

Visit 8
Monthly Phone Call

1. How are you feeling?

2. In the past week, have you had adequate relief of your stomach symptoms? _____ No = 0 Yes = 1

3. Have you started any new medicines (either prescribed or over the counter) since your last visit? _____ No = 0 Yes = 1

If no, go on to next question.

If yes, what medicines? (also list medications on page 3) _____

4. Since starting the study have you noticed a change in your mood? _____ No = 0 Yes = 1

If no, go on to 4.a.

If yes, obtain description from the participant

If the participant describes a depressed mood, obtain answers to the following questions:

- a. I still enjoy the things I used to enjoy:
- 1. ___ Definitely as much
 - 2. ___ Not quite as much
 - 3. ___ Only a little
 - 4. ___ Hardly at all
- b. I can laugh and see the funny side of things:
- 1. ___ As much as I always could
 - 2. ___ Not quite as much now
 - 3. ___ Definitely not as much now
 - 4. ___ Not at all
- c. I feel as if I am slowed down:
- 1. ___ Nearly all the time
 - 2. ___ Very often
 - 3. ___ Sometimes
 - 4. ___ Not at all
- d. I have lost interest in my appearance:
- 1. ___ Definitely
 - 2. ___ I don't take as much care as I should
 - 3. ___ I may not take as much care
 - 4. ___ I take as much care as ever

e. I feel cheerful:

- 1. ___ Not at all
- 2. ___ Not often
- 3. ___ Sometimes
- 4. ___ Most of the time

f. I look forward with enjoyment to things:

- 1. ___ As much as I ever did
- 2. ___ Rather less than I used to
- 3. ___ Definitely less than I used to
- 4. ___ Hardly at all

g. I can enjoy a good book or radio or TV program:

- 1. ___ Often
- 2. ___ Sometimes
- 3. ___ Not often
- 4. ___ Very seldom

Total: _____

NOTE: Use SOP for Scoring the HADS questionnaire to score Question 4 (a-g)

If the participant's score for the questions is > or = to 11, the participant is to be seen for an unanticipated study visit. The Principal Investigator at each site will encourage the participant to seek follow up care.

5. Have you seen your health care provider since the last call? _____ No = 0 Yes = 1

IF Yes, date of Doctor visit **Date** ___ ___ / ___ ___ / ___ ___

If yes, why?

Concomitant Medication/Significant Non-Drug Therapies prior to and after start of study drug

- Please list all medication and significant non-drug therapies.
- If there are no changes from previous visit, enter **NO CHANGES** (on line 1 below).

Period covered by this form: Start Date (visit 7) End Date (visit 8)
|_|_|_|_|_|_|_|_| |_|_|_|_|_|_|_|_| |_|_|_|_|_|_|_|_|
Month Day Year Month Day Year Month Day Year

Medication/Non-Drug Therapy (use trade name if possible)	Reason (Including Prophylaxis)
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____
13. _____	_____
14. _____	_____
15. _____	_____
16. _____	_____

Is an additional Concomitant Medications/Significant Non-Drug Therapies page used? 0__No 1__Yes

Please ensure that the data on this page are consistent with the data on the Relevant Medication History/Current Medical Conditions page of Visit 1.