Visit 9
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?

_____
_____
_____
_____

Study ID: _____
Visit Date: _____
Mo - Day – Year
Visit 9

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 8) |__|__|__|__|__|__|__|__| (Month Day Year) End Date (visit 9) |__|__|__|__|__|__|__|__| (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.