

Center Number: ____ Participant Number: ____ Participant's Initials: ____
first middle last

Anemia Episode

Anemia is defined as a decrease in hemoglobin and/or hematocrit level below the lower limit of normal (LLN) for the laboratory, followed by a confirmatory value satisfying the same criteria. Reporting starts when the **initial** value is observed, and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention.

A Identifying Information

1 Date of initial report: ____/____/____
day month year

2 Name of person making this report: _____

Please complete Section B according to whether the hemoglobin and/or hematocrit was below the lower limit of normal.

B Value(s) Below the Lower Limit of Normal:

3 Date of lab test: ____/____/____
day month year

	Value	Lower Limit of Normal (LLN)	Below LLN?
4 Hemoglobin:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
5 Hematocrit:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
6 RBC:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
7 Iron level:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes

C

D Repeat Test:

The hematology panel is repeated in two weeks. The iron level is also repeated.

11 Date of repeat lab test: ____/____/____
day month year

	Value	Lower Limit of Normal (LLN)	Below LLN?
12 Hemoglobin:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
13 Hematocrit:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
14 RBC:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
15 Iron level:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes

If the repeated test confirms the previous findings, a participant is advised to seek medical help outside of the study. Nevertheless, s/he continues the CR intervention.

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Anemia Episode (continued)

E Medical Help Outside the Study:

16 Was the participant advised to seek medical help outside the study?

No → If No: Indicate the reason why not:

Hematology panel and iron levels returned to acceptable values → If the hematology and iron levels return to acceptable values, then the episode has resolved. Stop here, sign the form on the last page, and store in the participant's binder.

Other (specify): _____

Yes → If Yes: Date on which patient was advised: ____/____/____
day month year

F One Month Follow-up Test

If the hematology and iron levels do **not** return to acceptable values, the hematology panel and iron levels are repeated one month after the treatment was initiated.

17 Date of one month follow-up lab test: ____/____/____
day month year

	Value	Lower Limit of Normal (LLN)	Below LLN?
18 Hemoglobin:			<input type="checkbox"/> No <input type="checkbox"/> Yes
19 Hematocrit:			<input type="checkbox"/> No <input type="checkbox"/> Yes
20 RBC:			<input type="checkbox"/> No <input type="checkbox"/> Yes
21 Iron level:			<input type="checkbox"/> No <input type="checkbox"/> Yes

G Temporary Discontinuation

If anemia is not improving or worsens, the CR intervention is temporarily discontinued.

22 Was the participant temporarily discontinued from the CR intervention?

No → If No: Indicate the reason why CR was not temporarily discontinued (check only one):

Hemoglobin panel and iron levels returned to acceptable values → If the hemoglobin and iron levels return to acceptable levels, the episode has resolved. Stop here, sign the form on the last page, and forward to the coordinating center with the next batch of data forms.

Other (specify): _____

Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

Continue to Section H, next page.

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Anemia Episode *(continued)*

H Two Month Follow-up Value

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: ____ / ____ / ____
day month year

	Value	Lower Limit of Normal (LLN)	Below LLN?
24 Hemoglobin:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
25 Hematocrit:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
26 RBC:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
27 Iron level:			<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes

I Permanent Discontinuation

28 Was the participant permanently discontinued from the CR intervention?

₀ No → If No: Indicate the reason why CR was not permanently discontinued (*check only one*):

₁ Hemoglobin panel and iron levels returned to acceptable values

₉₈ Other (*specify*): _____

₁ Yes → If Yes: Please complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately.

J Please provide a description of this episode including actions taken: _____

Study Manager's Signature:

Signature: _____ Date: ____ / ____ / ____
day month year