This form is created to capture malignancies developed by patient during and after therapy and may be related or unrelated to sickle cell disease. Data elements on this form are Supplemental (recommended based on study design) unless indicated otherwise.

New malignancy

1. Did a new malignancy develop (excluding non-melanoma skin cancer)?
	1. [ ]  Yes [ ]  No
		1. If yes, date of diagnosis: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)
	2. Was biopsy done to confirm diagnosis?
2. [ ]  Yes [ ]  No
3. If yes, indicated if copy of pathology report was submitted [ ]  Yes [ ]  No
	1. Type of malignancy:
		1. Acute myeloid leukemia
			1. Was a genetic mutational (myeloid) panel done?
				1. [ ]  Yes / [ ]  No / [ ]  unknown; if yes, attach results
				2. Date of test:
		2. Myelodysplastic syndrome
			1. Was a genetic mutational (myeloid) panel done?
				1. [ ]  Yes / [ ]  /No [ ]  unknown; if yes, attach results
4. Date of test: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)
	* 1. Lymphoma including post-transplant lymphoproliferative disorder (PTLD)
			1. Was there EBV reactivation in the blood?
				1. [ ]  Yes [ ]  No [ ]  unknown
		2. Other malignancy
			1. Acute lymphoblastic leukemia
				1. [ ]  Yes [ ]  No, if Yes, date of diagnosis, attach copy of pathology report
			2. Other acute leukemia
				1. [ ]  Yes [ ]  No, if Yes, date of diagnosis, attach copy of pathology report
5. If patient developed acute leukemia or myelodysplastic syndrome
	1. is there evidence of a unique vector insertion site in the malignant clone?
		1. [ ]  Yes / No
		2. if yes, is there an adjacent oncogene?
			1. [ ]  Yes [ ] No
			2. Is there evidence of a unique on-target gene modification in the malignant clone?
				1. [ ]  Yes [ ]  No
	2. Is there evidence of a unique off-target gene mediation in the malignant clone?
		1. [ ] Yes or [ ]  No,
			1. if yes, is the off-target modification linked to an adjacent oncogene?
				1. [ ] Yes [ ] No
	3. Is there an evidence of a unique chromosomal rearrangement in the malignant clone?
		1. Yes / No
			1. if yes, is it related to an off or on-target genomic modification?
				1. [ ] Yes [ ] No
6. Was there loss of engraftment of gene-modified cells?

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

* 1. [ ] Yes [ ]  No
		1. If Yes
			1. Date of event:
			2. Vector copy number:
				1. 50% - 75% genetically corrected RBC
				2. 25% - 50% genetically corrected RBC
				3. 0% - 25% genetically corrected RBC
			3. Engraftment of genetically modified product
				1. ≤20%
			4. Rescue with back-up autologous cells
				1. [ ] Yes [ ]  No

## General Instructions

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