Instructions for Sickle Cell Disease Post-Infusion Data (2130)

This section of the CIBMTR Forms Instruction Manual is intended to be a resource for completing the Sickle Cell Disease Post-Infusion Data.

2130: SCD Post-Infusion

The Sickle Cell Disease Post-Infusion (2130) Form is one of the Comprehensive Report Forms. This form captures Sickle Cell Disease (SCD) post-HCT data for the reporting period.

This form must be completed for all recipients whose primary disease, as reported on the Disease Classification (2402) Form, is **Sickle Cell Disease (SCD)**. The Sickle Cell Disease Post-Infusion (2130) Form must be completed in conjunction with each Post-Infusion Follow-up (2100) Form. This form is designed to capture specific data occurring within the timeframe of each reporting period (i.e., between day 0 and day 100; between day 100 and the six-month date of contact for six-month follow-up; and between the date of contact for the six-month follow-up and the date of contact for the one-year follow-up, etc.).

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Q115-124: Central Nervous System
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Manual Updates:

Sections of the Forms Instruction Manual are frequently updated. The most recent updates for the current manual version can be found below. For additional information, select the manual section and review the updated text.

To review the historical Manual Change History for this manual, reference the retired manual section on the Retired Forms Manuals webpage.

Date	Manual Section	Add/Remove/Modify	Description
11/20/2026	Sickle Cell Disease Post-Infusion (2130)	Add	Version 4 of the 2130: Sickle Cell Disease Post-Infusion section of the Forms Instructions Manual released. Version 4 corresponds to revision 6 of the Form 2130.

DRAFT

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Q1 – 5: Physical Assessments

Question 1: Date of evaluation

Report the date of the most recent physical evaluation where blood pressure was assessed in the reporting period. This evaluation will be used to answer *Blood pressure*.

Abdominal girth
Abdominal girth is currently disabled and cannot be answered at this time.

Questions 2 – 3: Abdominal girth

Indicate if the recipient's abdominal girth was measured on the date of evaluation specified in the question above. If **Known**, specify the recipient's abdominal measurement in centimeters. If the recipient's abdominal girth was not measured in the current reporting period or if no information is available, select **Unknown**.

Questions 4 – 5: Blood pressure

Indicate if the recipient's blood pressure was measured on the date of evaluation specified above. If **Known**, provide the recipient's blood pressure. If blood pressure was measured on multiple dates, report the most recent results in the reporting period. If the recipient's blood pressure was not measured in the current reporting period or if no information is available to determine if the recipient's blood pressure was measured, select **Unknown**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q6 – 8: Transfusion Therapy

Questions 6 – 7: Were red blood cell transfusions administered ?

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Red blood cell (RBC) transfusions are often given as supportive care to lower hemoglobin S for recipients with SCD.

Indicate if the recipient received RBC transfusion(s) in the current reporting period. If RBCs were transfused, select **Yes** and report the date of the *most recent* transfusion administered in the reporting period. If the recipient did not receive RBC transfusions in the reporting period or no information is available to determine if the recipient received RBC transfusions in the current reporting period, select **No**.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 8: Was the transfusion for a sickle cell related event?

Transfusions administered routinely to offset the effects of sickle cell-related events are often called "chronic transfusions" within progress notes. In the context of reporting, "chronic transfusions" are defined as eight or more transfusion events per year, for at least a year, or a lifetime cumulation of ≥ 20 transfusion events between diagnosis and referral for transplant.

If any of the red blood cell transfusions were administered to prevent sickle cell related events, report **Yes**.

Report **No** in the following scenarios:

- If the recipient did not receive transfusions to prevent sickle cell related events.
- There is no information available to determine if the recipient received transfusions to prevent sickle cell-related events.
- If the recipient is receiving transfusion therapy for reasons other than to prevent sickle cell-related events.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

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Q9 – 22: Therapy for Iron Overload

Questions 9 – 10: Serum ferritin

Ferritin is a protein that stores, transports, and release iron. Iron is toxic to cells, so it is stored within the ferritin protein for use. Ferritin that is too low might be indicative of iron deficiency-related anemia. Ferritin that is too high might be indicative of iron overload.

Indicate if the serum ferritin is **Known** in the current reporting period. If **Known**, report the value in ng / mL (µg / L). If the serum ferritin was assessed multiple times, report the most recent results in the current reporting period.

Question 11: Was iron chelation therapy given?

Iron chelation therapy is used to prevent or reduce iron overload. Examples include, but are not limited to, Deferoxamine (Desferal) and Deferasirox (Jadenu, Exjade).

Indicate if the recipient was given iron chelation therapy in the current reporting period. If iron chelation therapy was not given or if no information is available to determine if iron chelation therapy was given in the current reporting period, report **No** or **Unknown**, respectively.

Question 12: Was iron chelation previously reported?

Specify if the iron chelation start date was previously reported (i.e., the first phlebotomy of the series was started in a prior reporting period). If iron chelation was started in prior reporting period and continued into the current reporting period, report **Yes**.

The **Yes** option is not applicable for the Day 100 reporting period.

Questions 13 – 14: Date started

Indicate if the iron chelation start date is **Known**. If **Known**, report the date when this therapy began.

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For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 15 – 16: Is iron chelation ongoing?

Indicate if the recipient is still receiving iron chelation therapy on the contact date for the current reporting period.

If iron chelation therapy was no longer ongoing on the contact date, select **No** and report the date when the recipient received the last dose of iron chelation in the current reporting period.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 17: Was phlebotomy performed?

Phlebotomy is a procedure in which blood is removed from the body with the goal of reducing iron overload. Phlebotomy therapy is typically a series of these procedures.

Indicate if phlebotomy was performed in the current reporting period. If phlebotomy was not performed in the reporting period or it is not known if performed, select **No**.

Indicate if phlebotomy was performed in the current reporting period. If phlebotomy was not performed or if no information is available to determine if phlebotomy was performed in the current reporting period, report **No**.

Question 18: Was phlebotomy previously reported?

Specify if the phlebotomy start date was previously reported (i.e., the first phlebotomy of the series was started in a prior reporting period). If phlebotomy started in prior reporting period and continued into the current reporting period, report **Yes**.

The **Yes** option is not applicable for the Day 100 reporting period.

Questions 19 – 20: Date started

Indicate if the phlebotomy start date is **Known**. If **Known**, report the date when this therapy

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began.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 21 – 22: Is phlebotomy ongoing?

Indicate if phlebotomy was ongoing at the time of the contact date for the current reporting period.

If phlebotomy was no longer ongoing on the contact date, select **No** and report the date when phlebotomy ended in the reporting period (i.e., the last phlebotomy of the series).

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q23 – 28: Pulmonary Assessments

Question 23: Were pulmonary function tests (PFTs) performed? *(if multiple PFT tests were performed, attach the most recent report)*

Pulmonary function tests (PFTs) are non-invasive breathing evaluations that measure how much air your lungs can hold, how fast you can move air in and out, and how well your lungs transfer oxygen into your bloodstream. Indicate if pulmonary function tests (PFTs) were performed in the current reporting period.

If PFTs were not performed or unknown if PFTs were performed in the current reporting period, select **No**.

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WARRIOR-SCD
Attaching the report (when available) is required for WARRIOR-SCD.

Question 24: Indicate if the PFT report is attached

Indicate if the PFT report was **Attached** in FormsNet3SM. If multiple PFTs were performed in the current reporting period, attach the most recent report. Attaching PFT reports will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Children unable to perform PFTs
This question is only applicable for recipients ≤ 5 years of age.

Question 25: For children unable to perform PFTs, was oxygen saturation on room air > 95%? *(only required to answer if children are 5 years of age or less) (if multiple, report the most recent)*

Indicate if oxygen saturation on room air was > 95% during the current reporting period. If oxygen saturation is > 95% in the current reporting period, report **Yes**. If the oxygen saturation of room air was ≤ 95%, report **No**. If the oxygen saturation was assessed multiple times in the reporting period, report the most recent assessment.

If oxygen saturation was not assessed in the current reporting period, report **Not done**.

Questions 26 – 27: Was a 6-minute walk test performed?

A 6-minute walk test is used to assess total distance walked within 6 minutes to determine aerobic capacity and endurance. Indicate if a 6-minute walk test was performed during the current reporting period. If **Yes**, report the total distance walked and specify the unit of measure. If multiple walk tests were performed during the reporting period, report the results of the most recent assessment.

If a 6-minute walk test was not performed, recipient was unable to walk, or cannot perform the 6-minute walk test due to their current clinical status, report **No**.

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If no information is available to determine if a 6-minute walk test was performed in the current reporting period, report **Unknown**.

WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Question 28: Indicate if the 6-minute walk test report is attached

Indicate if documentation of the 6-minute walk test was **Attached** in FormsNet3SM. If multiple 6-minute walk tests were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q29 – 57: Cardiovascular Assessments

Question 29: Were lipid profiles assessed?

A lipid profile is a blood test that measures the amount of cholesterol and triglycerides within the blood. If lipid profiles were assessed in the current reporting period, report **Yes**.

If lipid profiles were not assessed or if no information is available to determine if lipid profiles were assessed in the current reporting period, report **No** or **Unknown**, respectively.

Questions 30 – 34: Specify which lipids were assessed *(check all that apply)*

Indicate which lipids were assessed and specify the units of measurement as document on the laboratory report. If multiple lipids were assessed, select all that apply. If multiple lipid profile

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assessments were performed in the current reporting period, report the results of the most recent assessment.

Question 35: Was an echocardiogram performed?

Indicate if an echocardiogram was performed in the current reporting period. If an echocardiogram was not performed or if no information is available to determine if an echocardiogram was performed in the current reporting period, select **No** or **Unknown**, respectively.

Questions 36 – 37: Was tricuspid regurgitant jet velocity (TRJV) measured?

Tricuspid regurgitant jet velocity (TRJV) measurements are used in determining the pulmonary artery pressure for recipients with sickle cell and other hemolytic disorders. An elevated TRJV is an indication of pulmonary hypertension, a condition common in adults with hemolytic diseases. TRJV is typically documented in the echocardiogram report. TRJV can be determined by echocardiography (ECHO); this information is typically documented in the echocardiogram report.

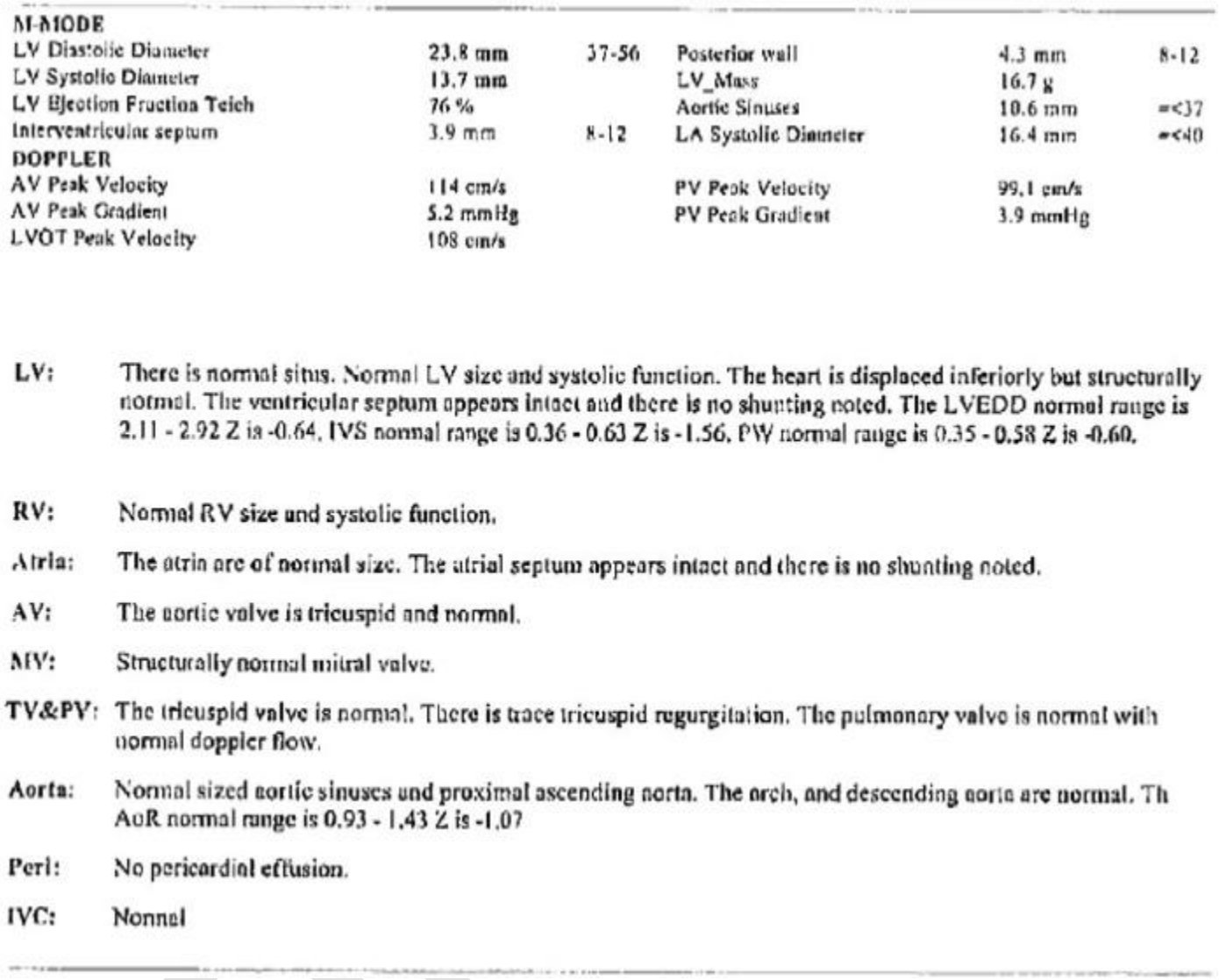
Indicate if TRJV was measured in the current reporting period. If **Yes**, provide the TRJV value as documented on the echo report. If the TRJV was measured multiple times in the reporting period, report the most recent value.

If TRJV was not measured, is not documented on the echo report, or if no information is available to determine if an TRJV was measured in the current reporting period, select **No**.

Figure 1: Echocardiogram

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M-MODE					
LV Diastolic Diameter	23.8 mm	37-56	Posterior wall	4.3 mm	8-12
LV Systolic Diameter	13.7 mm		LV_Mass	16.7 g	
LV Ejection Fraction Teich	76 %		Aortic Sinuses	10.6 mm	=<37
Interventricular septum	3.9 mm	8-12	LA Systolic Diameter	16.4 mm	=<40
DOPPLER					
AV Peak Velocity	114 cm/s		PV Peak Velocity	99.1 cm/s	
AV Peak Gradient	5.2 mmHg		PV Peak Gradient	3.9 mmHg	
LVOT Peak Velocity	108 cm/s				

LV: There is normal situs. Normal LV size and systolic function. The heart is displaced inferiorly but structurally normal. The ventricular septum appears intact and there is no shunting noted. The LVEDD normal range is 2.11 - 2.92 Z is -0.64, IVS normal range is 0.36 - 0.63 Z is -1.56, PW normal range is 0.35 - 0.58 Z is -0.60.

RV: Normal RV size and systolic function.

Atria: The atria are of normal size. The atrial septum appears intact and there is no shunting noted.

AV: The aortic valve is tricuspid and normal.

MV: Structurally normal mitral valve.

TV&PV: The tricuspid valve is normal. There is trace tricuspid regurgitation. The pulmonary valve is normal with normal doppler flow.

Aorta: Normal sized aortic sinuses and proximal ascending aorta. The arch, and descending aorta are normal. Th AoR normal range is 0.93 - 1.43 Z is -1.07

Peri: No pericardial effusion.

IVC: Normal

Questions 38 – 40: Was left ventricular ejection fraction (LVEF) or left ventricular shortening fraction reported?

The left ventricular ejection fraction (LVEF) is a percentage that represents the volume of blood pumped from the left ventricle into the aorta (also known as stroke volume) compared to the volume of blood in the ventricle just prior to the heart contraction (also known as end diastolic volume). The left ventricular shortening fraction is the percentage change in cavity dimensions of the left ventricle with systolic contraction. The LVEF and left ventricular shortening fraction are assessed via an echocardiogram. Refer to Figure 1 above for an example of an echocardiogram report.

Report **Yes** if *either* LVEF or left ventricular shortening fraction were assessed in the current

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reporting period and provide the percentage(s). If the LVEF *and* left ventricular shortening fraction were assessed, report the results of both. If the LVEF and/or left ventricular shortening fraction were assessed multiple times in the reporting period, report the most recent value(s).

If the LVEF and / or left ventricular shortening fraction was not assessed or if no information is available to determine if LVEF and / or left ventricular shortening fraction was assessed in the current reporting period, report **No**.

Questions 41 – 42: Is there a new onset of pulmonary hypertension?

Pulmonary hypertension (PH) refers to elevated pulmonary arterial pressure and is diagnosed either by an echocardiogram or right heart catheterization. PH can be due to a primary elevation of pressure in the pulmonary arterial system alone (pulmonary arterial hypertension), or secondary to elevations of pressure in the pulmonary venous and pulmonary capillary systems (pulmonary venous hypertension; post-capillary PH).

Indicate **Yes** if there was a new onset of pulmonary hypertension (has never been previously diagnosed) in the current reporting period and select the which method was used to diagnose PH.

Report **No** in in the following scenarios:

- There was not a new onset of PH in the current reporting period.
- PH was diagnosed prior to infusion or in a prior reporting period, resolved, and developed in the current reporting period.
- PH was diagnosed in a prior reporting period and persisted into the current reporting period. Documentation is unclear or there is not enough information available to determine if there was a new onset of PH in the current reporting period.

WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Questions 43: Indicate if the echocardiogram report is attached

Indicate if the echocardiogram was **Attached** in FormsNet3^{SM}. If multiple echocardiograms were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

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If the report is not available for any reason, select **Not available**.

For further instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Attaching Right Heart Catheterization Report
This question is only applicable to WARRIOR-SCD

WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Question 44: Indicate if the right heart catheterization report is attached

Indicate if the right heart catheterization report was **Attached** in FormsNet3^{SM}. If multiple right heart catheterizations were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For further instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Questions 45 – 46: Was cardiac MRI performed?

Cardiac MRI is a noninvasive test that uses a magnetic field and radiofrequency waves to create detailed pictures of the heart and arteries. A cardiac MRI may be performed to assess cardiac iron deposition. This information is typically listed within the MRI interpretation of the report.

Specify if a cardiac MRI was completed in the current reporting period. If **Yes**, indicate if the cardiac MRI shows evidence of abnormal cardiac iron deposition. If multiple MRIs were performed, report the results based on the most recent scan in the current reporting period.

Questions 47 – 48: Cardiac iron T2 imaging

Cardiac T2 mapping is a noninvasive MRI method that is used to identify myocardial iron accumulation in several iron storage diseases. Indicate if the cardiac iron T2 imaging is **Known**. If **Known**, specify the value from the MRI results in m/sec. If the cardiac iron T2 imaging was done multiple times, report the results from the most recent assessment in the reporting period.

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Attaching Cardiac MRI Report
This question is only applicable to WARRIOR-SCD

WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Questions 49: Indicate if the cardiac MRI report is attached

Indicate if the cardiac MRI report was **Attached** in FormsNet3^{SM}. If multiple cardiac MRIs were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For further instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Questions 50 – 52: Was brain natriuretic peptide (BNP) assessed?

Brain natriuretic peptide (BNP) is a hormone secreted by cardiac ventricle cells in response to increased ventricular blood volume. BNP is typically measured using various immunoassay techniques. Confirm with the attending physician on where to locate immunoassay results measuring BNP, if available.

Indicate if BNP was assessed during the current reporting period. If **Yes**, report the value as documented on the laboratory report (in pg / mL) and the date the sample was collected. If BNP was assessed multiple times in the current reporting period, report the most recent results. If BNP was not assessed or if no information is available to determine if BNP was assessed in the current reporting period, report **No** or **Unknown**, respectively.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 53 – 55: N-terminal pro-b type natriuretic peptide (NT-proBNP)

NT-proBNP has a central role in the regulation of blood pressure, blood volume, and sodium balance. Its levels increase with age, ventricular hypertrophy and in acute coronary syndromes, heart failure, and atrial fibrillation. NT-proBNP is considered a valuable predictor in diagnosis

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and prognosis of patients with symptoms of heart failure, left ventricular dysfunction, and acute coronary syndromes.

Indicate if the NT-proBNP value is **Known** in the current reporting period. If **Known**, report the value as documented on the laboratory report (in pg / mL) and the date the sample was collected. If NT-proBNP was assessed multiple times, report the most recent results in the current reporting period. If NT-proBNP was not assessed or if no information is available to determine if NT-proBNP was assessed, report **Unknown**.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 56: Was an electrocardiogram performed?

An electrocardiogram (ECG or EKG) is a test that records the electrical activity of the heart, providing information about its rhythm and structure.

Indicate if an electrocardiogram was completed in the current reporting period. If an electrocardiogram was not performed or if no information is available to determine if an electrocardiogram in this reporting period, report **No**.

WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Question 57: Indicate if the electrocardiogram report is attached

Indicate if the electrocardiogram report was **Attached** in FormsNet3SM. If multiple electrocardiograms were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Section Updates

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Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q 58– 81: Hepatic Assessments

Questions 58-60: Did the recipient have hepatomegaly?*(>2 cm below costal margin)*

Indicate if the recipient had hepatomegaly (i.e. abnormal enlargement of the liver) in the current reporting period. Hepatomegaly is often documented during the physician's physical assessment of the recipient and represents an abnormal finding. If **Yes**, indicate if the liver size is known, If **Yes**, report the size of the liver in centimeters, measured below the right costal margin as assessed by the physical exam or radiologic assessment. If there are multiple liver measurements documented, report the most recent measurement in the reporting period.

If the recipient did not have hepatomegaly or if no information is available to determine if the recipient had hepatomegaly in the current reporting period, report **No** or **Unknown**, respectively. If the recipient did have hepatomegaly but the liver size is not known, report **No**.

Questions 61 – 63: Was liver iron content (LIC) tested?

Transfusion support for hemolytic diseases can often lead to iron build up or accumulation in the liver and other target organs. Liver iron content (LIC) is commonly used to measure total iron storage for recipients at risk of hemosiderosis. LIC is a more sensitive method of testing for measuring the level of iron in the liver. Common methods include, but are not limited to, liver biopsy, T2*MRI, and FerriScan.

Specify if the liver iron content was assessed in the current reporting period. If **Yes**, report the value, unit of measure documented in the laboratory report, and the method used to estimate the LIC. If the method of assessment is not listed, select **Other**.

Report **No** if liver iron content was not assessed or it is not known if assessed in the current reporting period.

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WARRIOR-SCD
Attaching the report is required for WARRIOR-SCD.

Question 64: Indicate if the LIC method report is attached

Indicate if the LIC method report was **Attached** in FormsNet3SM. If multiple LIC assessments were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For further instructions on how to attach documents in FormsNet3SM, refer to the Training Guide.

Questions 65 - 67: Was a liver biopsy performed?

Evaluation of liver tissue may be necessary to determine the extent of the recipient's disease. Indicate if a liver biopsy was performed during the current reporting period.

If **Yes**, report if the assessment date was known and if **Known**, the date of the liver biopsy. If multiple liver biopsies were performed since diagnosis, report the date of the most recent biopsy.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

If a liver biopsy was not performed or if no information is available to determine if a liver biopsy was performed in the current reporting period, report **No**.

Hepatic Assessments
Was there evidence of liver cirrhosis?, Was there evidence of liver fibrosis?, Was there evidence of chronic hepatitis? should be answered based on the same liver biopsy reported above.

Question 68: Was there evidence of cirrhosis?

Indicate if the liver biopsy performed on the date reported above showed evidence / characteristics of liver cirrhosis. If the results are unclear, seek physician clarification.

Select **Unknown** if no information is available to determine if the biopsy showed characteristics of liver cirrhosis.

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Questions 69 – 70: Was there evidence of liver fibrosis?

Indicate if the liver biopsy performed on the date reported above showed evidence / characteristics of liver fibrosis. If the results are unclear, seek physician clarification. If **Yes**, specify the type of fibrosis observed.

- **Bridging fibrosis:** Bands of fibrous tissue and collagen with span portal spaces / and or centrilobular spaces creating a 'bridge-like' appearance
- **Periportal fibrosis:** Fibrous expansion of portal fields with fibrosis extending along the terminal portal veins.
- **Other:** Select this option if fibrosis was present but the type is something other than 'bridging fibrosis' or 'periportal fibrosis.'

Select **Unknown** if no information is available to determine if the biopsy showed characteristics of liver fibrosis.

Question 71: Was there evidence of chronic hepatitis?

Indicate if the liver biopsy performed on the date reported above showed evidence / characteristics of chronic hepatitis. If the results are unclear, seek physician clarification.

Select **Unknown** if no information is available to determine if the biopsy showed characteristics of chronic hepatitis or if the results were inconclusive.

WARRIOR-SCD
Attaching the report (when available) is required for WARRIOR-SCD.

Question 72: Indicate if the liver biopsy report is attached

Indicate if the most recent liver biopsy report performed on the date reported above was **Attached** in FormsNet3^{SM}. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

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Questions 73 – 81: Laboratory studies performed *(check all that apply)*

Select all lab values assessed in the current reporting period. Testing may be performed multiple times; report the most recent values obtained.

- **ALT (SGPT):** Alanine aminotransferase, or serum glutamic pyruvic transaminase, is an enzyme measured in the blood that reflects liver function. Elevated levels of ALT indicate liver injury, minor or severe. If assessed, report the most recent value in the reporting period and specify the units of measurement as noted on the laboratory report.
- **AST(SGOT):** Aspartate aminotransferase, or serum glutamic oxalic transaminase, is an enzyme measured in serum or plasma that reflects liver function and liver cell integrity. Elevated levels of AST may indicate liver damage. If assessed, report the most recent value in the reporting period and specify the units of measurement as noted on the laboratory report.
- **Direct bilirubin**: also known as conjugated bilirubin. Specify the most recent value in the reporting period, the units of measurement, and the upper limit of normal as documented on the laboratory report.
- **Lactate dehydrogenase (LDH)**: an enzyme found in the cytoplasm of almost all tissues, which converts L-lactate into pyruvate, or pyruvate into L-lactate depending on the oxygen level. Specify the most recent value in the reporting period, the units of measurement, and the upper limit of normal as listed on the laboratory report.
- **Total serum bilirubin**: Bilirubin is a pigment that is formed from the breakdown of hemoglobin in red blood cells. Serum bilirubin is a test of liver function that reflects the ability of the liver to take up, process, and secrete bilirubin. Total bilirubin includes the *direct* (conjugated) and *indirect* (unconjugated) bilirubin values. If the laboratory reports direct and indirect separately, add the two together to report the total serum bilirubin. Specify the most recent value in the reporting period, units of measurement, and the upper limit of normal as listed on the laboratory report.

If none of the laboratory values were assessed in the reporting period, select **None**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

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Q82 – 91: Renal Assessments

Question 82: Was proteinuria detected? *(excluding microalbuminuria)*

Proteinuria, also known as albuminuria, is excess protein in the urine and may be a sign of kidney disease. Proteinuria may be assessed by 24-hour urine collection or by a dipstick analysis. A value of > 150 mg by 24-hour urine collection or 'positive' by a dipstick analysis is indicative of proteinuria.

Indicate if proteinuria was detected (excluding microalbuminuria) in the current reporting period.

Report **Yes** if the proteinuria was:

- 150 mg by 24-hour urine collection or
- Positive' or trace, 1+, 2+, 3+, or 4+ result by urine dipstick analysis.

Report **No** if the proteinuria was:

- ≤ 150 mg (by 24-hour urine collection) or
- 'Negative' result (by urine dipstick analysis)

If proteinuria was assessed multiple times during the reporting period, report based on the results of the most recent assessment.

If proteinuria was not assessed or it is unknown if proteinuria was assessed during the current reporting period, select **Not done**.

Questions 83 – 84: Urine albumin *(if multiple, report the most recent tested)*

Indicate if urine albumin was measured in the current reporting period. If measured, select **Known**, report the laboratory value and unit of measure documented on the laboratory report. If urine albumin was assessed multiple times within the reporting period, report the most recent results. If urine albumin was not measured or if no information is available to determine if urine albumin was measured in the current reporting period, select **Unknown**.

If the urine albumin is < 30 mg / g, report the urine albumin value as "29 mg / g" (29,000 mg /

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kg).

Question 85 – 86: Urine creatine *(one time urine)*

Indicate if urine creatine was measured in the current reporting period. This should be a *random urine creatine* not a *24 hour urine creatine*. If measured, select **Known**, report the laboratory value and unit of measure documented on the laboratory report. If urine creatine was assessed on multiple dates in the current reporting period, report the most recent results. If urine creatine was not measured or if no information is available to determine if urine creatine was measured in the current reporting period, report **Unknown**.

Question 87: Serum creatinine *(if multiple, report the most recent tested)*

Report the laboratory value and unit of measurement as documented on the laboratory report in the current reporting period. If serum creatinine was measured multiple times in the reporting period, report the most recent results.

If serum creatinine was not measured in the current reporting period, leave the question blank and override the error using the code "Not tested."

Questions 88 – 89: Glomerular filtration rate (GFR) *(if multiple, report the most recent tested)*

GFR is a key measure of kidney function and represents the rate at which the kidneys filter blood to remove waste and excess fluids. GFR may be measured directly through a specialized test or estimated.

Indicate whether the GFR was measured in the current reporting period reporting period. If measured, select **Known** and report the laboratory value as documented on the laboratory report (in mL/min/1.73m^2). If the GFR is an estimated value, select **GFR estimated**. If the GFR was measured multiple times in the reporting period, report the most recent results.

GFR may be reported to the CIBMTR as "actual" or "calculated." If the lab does not calculate the actual GFR value, the following equations may be used to determine the calculated value.

Cockcroft-Gault Equation

GFR = [(140 – age) x Wt] / (72 x Cr)

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- GFR_cg = Glomerular Filtration Rate (Cockcroft) (mL / min)
- Age = Patient Age (years)
- Sex = Gender (Male)
  - If female, multiply result by 0.85
- Wt = Body Weight (kg)
- Cr = Creatinine (S, mg / dL)

An online calculator for this equation can be found here: https://www.kidney.org/professionals/kdoqi/ gfr_calculatorCoc

Bedside Schwartz Equation

eGFR = K x H / Cr

- H = Height (cm)
- Cr = Creatinine (S, mg / dL)
- K =
  - 0.33 for preemies
  - 0.45 for infants to 1 year
  - 0.55 for 1 year to 18 years for females
  - 0.55 for 1 year to 13 years for males
  - 0.70 for adolescent to 18 years for males

An online calculator for this equation can be found here: https://www.kidney.org/professionals/KDOQI/ gfr_calculatorPed

If the laboratory report indicates the GFR as a range, report the average. Example, the laboratory report indicates GFR is 80 – 120, report "100."

If the GFR value is expressed as "> X," report the value as "X+1." Example, the laboratory report indicates the GFR is > 120, report "121."

If the GFR value is reported as "< X", report "X-1." Example, the laboratory report indicates the GFR is < 80, report "79."

If the GFR was not measured or if no information is available to determine if the GFR was assessed in the current reporting period, select **Unknown**.

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Questions 90 – 91: Cystatin-C *(if multiple, report the most recent tested)*

Cystatin-C is a protein produced by all nucleated cells in the body. It plays a key role in regulating the activity of proteases, which are enzymes that break down proteins. Cystatin-C is a biomarker that is primarily used to assess kidney function.

Indicate whether cystatin-C was measured in the current reporting period reporting period. If measured, select **Known** and report the laboratory value as documented on the laboratory report (in mg/L). If cystatin-C was measured multiple times in the reporting period, report the most recent results.

If the cystatin-C was not measured or if no information is available to determine if the cystatin-C was measured in the current reporting period, report **Unknown**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q92 – 98: Splenic Assessments

Question 92: Did the recipient have a splenectomy?

Indicate if the recipient had a splenectomy in the current reporting period.

Report **Not applicable** in the following scenarios:

- **Yes** was reported in a prior reporting period (i.e., splenectomy occurred in a previous reporting period)
- The recipient had a splenectomy prior to infusion
- The recipient was born without a spleen (congenital asplenia).

The **Unknown** option should be used sparingly and only if there is no information to determine if the recipient had a splenectomy.

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Question 93: Did the recipient have splenomegaly?

Indicate if the recipient had splenomegaly (i.e., abnormal enlargement of the spleen) in the current reporting period. Splenomegaly is often documented during the physician's physical assessment of the recipient and represents an abnormal finding. Splenomegaly can also be detected by imaging techniques such as ultrasonography, CT or MRI.

If the recipient did not have splenomegaly or if no information is available to determine if the recipient has splenomegaly in this reporting period, report **No** or **Unknown**, respectively.

Splenic Assessments

The splenic assessment questions can only be completed on the Day 100, six-month, one-year, and two-year follow-up forms. These questions will be skipped for all subsequent reporting periods.

Question 94: Was splenic function assessed?

Evaluation of splenic tissue may be necessary to determine the extent of the recipient's disease. Splenic assessments include the following:

- **Complete RBC**: Also called an erythrocyte count, this assessment is used to determine how many red blood cells are present. One of the several tests included in a CBC.
- **Pitted RBC score**: As red blood cells (RBC) age, membrane vacuoles ("pits") occur. Pitted RBCs may be listed on laboratory reports as a "PIT count."
- **Splenic scan**: Radionuclide spleen scans (liver-spleen scans) are nuclear scan utilizing a radioactive tracer substance that is administered intravenously. The tracer collects in large amounts and shows as bright spots on imaging results. One of the most common methods used is single photon emission computed tomography (SPECT / CT).

Indicate **Yes** if splenic function was assessed by a complete RBC, pitted RBC score, or splenic scan at any time during the current reporting period.

If splenic function was not assessed or no information is available to determine if splenic function was assessed during the current reporting period, select **No** or **Unknown,** respectively. **Unknown** should be used sparingly.

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Report **Not applicable** if the recipient had a prior splenectomy or was born without a spleen (congenital asplenia).

Questions 95 – 98: Select which splenic test was completed

Indicate which splenic test (completed RBC, pitted RBC score, or splenic scan) was completed.

If a **Complete red blood cell count** was performed, specify the value and units of measurement as documented on the laboratory report.

If a **Pitted RBC score** was performed, specify the percentage.

If a **Splenic scan** was performed, specify the results as either **Normal** *(radionuclide uptake)* or **Abnormal** *(no radionuclide uptake)*.

If any of the assessments were performed multiple times in the current reporting period, report the most recent results.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q99– 101: Acute Chest Syndrome

Question 99: Has acute chest syndrome (ACS) occurred?

Acute chest syndrome (ACS) is a term used to identify symptoms of chest pain, cough, fever, decreased oxygen (hypoxia), and lung infiltrates. Due to the sickling nature of red blood cells as a result of sickle cell disease, ACS may result in pulmonary infarction / emboli or viral / bacterial pneumonia. Diagnosis of ACS should be made based on clinical judgement.

Report **Yes** in the following scenarios:

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- There was a new onset of ACS since the date of last report.
- ACS was diagnosed prior to HCT or in a prior reporting period, resolved, and developed in the current reporting period.

Report **No** in the following scenarios:

- There was not a new onset of ACS since the date of last report.
- ACS was diagnosed in a prior reporting period and persisted into the current reporting period.

If the recipient did not experience ACS or if no information is available to determine if the recipient experienced ACS in this reporting period, report **No** or **Unknown**, respectively.

Multiple ACS Events
Complete *Date of ACS event* and *Did this ACS event require hospitalization?* for each ACS event the recipient experienced in the current reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 100: Date of ACS event

Report the date of each acute chest syndrome event that the recipient experienced in the current reporting period.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 101: Did this ACS event require hospitalization?

Indicate if the acute chest syndrome event required hospitalization. Acute chest syndrome must be the primary indication for hospitalization.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

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Q102 – 106: Pain

Question 102: Has vaso-occlusive pain occurred requiring hospitalization or treatment? *(treatment that is in a hospital or clinic setting)*

Vaso-occlusive pain, sometimes called a pain crisis, is a common painful complication of sickle cell disease in adolescents and adults. Recurrent episodes may cause irreversible organ damage.

Report **Yes** in the following scenarios:

- The recipient experienced vaso-occlusive pain requiring hospitalization or treatment (i.e., ER admission, day hospital, inpatient admission, etc.) in the current reporting period.
- The recipient experienced vaso-occlusive pain requiring hospitalization or treatment prior to HCT or in a prior reporting period, resolved, and developed in the current reporting period.

Report **No** in any of the following scenarios:

- The recipient did not experience vaso-occlusive pain the current reporting period
- Vaso-occlusive pain occurred in the reporting period, but hospitalization or treatment was not required
- The recipient was hospitalized or received treatment in a prior reporting period for vaso-occlusive pain and continued hospitalization or treatment into the current reporting period

If no information is available to determine if the recipient required hospitalization or treatment for vaso-occlusive pain since the date of last report, select **Unknown**.

Reporting Multiple Pain Events
Complete *Date of vaso-occlusive pain event* and *Did this vaso-occlusive pain event require hospitalization?* for each ACS event the recipient experienced in the reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 103: Date of vaso-occlusive pain event

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Report the date of each vaso-occlusive pain event that the recipient experienced in the reporting period.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 104: Did this event require hospitalization?

Indicate if the vaso-occlusive pain event required hospitalization. Vaso-occlusive pain must be the primary indication for hospitalization.

Question 105: Has there been any new onset of chronic pain?

Indicate if the recipient experienced a new onset of chronic pain in the current reporting period. Chronic pain is defined as pain that is present a majority of days per month, lasting for ≥ 6 months with one more of the following:

- Without contributory SCD complications (acute vaso-occlusive pain, acute chest syndrome, leg ulcers, avascular necrosis; or,
- Mixed pain type in which chronic pain is occurring at site(s) (arms, back, chest, or abdominal pain) but unrelated to any sites associated with SCD complications

The progress notes should clearly document if chronic pain is present or absent. If is not clear, based on the documentation available, whether chronic pain is present or absent, report **Unknown**.

Chronic Pain Prior to Infusion
For recipients with chronic pain prior to infusion, chronic pain may be reported in the Day 100 reporting period. However, for recipients who did not have chronic pain prior to infusion, the earliest reporting period in which chronic pain should be reported is the six-month reporting period.

Question 106: Were opioids prescribed for the treatment of pain?

Opioids are typically listed in the medical administration record (MAR) and / or in the medication list documented on the progress note within the medical record. Examples of opioid treatment may include Morphine, Hydrocodone, Methadone, Hydromorphone (Dilaudid), etc.

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Indicate if the recipient was prescribed opioids for treatment of either vaso-occlusive or chronic pain related to the primary disease for infusion during this reporting period. If opioids were prescribed for treatment of pain, either intravenous or oral, report **Yes**. If opioids were not prescribed for treatment of pain or if no information is available to determine if opioids were prescribed for treatment of pain, report **No**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q107 – 114: Avascular Necrosis

Question 107: Is there a new area affected by avascular necrosis?

Avascular necrosis is the death of bone tissue due to a lack of adequate blood supply. It is sometimes called osteonecrosis and can lead to minute fractures in the bone followed by eventual collapse. Avascular necrosis can spread from joint to joint and commonly occurs in the hips and shoulders.

Indicate if there was a new onset of avascular necrosis in the current reporting period. Report **Yes** in the following scenarios:

- A new onset of avascular necrosis occurred since the date of last report
- There is a prior diagnosis of avascular necrosis of a joint and a new joint(s) was diagnosed with avascular necrosis since the date of last report (see example below)

Report **No** in the following scenarios:

- If a new onset of avascular necrosis did not occur in the current reporting period
- Avascular necrosis of a specific joint occurred in a prior reporting period and persisted into the current reporting period

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If no information is available to determine if a new onset of avascular necrosis was experienced since the date of last report, **Unknown**.

See examples of reporting scenarios listed below.

Questions 108 – 109: Specify joint(s) affected *(check all that apply)*

Specify the joint(s) affected by the new onset of avascular necrosis; check all that apply. If there was avascular necrosis of a joint not listed, report **Other** and specify the affected joint.

Avascular Necrosis Reporting Scenarios:
Example A. A recipient is diagnosed with avascular necrosis of the hip pre-transplant. Following infusion, the recipient develops avascular necrosis of the left shoulder.

- 100 Day Post-Infusion Data Form
  - *Is there a new area affected by avascular necrosis?*: Report **Yes** to capture the new development of avascular necrosis of the left shoulder.
  - *Specify joint(s) affected*: Select **Shoulder** and continue with the form. "Hip" will not be selected as this was diagnosed pre-transplant.

Example B. A recipient with diagnosed with avascular necrosis of the right knee and resolves in the Day 100 reporting period. In the six-month reporting period, the recipient does not experience avascular necrosis but in the one-year reporting period, the recipient is diagnosed with avascular necrosis of both the right and left knees.

- Day 100 Post-Infusion Data Form
  - *Is there a new area affected by avascular necrosis?*: Report **Yes** to indicate the diagnosis of avascular necrosis of the right knee.
  - *Specify joint(s) affected*: Select **Knee**.

- Six Month Post-Infusion Data Form
  - *Is there a new area affected by avascular necrosis?*: Report **No** as there was not a new onset of avascular necrosis during the reporting period.

- One Year Post-Infusion Data Form

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- *Is there a new area affected by avascular necrosis?*: Report **Yes** to capture the onset of avascular necrosis of the left knee.
- *Specify joint(s) affected*: Select **Knee** again.

Question 110: Was a musculoskeletal MRI performed?

A musculoskeletal (MSK) MRI is a radiation-free imaging scan that uses a strong magnetic field and radio waves to create detailed pictures of bones, joints, muscles, tendons, ligaments, and soft tissues.

Indicate if a musculoskeletal MRI was performed during the current reporting period. If musculoskeletal MRI was not performed or if no information is available to determine if a musculoskeletal MRI was performed in this reporting period, report **No**.

WARRIOR-SCD

Attaching the report (when available) is required for WARRIOR-SCD.

Questions 111: Indicate if the musculoskeletal MRI report is attached

Indicate if the musculoskeletal MRI report was **Attached** in FormsNet3^{SM}. If multiple musculoskeletal MRIs were performed in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Questions 112 – 114: Did the recipient undergo a joint replacement?

Osteonecrosis can lead to severe joint pain and early development of arthritis. Osteonecrosis is the most common reason for joint replacement in young recipients with sickle cell disease. This information should be under surgical history in the EMR.

Specify if the recipient underwent joint replacement during the current reporting period. If **Yes**, specify the location of the joint replacement. If more than one joint was replaced in the reporting

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period, select all that apply. If joint replacement took place in a location not listed, report **Other** and specify the replaced joint.

If joint replacement did not occur or no information is available to determine if joint replacement occurred during the current reporting period, report **No**.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q115 – 124: Central Nervous System

Questions 115 – 117: Was transcranial doppler velocity assessed at any time?

Transcranial doppler and transcranial color doppler are types of ultrasonography that measure the velocity of blood flow through the brain's blood vessels by measuring the echoes of ultrasound waves moving trans-cranially.

Indicate if transcranial doppler velocity was assessed at any time in the current reporting period. If **Yes**, report the date of the most recent assessment and the transcranial doppler velocity value in cm / sec.

If transcranial doppler velocity was not assessed or if no information is available to determine if transcranial doppler velocity was assessed in the current reporting period, report **No** or **Unknown**.

Attaching Transcranial Doppler Velocity Report
This question is only applicable to WARRIOR-SCD

WARRIOR-SCD
Attaching the report (when available) is required for WARRIOR-SCD.

Question 118: Indicate if the transcranial doppler velocity report is attached

Indicate if the transcranial doppler velocity report was **Attached** in FormsNet3^{SM}. If transcranial

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doppler velocity was assessed multiple times in the current reporting period, attach the most recent report. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Question 119: Have any new sickle cell central nervous system (CNS) complications occurred?

A CNS complication is the development of different neurologic signs and symptoms that occur in recipients with sickle cell disease. See *Specify type of CNS complication* below for a list of CNS events.

Report **Yes** if the recipient experienced a new manifestation of a CNS complication(s) reporting the current reporting period.

Report **No** in the following scenarios:

- A new CNS complication did not occur in the current reporting period.
- The recipient experienced a CNS complication in a prior reporting period and follow-up scans are performed in the current reporting period.

If no information is available to determine if a new CNS complication occurred in the reporting period, report **Unknown**.

Reporting Multiple CNS Events
Complete *Specify type of CNS complication, Year of onset,* and *Was an MRI / MRA of the brain performed for the diagnosis of this reported CNS complication?* for each complication in the reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 120: Specify type of CNS complication

Indicate the type of CNS complication(s) that occurred. If multiple CNS complications occurred, report each CNS complication as a separate instance. If the same CNS complication occurred multiple times throughout the reporting period (e.g. multiple seizures), only one instance needs to be reported.

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- **Cerebral venous thrombosis:** A blood clot in the cerebral vein in the brain.
- **Hemorrhagic stroke:** Blood vessels break and bleeds in the brain.
- **Ischemic stroke:** The most common type of stroke. Occurs when a blood vessel in the brain is blocked or narrowed, causing reduced blood flow.
- **Moyamoya:** A rare condition where the carotid artery is blocked or narrowed which reduces the blood flow to the brain.
- **Overt stroke:** A focal neurologic deficit lasting more than 24 hours. If the type of CNS event is not documented and only noted as a "stroke," select this option.
- **Posterior reversible encephalopathy syndrome (PRES)**: An acute neurotoxic syndrome that is characterized by a spectrum neurological and radiological feature from various risk factors. Common neurological symptoms includes headache, impairment in level of consciousness, seizures, visual disturbances, and focal neurological deficits
- **Seizure:** Uncontrolled electrical activity in the brain, which may produce a physical convulsion, minors physical sings, thought disturbances or a combination of symptoms.
- **Silent stroke:** Asymptomatic stroke, usually found on a screening brain MRI. Often associated with cognitive deficits.
- **Transient ischemic stroke:** A temporary period of mild stroke symptoms that lasts only a few minutes and does not result in permanent damage. This is also known as transient ischemic attack or a ministroke.

Questions 121 – 122: Date of onset

Indicate if the date of onset of the CNS event being reported in this instance is **Known**. If **Known**, report the date of onset.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 123: Was an MRI / MRA of the brain performed for the diagnosis of this reported CNS complication ?

Magnetic resonance imaging (MRI) is an imaging technique used to form pictures of the anatomy and the physiological processes of the body. Magnetic resonance angiography (MRA) is similar to MRI but is used to specifically examine blood vessels.

Indicate if an MRI or MRA of the brain was performed to diagnose the CNS event being reported in

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this instance.

If an MRI / MRA of the brain was not performed to diagnose the CNS event being reported in this instance or if no information is available to determine if an MRI / MRA of the brain was performed to diagnose the CNS event being reported in this instance, report **No** or **Unknown**, respectively.

WARRIOR-SCD
Attaching the report (when available) is required for WARRIOR-SCD.

Question 124: Indicate if the MRI / MRA report is attached

Indicate if the MRI / MRA report performed to diagnose the CNS event being reported in this instance was **Attached** in FormsNet3^{SM} . The diagnostic MRI / MRA report may not be the most recent scan performed prior to the start of the preparative regimen / infusion. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q125 – 132: Other Symptoms

Priapism
Questions regarding priapism are applicable to only biologically male recipients.

Question 125: Did one or more episodes of priapism occur? *(to be answered for males only)*

Priapism is defined as prolonged erection of the penis, usually without sexual arousal.

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Indicate if the recipient experienced one or more episodes of priapism (with or without treatment) in the current reporting period. If the recipient did not experience any episodes of priapism in the current reporting period or if no information is available to determine if priapism occurred in the current reporting period, report **No** or **Unknown**, respectively.

Reporting Multiple Priapism Episodes
Complete *Date of priapism episode* for each priapism episode in the current reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 126: Date of priapism episode

Report the date of each priapism episode that the recipient experienced in the current reporting period.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 127: Has a new onset of sickle cell retinopathy developed?

Sickle cell retinopathy is an ocular manifestation of sickle cell disorders characterized by ocular damage due to trapping of sickle-shaped cells in the small blood vessels in various structures of the eye. Diagnosis of sickle cell retinopathy should be made by an ophthalmologist and is typically documented within the recipient's medical record. Seek physician clarification if it is unclear if there was a new onset of sickle cell retinopathy in the current reporting period.

Indicate **Yes** if the recipient developed a new onset of sickle cell retinopathy in the current reporting period.

Report **No** in in the following scenarios:

- There was not a new onset of sickle cell retinopathy since the date of last report.
- Sickle cell retinopathy was diagnosed in a prior to HCT or in a prior reporting period, resolved, and developed again in the current reporting period.
- Sickle cell retinopathy was diagnosed in a prior reporting period and persisted into the current reporting period.

If documentation is not clear or is not available to determine if sickle retinopathy occurred in the

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current reporting period, report **Unknown**.

Question 128: Have chronic leg ulcers developed?

Chronic leg ulcers are defined as a defect of the skin below the level of the knee persisting for more than six weeks with no tendency to heal after three or more months.

Indicate whether the recipient developed chronic leg ulcers during the current reporting period.

If chronic leg ulcers were diagnosed in the current reporting period (first onset), report **Yes**.

Report **No** in the following scenarios:

- Chronic leg ulcers did not develop in the current reporting period.
- Chronic leg ulcers developed prior to HCT or in a prior reporting period and persisted into the current reporting period.
- Chronic leg ulcers developed in a prior reporting period, resolved, and developed again in the current reporting period.

If no information is available to determine if chronic leg ulcers developed in the current reporting period, select **Unknown**.

Question 129: Is there a new diagnosis of asthma or a reactive airway disease?

Asthma is a condition where the airways narrow, swell, and produce extra mucus which results in breathing difficulty, coughing, wheezing, and shortness of breath. Reactive airway disease (RAD) is a general term used to describe coughing, wheezing or shortness of breath when a specific diagnosis has not been made (i.e., asthma, chronic obstructive pulmonary disease, etc.).

Indicate if there was a new diagnosis of asthma or a reactive airway disease during the current reporting period.

If the recipient was clinically diagnosed with asthma or reactive airway disease in the current reporting period, select **Yes**.

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Report **No** in the following scenarios:

- There was not a diagnosis of asthma or reactive airway disease in the current reporting period.
- Asthma and reactive airway disease were diagnosed in a prior reporting period.

If there is no information available to determine if there was a diagnosis of asthma or reactive airway disease in the current reporting period, select **Unknown**.

Question 130 : Has a venous thromboembolism developed?

Venous thrombosis embolism, also called a venous thromboembolism, is a condition characterized by formation of blood clots in deep veins of the body. These clots typically manifest in the lower leg, thigh, or pelvis, but have been noted to occur in the arm.

Indicate if the recipient developed venous thromboembolism during the current reporting period.

If the recipient developed a venous thromboembolism, report **Yes**.

Report **No** in any of the following scenarios:

- A venous thrombosis did not develop in the current reporting period.
- A venous thrombosis developed in a prior reporting period and persisted into the current reporting period.

If no information is available to determine if a venous thrombosis embolism developed in the current reporting period, select **Unknown**.

Question 131: Was it associated with an indwelling catheter?

There are several types of long-term indwelling central line catheters used to access veins. Examples include Hickman, Broviac, PICC, etc. which carry a risk of developing a blood clot.

Indicate if the venous thrombosis embolism was associated with the recipient's indwelling catheter. If the venous thromboembolism was not associated with the recipient's indwelling catheter or if no information is available to determine if the venous thromboembolism was associated with the recipient's indwelling catheter in the current reporting period, report **No**.

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Multiple Splenic Sequestration Events
For each splenic sequestration event the recipient experienced in the reporting period, complete *Date of splenic sequestration event* for each event in the reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 132 : Date of splenic sequestration event

Report the date of each splenic sequestration event that the recipient experienced in the reporting period.

If there were no splenic sequestration events in this reporting period, leave the question blank and override the error using the code "Verified Correct."

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q133 – 145 : Existing Organ Impairments

Multiple Organ Impairments
Complete *Specify organ impairments or disorders developed, Date of diagnosis, Method used to assess osteopathies, DEXA scan vertebral, DEXA scan hip, Quantitative CT vertebral* and *Quantitative CT vertebral* for each organ impairment in the reporting period by adding an additional instance in the FormsNet3^{SM} application.

Question 133: Specify organ impairments or disorders developed

Indicate if the recipient developed any of the co-existing disease or organ impairments listed below during the current reporting period.

- **Amenorrhea**: Absence of menstruation

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- **Cardiomyopathy**: A disease of the heart muscle that makes it more difficult for the heart to pump blood to the rest of the body
- **Cholelithiasis**: Presence of one or more gallstones in the gallbladder
- **Growth hormone deficiency / short stature**: A condition in which the body does not produce enough growth hormone / a reduced overall rate of growth.
- **Hypersplenism**: Overactive spleen. Diagnosis is typically based on a physician's exam (checking for splenomegaly), a CBC to assess the concentration of red and white blood cells, and / or an ultrasound, measuring the size of the spleen.
- **Hypogonadism / gonadal dysfunction**: A condition where there is a hyperfunction of the gonads. It can manifest as precocious puberty, and is caused by abnormally high levels of testosterone or estrogen, crucial hormones for sexual development.
- **Hypothyroidism requiring replacement therapy**: Decreased activity of the thyroid gland. Diagnosis of hypothyroidism includes high levels of thyroid-stimulating hormone (TSH). Symptoms of hypothyroidism include fatigue, depression, weakness, weight gain, musculoskeletal pain, decreased taste, hoarseness, and / or puffy face.
- **Osteonecrosis**: Flow to part of a bone is disrupted. This results in death of bone tissue, and the bone can eventually break down and the joint will collapse.
- **Osteopathies (porosis, penia)**: Includes osteoporosis or osteopenia. Osteopathies should be reported if osteopenia or osteoporosis is documented within the medical record by the physician or based on the Z or T-score. Osteopenia is defined as a Z or T-score between -1.0 and -2.0 by a DEXA or quantitative CT scan. Osteoporosis is defined as a Z or T-score less than -2.0 by a DEXA or quantitative CT scan.
- **Retinal changes**: Changes include but are not limited to macular degeneration, floaters, diabetic eye disease, retinal detachment, and retinitis pigmentosa.
- **Thrombosis**: Blood clot within the vein or artery.

The co-existing disease or organ impairment should be reported in any of the following scenarios:

- The co-existing disease or organ impairment was first diagnosed in the current reporting period.
- The co-existing disease or organ impairment was diagnosed prior to infusion or in a prior reporting period and persisted into the current reporting period.
- The co-existing disease or organ impairment was diagnosed prior to infusion or in a prior reporting period, resolved, and then recurred in the current reporting period.

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Report **None** in any of the following scenarios:

- No co-existing disease or organ impairments developed during the current reporting period.
- A co-existing disease or organ impairment developed prior to start of the preparative regimen / infusion or in a prior reporting period but resolved before the current reporting period.

Question 134 : Was this organ impairment previously reported?

Specify if the co-existing disease or organ impairment diagnosis date was previously reported.

If the co-existing disease or organ impairment was diagnosed prior to infusion or in a prior reporting period, resolved, and then recurred in the current reporting period, report **No**.

Question 135 : Date of diagnosis

Report the diagnosis date of the co-existing disease or organ impairment.

If the co-existing disease or organ impairment was diagnosed prior to infusion or in a prior reporting period, resolved, and then recurred in the current reporting period, report the diagnosis date as the date of the most recent episode.

If the exact date is not known report an estimated date and check the **Date estimated** box.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Question 136 : Method used to assess osteopathies *(report the most recent Z or T-score available. Z-scores are used in patients younger than or equal to 20 and T-scores in patients older than 20) (check all that apply)*

Specify the method used to assess osteopathy being reported in this instance. Select all that apply.

If the method was not documented or if no information is available to determine the method, report **Unknown**.

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Questions 137 – 138: DEXA scan vertebral

Indicate if the vertebral Z-score by DEXA is **Known**. If **Known**, report the Z or T-score. Select Negative value if the Z or T-score is a negative (i.e., Z-score is -1.0).

If multiple DEXA scans were performed during the current reporting period, report the most recent vertebral Z or T-score.

Questions 139 – 140: DEXA scan hip

Indicate if the hip Z-score by DEXA is **Known**. If **Known**, report the Z or T-score. Select Negative value if the Z or T-score is a negative (i.e., Z-score is -1.0).

If multiple DEXA scans were performed during the current reporting period, report the most recent hip Z or T-score

Questions 141 – 142: Quantitative CT vertebral

Indicate if the vertebral Z-score by quantitative CT is **Known**. If **Known**, report the Z or T-score. Select Negative value if the Z or T-score is a negative (i.e., Z-score is -1.0).

If multiple quantitative CT scans were performed during the current reporting period, report the most recent vertebral Z or T-score.

Questions 143 – 144: Quantitative CT hip

Indicate if the hip Z-score by quantitative CT is **Known**. If **Known**, report the Z or T-score. Select Negative value if the Z or T-score is a negative (i.e., Z-score is -1.0).

If multiple quantitative CT scans were performed during the current reporting period, report the most recent hip Z or T-score.

Attaching DEXA Scan report
This question is only applicable to WARRIOR-SCD

WARRIOR-SCD
Attaching the report (when available) is required for WARRIOR-SCD.

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Question 145: Indicate if the DEXA scan report is attached

Indicate if the DEXA scam was **Attached** in FormsNet3^{SM}. If multiple DEXA scans were performed, attach the most recent report in the current reporting period. Attaching the report will prevent future requests to submit additional data for research studies.

If the report is not available for any reason, select **Not available**.

For instructions on how to attach documents in FormsNet3^{SM}, refer to the Training Guide.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q146 – 152: Disease Modifying Therapies

Question 146: Were disease modifying therapies given or stopped? *(excludes blood transfusions)*

Indicate if the recipient received any disease modifying therapies or if the recipient discontinued a disease modifying therapy in the current reporting period; excluding blood transfusion(s). See the question below for a list of common disease modifying therapies)

If the recipient received disease modifying therapy(ies) or discontinued a disease modifying therapy in the current reporting period, select **Yes**.

If the recipient did not receive disease modifying therapy(ies) or if no information is available to determine if disease modifying therapy was given in the current reporting period, select **No** or **Unknown**, respectively.

Report **Not applicable** if the recipient started a disease modifying therapy in a prior reporting period and is still receiving therapy on the date of contact for the current reporting period.

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Disease Modifying Therapies
Complete questions *Specify the disease modifying therapy, Date therapy started, Date therapy stopped* for each disease modifying therapy received in the reporting period by adding an additional instance in the FormsNet3^{SM} application.

Same Therapy Restarted
If the same therapy was started and stopped in the current reporting period, only one instance needs to be reported. In this case, report the therapy start date as the date when therapy first began.

Questions 147 – 148: Specify the disease modifying therapy

Select the disease modifying therapy the recipient received. If the recipient received a therapy which is not listed, report **Other** and specify the agent. Report the generic name of the agent, not the brand name.

- **Crizanlizumab (Adakveo)**: A monoclonal antibody given to reduce the frequency of vaso-occlusive crises.
- **Hydroxyurea**: A type of chemotherapy. Common brand names include Droxia, Hydrea, and Xromi.
- **L-Glutamine**: An amino acid in the form of an oral powder given to reduce the complications of sickle cell disease. Also known as Endari.
- **Voxelotor (Oxbryta)**: An oral medication given to inhibit sickle hemoglobin polymerization.

Questions 149 – 150: Date therapy started

Indicate whether the start date is **Known**. If **Known**, report the date the recipient began this line of therapy. If the exact date is not known report an estimated date and check the **Date estimated** box.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

If therapy was started in a prior reporting period and continued to the current reporting period, select **Previously reported**. This option is not applicable for the Day 100 reporting period.

Questions 151 – 152: Date therapy stopped

Indicate if the therapy stop date is **Known**. If **Known**, use the following instructions to report the end date:

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- If the therapy is administered in cycles, report the date the recipient started the last cycle for this line of therapy.
- If the therapy is administered on a daily basis, report the last date the recipient received the line of therapy being reported.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Report **Not applicable** if the recipient is still receiving therapy on the contact date for the current reporting period.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q153 – 178: Other Laboratory Studies

Questions 153 – 154 : Was hemoglobin electrophoresis performed? *(do not include results if an RBC transfusion occurred within 4 weeks of the electrophoresis study)*

Indicate if hemoglobin electrophoresis studies were performed during the current reporting period. If **Yes,** provide the date of the *most recent* hemoglobin electrophoresis study performed in the current reporting period.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

If hemoglobin electrophoresis studies were not performed or if no information is available to determine if hemoglobin electrophoresis studies were performed in the current reporting period, select **No** or **Unknown**, respectively.

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If RBC transfusion(s) were given within four weeks of the hemoglobin electrophoresis, report **Not applicable**.

Hemoglobin Electrophoresis

Some centers do not routinely perform hemoglobin electrophoresis studies and may perform chimerism studies instead. The chimerism results are reported in the Chimerism Studies section of the Post-Infusion Follow-Up (2100) Form. For centers that performed both hemoglobin electrophoresis and chimerism studies, report the results of both on the appropriate forms.

Hemoglobin Types: Hb A and Hb A1

Hb A and Hb A1 are the same hemoglobin types. If Hb A1 is assessed, report these results under **Hb A**.

Questions 155 – 167: Specify the hemoglobin allele types based on the reported sample

Specify the hemoglobin allele types identified in the reported hemoglobin electrophoresis study reported above. If the hemoglobin allele type was assessed, report **Yes** and specify the percentage. If additional sickle related hemoglobin allele types are identified and not listed as options on the form, report **Yes** for *Other sickle related hemoglobin allele type*, specify the other hemoglobin type, and provide the percentage.

Report **No** if the specified hemoglobin allele type was not assessed in the hemoglobin electrophoresis study reported above.

Questions 168 – 170: Were absolute reticulocyte counts tested?

Indicate if absolute reticulocyte counts were assessed in the current reporting period. If report **Yes**, provide the absolute reticulocyte cell count, the units of measurement as noted on the laboratory report, and specify the date the sample was collected for examination. If the absolute reticulocyte count was assessed multiple times in the current reporting period, report the value and date of the most recent assessment.

If absolute reticulocyte counts were not tested or if no information is available to determine if absolute reticulocyte counts were tested in the current reporting period, select **No** or **Unknown**, respectively.

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For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 171 – 173: Were soluble transferrin receptors (sTfR) tested?

Soluble transferring receptors (sTfR) are proteins found in the blood and are used as a measure of functional iron status. These levels are typically elevated in individuals with an iron deficiency (i.e., iron deficiency anemia). This assessment is a blood test and may be performed at the transplant center or by an outside facility.

Indicate if sTfR was tested in the current reporting period. If **Yes**, provide the sTfR value in mg / L, and specify the date the sample was collected for examination. If sTfR was measured multiple times in the current reporting period, report the most recent results.

If the sTfR was not tested or if no information is available to determine if sTfR counts were tested in the current reporting period, select **No** or **Unknown**, respectively.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 174 – 176: Was an erythropoietin (EPO) level obtained?

Erythropoietin (EPO) is a hormone predominantly produced in the kidneys which plays a critical role in the production of red blood cells.

Indicate if EPO was tested in the current reporting period. If **Yes**, provide the EPO level in IU / L, and report the date the sample was collected for examination. If EPO was measured multiple dates in the current reporting period, report the results of the most recent assessment.

If EPO levels were not tested or if no information is available to determine if EPO levels were tested in the current reporting period, select **No** or **Unknown**, respectively.

For more information regarding reporting partial or unknown dates, see General Instructions, General Guidelines for Completing Forms.

Questions 177 – 178: Was a D-dimer level tested?

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D-dimer is a byproduct of the blood clotting and breakdown process, serving as a marker of ongoing coagulation and fibrinolysis. The D-Dimer test is a quantitative immunoturbidimetric test, elevated levels may indicate the presence of pulmonary embolism, deep vein thrombosis, arterial thrombosis or DIC.

Indicate if a D-Dimer test was conducted in the current reporting period. If **Yes**, provide the D-dimer level and units of measurement. If the D-dimer test was taken multiple times, report the most recent value in the current reporting period.

If D-dimer tests were not measured or if no information is available to determine if D-dimer tests were conducted in the current reporting period, select **No** or **Unknown**, respectively.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q179: Disease Status

Question 179: What is the status of sickle cell disease at the time of this report, or at the time of death?

Report the status of the recipient's sickle cell disease based on the Hb S and clinical symptoms at the time of evaluation, or death, for this reporting period. The term "clinical symptoms" refers to the clinical complications captured above (i.e., vaso-occlusive pain, acute chest syndrome, avascular necrosis, etc.). See below for additional details regarding the available disease status options:

- **Hb electrophoresis (Hb S) ≤ 50% and clinical symptoms described are absent:** The Hb S value at the time of evaluation for the current reporting period is ≤ 50% (reported above), the clinical symptoms are absent, and the recipient is not receiving disease modifying agents.
- **Hb S > 50% and clinical symptoms described are absent:** The Hb S value at the time

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of evaluation for the current reporting period is > 50% (reported above), the clinical symptoms are absent, and the recipient is not receiving disease modifying agents.

- **Hb S > 50% and clinical symptoms described are present:** The Hb S value at the time of evaluation for the current reporting period is > 50% (reported above), the clinical symptoms are present, and the recipient is not receiving disease modifying agents.
- **Recipient is receiving disease modifying therapy:** Select this disease response option if the recipient is still receiving disease modifying agents on the date of contact for the current reporting period, regardless of if improvement was observed in Hb S values.

If therapy was discontinued prior to the contact date and Hb S was not re-assessed, report the disease status as either **Hb S > 50% and clinical symptoms described are absent** or **Hb S > 50% and clinical symptoms described are present** based on the absence or presence of clinical symptoms.

If the Hb S is ≤ 50% but clinical symptoms are present, leave the question blank and override the error using the code "Unable to answer," and explain the Hb S is ≤ 50%; however, clinical symptoms are present in the comment section.

If it is unclear whether clinical symptoms are still present at the time of evaluation for the current reporting period, confirm with the attending physician.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

Q180: Marrow Evaluation

Marrow Evaluation
Complete *Was a marrow aspirate and / or biopsy performed?* for gene therapy infusions only.

Question 180: Was marrow aspirate and /or biopsy performed?

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Indicate if a marrow aspirate and or biopsy was performed in this reporting period.

If the recipient is enrolled in WARRIOR-SCD, also complete the Laboratory Studies (3502) Form and Marrow Surveillance (3506) Form. The intent is to screen for and/or identify changes in the marrow such as dysplasia, MDS, or new hematologic malignancy.

Report **Unknown** if there is no information to determine if a marrow aspirate or biopsy was completed in the current reporting period.

Section Updates

Question Number	Date of Change	Add/Remove/Modify	Description	Reasoning (if applicable)

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