy	☐	☐			
45. Diabetes mellitus	☐	☐			
46. Iron overload (liver iron content > 3 mg/g of dry weight liver on MRI or serum ferritin above 1,000 ng/dL for >3 separate measurements or >18 PRBCs)	☐	☐			
47. Chronic refractory pain	☐	☐			
48. Seizure disorder	☐	☐			
49. Anxiety	☐	☐			
50. Depression	☐	☐			
51. Other psychiatric disorder, specify:	☐	☐			
52. Other major health condition, specify:	☐	☐			
Liver Conditions					
53. Liver cirrhosis	☐	☐			
54. Intrahepatic cholelithiasis	☐	☐			
55. Hepatitis B	☐	☐			
56. Hepatitis C	☐	☐			
57. Hepatic sequestration	☐	☐			
58. Hepatomegaly	☐	☐			
59. Bridging fibrosis	☐	☐			

60. Has the subject ever been diagnosed with a primary cancer?

- ☐ Yes
- ☐ No ➔ GO TO Q61
- ☐ Don't know ➔ GO TO Q61

a. CANCER TYPE AND LOCATION_____

b. CANCER STAGE_____

c. DATE OF DIAGNOSIS (MM/YYY): |___|___| |___|___|___|___|

61. What kind of health insurance or health care coverage does the subject currently have? (Choose all that apply.)

- ☐ None
- ☐ Private health insurance
- ☐ Medicare
- ☐ Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-sponsored assistance
- ☐ TRICARE or other military health care, including VA health care
- ☐ Support from Charities or Donations
- ☐ Other type of health insurance, specify:_____

Name of Abstractor: _____ PI review and sign-off: _____