

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

Excessive Weight Loss Episode

Excessive weight loss is defined as a BMI < 18.5 kg/m². This report is completed for each episode of excessive weight loss. Reporting starts when the BMI level is first observed to be < 18.5 kg/m², and ends when the episode either resolves or the participant is permanently discontinued from the CR intervention as a direct result of this episode.

A Identifying information

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

2 Name of person making this report: _____

B BMI below 18.5 kg/m²

3 Date of threshold value: ____/____/____
day month year

4 Height: ____ . ____ cm (from original measurement at Screening)

5 Weight: ____ . ____ kg

6 Calculated BMI: _____ kg/m²

C Temporary Discontinuation

If BMI < 18.5 kg/m², the participant is advised about the risks of excessive weight loss and is prescribed a diet plan with increased number of calories up to the baseline level for up to one month.

7 Was CR temporarily discontinued and a diet plan prescribed?

No → If No: Indicate the reason why it was not temporarily discontinued: _____

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

D Follow-up BMI Value

The CR intervention is only restarted if the BMI increases to 18.5 kg/m² or higher after one month of treatment.

8 Date of follow-up value: ____/____/____
day month year

9 Weight: ____ . ____ kg

10 Calculated BMI: _____ kg/m²

E Permanent Discontinuation

If BMI is still < 18.5 kg/m² after one month of increased calorie intake, CR intervention is permanently discontinued.

11 Was the participant permanently discontinued from the CR intervention?

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

BMI returned to 18.5 kg/m² or higher

Other (specify): _____

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

Note that a participant is permanently discontinued from the CR intervention if a BMI < 18.5 kg/m² occurs at any point after the CR was restarted. If this happens, complete the Permanent Discontinuation from CR Intervention form.

Fax to Safety Surveillance at 1-866-668-7138

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

Excessive Weight Loss Episode (continued)

F Please provide a description of this episode including actions taken:

Study Manager's Signature

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