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**GaPP 2**

# BASELINE QUESTIONNAIRES

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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## SF-12

1. In general, would you say your health is:

Excellent <input type="checkbox"/>	Very good <input type="checkbox"/>	Good <input type="checkbox"/>	Fair <input type="checkbox"/>	Poor <input type="checkbox"/>
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2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Were limited in the kind of work or other activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Did work or other activities less carefully than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all <input type="checkbox"/>	A little bit <input type="checkbox"/>	Moderately <input type="checkbox"/>	Quite a bit <input type="checkbox"/>	Extremely <input type="checkbox"/>
-------------------------------------	---------------------------------------	-------------------------------------	--------------------------------------	------------------------------------

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the **one** answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Have you felt downhearted and low?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time <input type="checkbox"/>	Most of the time <input type="checkbox"/>	Some of the time <input type="checkbox"/>	A little of the time <input type="checkbox"/>	None of the time <input type="checkbox"/>
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# GaPP 2

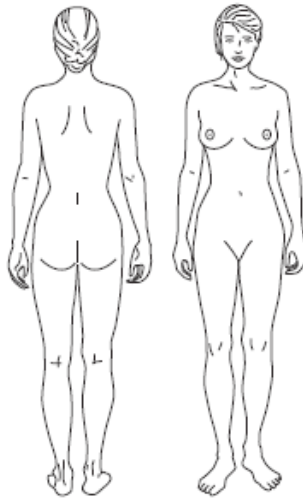
CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## BPI

Throughout our lives, most of us have pain from time to time (such as minor headaches, sprains and toothache). Have you had pain **other** than these everyday kind of pain today?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
------------------------------	-----------------------------

On the diagram, shade in the areas where you feel pain. Put an **X** on the area that hurts the most.



1. Please rate your pain by circling the one number that best describes your pain at its **worst** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain					Pain as bad as you can imagine					

2. Please rate your pain by circling the one number that best describes your pain at its **least** in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain					Pain as bad as you can imagine					

3. Please rate your pain by circling the one number that best describes your pain on **average**.

0	1	2	3	4	5	6	7	8	9	10
No Pain					Pain as bad as you can imagine					

4. Please rate your pain by circling the one number that best describes your pain you have **right now**.

0	1	2	3	4	5	6	7	8	9	10
No Pain					Pain as bad as you can imagine					

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CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

5. What treatments or medications are you receiving for your pain?

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6. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much **relief** you have received?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
----	-----	-----	-----	-----	-----	-----	-----	-----	-----	------

No relief

Complete relief

7. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

a. **General activity**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

b. **Mood**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

c. **Walking ability**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

d. **Normal work (includes both work outside the home and housework)**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

e. **Relations with other people**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

f. **Sleep**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

g. **Enjoyment of life**

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

Does not interfere

Completely interferes

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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## BFI

Throughout our lives, most of us have times when we feel very tired or fatigued. Have you felt unusually tired or fatigued in the last week?

Yes <input type="checkbox"/>	No <input type="checkbox"/>
------------------------------	-----------------------------

1. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your fatigue **right now**.

0	1	2	3	4	5	6	7	8	9	10
No Fatigue					As bad as you can imagine					

2. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **usual** level of fatigue during the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Fatigue					As bad as you can imagine					

3. Please rate your fatigue (weariness, tiredness) by circling the one number that best describes your **worst** level of fatigue during the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Fatigue					As bad as you can imagine					

4. Circle the one number that describes how, during the past 24 hours, fatigue has interfered with your:

a. **General activity**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

b. **Mood**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

c. **Walking ability**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

d. **Normal work (includes both work outside the home and housework)**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

e. **Relations with other people**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

f. **Enjoyment of life**

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

						2	0	1	
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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## WPAIQ

The following questions ask about the effect of your **health problem** on your ability to work and perform regular activities. Please fill in the blanks or circle a number, as indicated.

	Yes	No
1. Are you currently employed (working for pay)?	<input type="checkbox"/>	<input type="checkbox"/>
<i>If NO, check "NO" and skip to question 6.</i>		

The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems <b>associated with your health problems?</b>	_____ hours
<i>Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. Do not include time you missed to participate in this study.</i>	

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?	_____ hours
--	-------------

4. During the past seven days, how many hours did you actually work?	_____ hours
<i>(If "0", skip to question 6.)</i>	

5. During the past seven days, how much did your <b>health problem</b> affect your productivity <b>while you were working?</b>
Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problem affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.
Consider only how much <b>health problems</b> affected productivity <b>while you were working</b>

0	1	2	3	4	5	6	7	8	9	10
No effect on my work					Prevented me from working					

6. During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?
<i>By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.</i>
Consider only how much <b>health problems</b> affected your ability to do your regular daily activities, other than work at a job.

0	1	2	3	4	5	6	7	8	9	10
Does not interfere					Completely interferes					

					2	0	1	
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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## GHQ

We want to know how your health has been in general over the last few weeks. Please read the questions below and each of the four possible answers. Circle the response that best applies to you.

Have you recently...	Better than usual	Same as usual	Less than usual	Much less than usual
1. Been able to concentrate on what you are doing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
2. Lost much sleep over worry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	More so than usual	Same as usual	Less than usual	Much less than usual
3. Felt that you are playing a useful part in things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	More so than usual	Same as usual	Less than usual	Much less than usual
4. Felt capable of making decisions about things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
5. Felt constantly under strain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
6. Felt you couldn't overcome your difficulties?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	More so than usual	Same as usual	Less than usual	Much less than usual
7. Been able to enjoy your normal day to day activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	More so than usual	Same as usual	Less than usual	Much less than usual
8. Been able to face up to your problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
9. Been feeling unhappy or depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
10. Been losing confidence in yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not at all	No more than usual	Rather more than usual	Much more than usual
11. Been thinking of yourself as a worthless person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	More so than usual	Same as usual	Less than usual	Much less than usual
12. Been feeling reasonably happy, all things considered?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## PCQ

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

When I'm in pain...	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
I worry all the time about whether the pain will end	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel I can't go on	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It's terrible and I think it's never going to get any better	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
It's awful and I feel that it overwhelms me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I feel I can't stand it anymore	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I become afraid that the pain will get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I keep thinking about other painful events	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I anxiously want the pain to go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I can't seem to keep it out of my mind	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I keep thinking about how much it hurts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I keep thinking about how badly I want the pain to stop	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There's nothing I can do to reduce the intensity of the pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I wonder whether something serious may happen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>





# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## SAQ

Occasionally, some women notice hormonal changes which may affect their sexual relationship. Although the following questions are sensitive and personal, they are important in determining how treatment affects this part of your life. Please be assured that your responses to these questions will remain confidential.

	Yes	No
1. Are you currently married or having an intimate relationship with someone?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you changed your sexual partner in the last six months?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you engage in sexual activity with anyone at the moment?	<input type="checkbox"/>	<input type="checkbox"/>

If 'yes' please go to next page

If 'no' please answer the remaining questions on this page

I am not sexually active at the moment because...

*(please tick as many of these items as apply)*

a. I do not have a partner at the moment	<input type="checkbox"/>
b. I am too tired	<input type="checkbox"/>
c. My partner is too tired	<input type="checkbox"/>
d. I am not interested in sex	<input type="checkbox"/>
e. My partner is not interested in sex	<input type="checkbox"/>
f. I have a physical problem which makes sexual relations difficult or uncomfortable	<input type="checkbox"/>
g. My partner has a physical problem which makes sexual relations difficult or uncomfortable	<input type="checkbox"/>
h. Other reasons <i>(please describe)</i>	



# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## SAQ (cont)

Please read each of the following questions carefully and tick the box that best indicated your sexual feeling and experiences during the past month.

During the past month:	Very much	Somewhat	A little	Not at all
1. Was 'having sex' an important part of your life this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Did you enjoy sexual activity this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. In general, were you too tired to have sex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did you desire to have sex with your partner(s) this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. During sexual relations, how frequently did you notice dryness of your vagina this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Did you feel pain or discomfort during penetration this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. In general, did you feel satisfied after sexual activity this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	5 times or more	3-4 times	1-2 times	Not at all
8. How often did you engage in sexual activity this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Much more	Somewhat more	About the same	Less than usual
9. How did this frequency of sexual activity compare with what is usual for you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very much	Somewhat	A little	Not at all
10. Were you satisfied with the frequency of sexual activity this month?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## PainDETECT

Please tick box beside the picture that best describes the course of your pain:



Persistent pain with slight fluctuations



Persistent pain with pain attacks



Pain attacks without pain between them



Pain attacks with pain between them

Does your pain radiate to other regions of your body?

Yes

No

Do you suffer from a burning sensation (for example, stinging nettles) in the marked areas?

never  hardly noticed  slightly  moderately  strongly  very strongly

Do you have a pricking sensation in the area of your pain (like crawling ants or electrical tingling)?

never  hardly noticed  slightly  moderately  strongly  very strongly

Is light touching (clothing, a blanket) in this area painful?

never  hardly noticed  slightly  moderately  strongly  very strongly

Do you have sudden pain attacks in the area of your pain, like electric shocks?

never  hardly noticed  slightly  moderately  strongly  very strongly

Is cold or heat (bath water) in this area occasionally painful?

never  hardly noticed  slightly  moderately  strongly  very strongly

Do you suffer from a sensation of numbness in the areas that you marked?

never  hardly noticed  slightly  moderately  strongly  very strongly

Does slight pressure in this area, for example, with a finger, trigger pain?

never  hardly noticed  slightly  moderately  strongly  very strongly

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# GaPP 2

CLINICAL TRIAL TO DETERMINE THE EFFICACY OF GABAPENTIN FOR THE MANAGEMENT OF CHRONIC PELVIC PAIN IN WOMEN

## PUF (Baseline only)

Please circle the answer that best describes how you feel about each question.

1. How many times do you go to the bathroom during the day?	3-6	7-10	11-14	15-19	20+
2a. How many times do you go to the bathroom at night?	0	1	2	3	4+
2b. If you get up at night to go to the bathroom, does it bother you?	Never	Mildly	Moderate	Severe	
3. Are you currently sexually active?	Yes <input checked="" type="checkbox"/>	<input type="checkbox"/>	No <input checked="" type="checkbox"/>	<input type="checkbox"/>	
4a. If you are sexually active, do you now or have you ever had pain or symptoms during or after sexual intercourse?	Never	Occasionally	Usually	Always	
4b. If you have pain, does it make you avoid sexual intercourse?	Never	Occasionally	Usually	Always	
5. Do you have pain associated with your bladder or in your pelvis (vagina, lower abdomen, urethra, perineum).	Never	Occasionally	Usually	Always	
6. Do you have urgency after going to the bathroom?	Never	Occasionally	Usually	Always	
7a. If you have pain, is it usually...		Mild	Moderate	Severe	
7b. Does your pain bother you?	Never	Occasionally	Usually	Always	
8a. If you have urgency, is it usually...		Mild	Moderate	Severe	
8b. Does your urgency bother you?	Never	Occasionally	Usually	Always	