

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

Depression Episode

Depression is defined as a BDI score ≥ 20 . This report is completed for each episode of depression. Reporting starts when the initial BDI is ≥ 20 , 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: _____

B Initial Elevation in BDI Score ≥ 20

3 Date of initial elevation: ____/____/____
day month year

4 BDI score: _____

C Repeat BDI Score

The questionnaire is repeated in **one week**.

5 Date of follow-up questionnaire: ____/____/____
day month year

6 BDI score: _____

D Temporary Discontinuation

If the repeat score is ≥ 20 , the CR intervention is temporarily discontinued and a participant is advised to seek medical help outside of the study.

7 Was the participant temporarily discontinued from the CR intervention?

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

BDI score returned to < 20 → If the BDI score returned to < 20 , then stop here; the episode has resolved.

Sign the form on the last page and store in participant's binder.

Other (specify): _____

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

E Follow-up BDI Score

The questionnaire is repeated in **one month**.

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

9 BDI score: _____

Center Number: ____ Participant Number: ____ Participant's Initials: ____
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Depression Episode (continued)

F Permanent Discontinuation

If BDI score is ≥ 20 after one month of treatment, or a qualified mental health professional indicates that it is unsafe to restart the CR, intervention will be permanently discontinued.

10 Was the participant permanently discontinued from the CR intervention?

- No → If No: Indicate why CR was not permanently discontinued (check only one):
- ₁ BDI score returned below 20
 - ₂ Mental health professional indicated it is safe to resume
 - ₉₈ 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 BDI score ≥ 20 occurs at any point after the CR was restarted. If this happens, please complete the Permanent Discontinuation from CR Intervention form.

G Please provide a description of this episode, including actions taken:

Study Manager's Signature

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