

## **Anemia Episode Report**

	Center Number: _	Participant Number:	Participant's Initials:				
nemia Episode							
onfirmatory value satisfying		rit level below the lower limit of normal (LLN) for when the <b>initial</b> value is observed, and ends w CR intervention.	•				
Identifying Information	on						
1 Date of initial report	pate of initial report:/						
	king this report:						
ease complete Section rmal. Value(s) Below the Lo	-	hemoglobin and/or hematocrit was be	elow the lower limit				
3 Date of lab test:	y month year						
	Value	Lower Limit of Normal (LLN)	Below LLN?				
4 Hemoglobin:			□ <sub>0</sub> No □ <sub>1</sub> Ye				
5 Hematocrit:			□ <sub>0</sub> No □ <sub>1</sub> Ye				
6 RBC:			□ <sub>0</sub> No □ <sub>1</sub> Ye				
7 Iron level:			□ □ No □ 1 Yes				
<b>5.</b> .	epeated in two weeks. The iron lev	·					
11 Date of repeat lab to	day month year						
	Value	Lower Limit of Normal (LLN)	Below LLN?				
12 Hemoglobin:			□ <sub>0</sub> No □ <sub>1</sub> Ye				
			$\square_0$ No $\square_1$ Ye				
13 Hematocrit:			0140 1116				
13 Hematocrit: 14 RBC:							



## **Anemia Episode Report**

	Center Number:	Participant Number:	Participant's Initials:			
Anemia Episode	(continued)					
Medical Help Outsic	de the Study:					
-	nt advised to seek medical help ou	itside the study?				
	ndicate the reason why not:	nside ine siedy.				
		returned to acceptable values → If the he	matology and iron levels			
_			acceptable values, then the			
		episode has resolved. Stop he				
	-	sign the form on the last page, and				
		_	he participant's binder.			
Г	98 Other (specify):		no parneipani s sinaon			
	Date on which patient was advised	day month year				
One Month Follow-u	-					
= -		e values, the hematology panel and iron leve	ls are repeated one month afte			
the treatment was initiat						
17 Date of one month	h follow-up lab test:/	/				
	Value	Lower Limit of Normal (LLN)	Below LLN?			
1						
18 Hemoglobin:			$\square_{0}$ No $\square_{1}$ Yes			
18 Hemoglobin: 19 Hematocrit:			□ <sub>0</sub> No □ <sub>1</sub> Yes □ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit:			□ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit: 20 RBC: 21 Iron level:	· · · · · · · · · · · · · · · · · · ·		□ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit: 20 RBC: 21 Iron level: Temporary Discont		emporarily discontinued	□ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilif anemia is not improvin	ng or worsens, the CR intervention is to	•	□ No □ Yes			
19 Hematocrit: 20 RBC: 21 Iron level: Temporary Discontill anemia is not improving 22 Was the participa	ng or worsens, the CR intervention is to int temporarily discontinued from t	he CR intervention?	□ <sub>0</sub> No □ <sub>1</sub> Yes □ <sub>0</sub> No □ <sub>1</sub> Yes □ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and improving a series of the participation o	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	he CR intervention? ot temporarily discontinued (check only o	□ <sub>0</sub> No □ <sub>1</sub> Yes			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and improving a series of the participation o	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	the CR intervention?  of temporarily discontinued (check only of streturned to acceptable values → If the he	□ No □ Yes			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and improving a series of the participation o	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	he CR intervention?  ot temporarily discontinued (check only o  s returned to acceptable values → If the he  return to	ne):  o No			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and improving a series of the participation o	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	the CR intervention?  of temporarily discontinued (check only of streturned to acceptable values → If the here return to episode	ne):  moglobin and iron levels acceptable levels, the has resolved. Stop here, sig			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and improving a series of the participation o	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	the CR intervention?  of temporarily discontinued (check only of streturned to acceptable values → If the here return to episode	ne): moglobin and iron levels acceptable levels, the			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilif anemia is not improvint 22 Was the participa  □₀ No → If No: I	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	the CR intervention?  ot temporarily discontinued (check only of some statement of the head of the head of the head of the form to the form the fo	ne):  moglobin and iron levels acceptable levels, the has resolved. Stop here, sig			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilif anemia is not improvint 22 Was the participat  □ No → If No: I	ng or worsens, the CR intervention is to int temporarily discontinued from t Indicate the reason why CR was no	he CR intervention?  ot temporarily discontinued (check only of streturned to acceptable values → If the head return to episode the form forward	ne): moglobin and iron levels acceptable levels, the has resolved. Stop here, sig			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilif anemia is not improving 22 Was the participa  □₀ No → If No: I	ng or worsens, the CR intervention is to not temporarily discontinued from to temporarily discontinued from to temporarily discontinued from the temporarily discontinued from the temporary discontinued in the temporary discontinued from the t	he CR intervention?  ot temporarily discontinued (check only of streturned to acceptable values → If the head return to episode the form forward	me):  moglobin and iron levels acceptable levels, the has resolved. Stop here, sig on the last page, and to the coordinating center next batch of data forms.			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and its not improving 22 Was the participation in No. If Yes.	ng or worsens, the CR intervention is to ant temporarily discontinued from to a surface the reason why CR was not a surface. Hemoglobin panel and iron levels are a surface. Surface of the specify:  Complete the Temporary Discontinuation of the complete surface.	the CR intervention?  ot temporarily discontinued (check only of streturned to acceptable values → If the here return to episode the form forward with the	me):  moglobin and iron levels acceptable levels, the has resolved. Stop here, sign on the last page, and to the coordinating center next batch of data forms.			
19 Hematocrit: 20 RBC: 21 Iron level:  Temporary Discontilification and its not improving 22 Was the participation in No. If Yes.	ng or worsens, the CR intervention is to ant temporarily discontinued from to a second the second that the reason why CR was not a second to a second the second that the seco	he CR intervention?  ot temporarily discontinued (check only of streturned to acceptable values → If the head return to episode the form forward with the	me):  moglobin and iron levels acceptable levels, the has resolved. Stop here, sign on the last page, and to the coordinating center next batch of data forms.			



## **Anemia Episode Report**

		Center Number:	Participant Number:	Participant's Initials:					
A	nemia Episode (conti	nued)							
	Two Month Follow-up Val								
	If anemia is not improving or is worsening after the CR intervention was temporarily discontinued for one month, the intervention is permanently discontinued.								
	23 Date of two month follow-up lab test:/								
		Value	Lower Limit of Normal (LLN)	Below LLN?					
	24 Hemoglobin:			□₀ No □₁ Yes					
	25 Hematocrit:			□ <sub>0</sub> No □ <sub>1</sub> Yes					
	<b>26</b> RBC:			□ <sub>0</sub> No □ <sub>1</sub> Yes					
	27 Iron level:			□ <sub>0</sub> No □ <sub>1</sub> Yes					
Permanent Discontinuation  28 Was the participant permanently discontinued from the CR intervention?  □ No → If No: Indicate the reason why CR was not permanently discontinued (check only one): □ Hemoglobin panel and iron levels returned to acceptable values □ Solther (specify): □ Yes → If Yes: Please complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.  Please provide a description of this episode including actions taken:									
C	tudy Managay's Si	ma minus de la companya de la compan							
3	Study Manager's Signature:								
Si	gnature:		Date:/_	/					