Patient Questionnaire Booklet

Date of Completion: ☐☐ ☐☐☐ ☐☐☐☐ *(DD/MON/YYYY)*

Patient Initials: ☐☐☐

Participant Trial Number: ☐☐☐☐

Time-point:

- Baseline (before randomisation) ☐
- 3 months post informed consent ☐
- 6 months post informed consent ☐
- 12 months post informed consent ☐
- 24 months post informed consent ☐

COMPLETION INSTRUCTIONS

When you entered the OPTIMA trial you kindly agreed to complete this questionnaire. This is an important part of the trial and we would very much appreciate your efforts in completing and returning it.

The following pages contain questions that relate to you, your general health and how any treatments are affecting you. Please complete them to record the amount of care you have received and expenses you have incurred, including help and support from your family and your friends. This can include those due to any health problems, not just your cancer and its treatment.

If possible please fill in this questionnaire within a week of receiving it. If this is not possible we would still like you to complete the questionnaire at your earliest possible convenience.

Once you have completed the questionnaire please return it in the pre-paid envelope provided to:

OPTIMA Trial Office
Warwick Clinical Trials Unit,
Division of Health Sciences, Warwick Medical School
The University of Warwick
Coventry, CV4 7AL

If you have any questions about this questionnaire please contact: _____

Thank you very much for your time and effort.

Health questions

EUROQOL© (EQ-5D) Quality of Life Questionnaire

By placing a tick in one box in each group below, please indicate which statement best describes your own health state today. Please do **not** tick more than one box in each group**.**

1. Mobility

I have no problems in walking about…… ☐

I have some problems in walking about…… ☐

I am confined to bed…… ☐

2. Self-care

I have no problems with self-care…… ☐

I have some problems washing or dressing myself…… ☐

I am unable to wash or dress myself…… ☐

3. Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities…… ☐

I have some problems with performing my usual activities…… ☐

I am unable to perform my usual activities…… ☐

4. Pain/Discomfort

I have no pain or discomfort…… ☐

I have moderate pain or discomfort…… ☐

I have extreme pain or discomfort…… ☐

5. Anxiety/Depression

I am not anxious or depressed…… ☐

I am moderately anxious or depressed…… ☐

I am extremely anxious or depressed…… ☐

Below is a list of statements that other people with your illness have said are important. Please circle or mark <u>one number per line</u> to indicate your response as it applies to the <u>past 7 days.</u>

PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
I have a lack of energy……	0	1	2	3	4
I have nausea……	0	1	2	3	4
Because of my physical condition, I have trouble meeting the needs of my family……..	0	1	2	3	4
I have pain……	0	1	2	3	4
I am bothered by side effects of treatment…….	0	1	2	3	4
I feel ill……	0	1	2	3	4
I am forced to spend time in bed……	0	1	2	3	4

SOCIAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
I feel close to my friends……	0	1	2	3	4
I get emotional support from my family……	0	1	2	3	4
I get support from my friends……..	0	1	2	3	4
My family has accepted my illness……	0	1	2	3	4
I am satisfied with my family communication about my illness……..	0	1	2	3	4
I feel close to my partner (or the person who is my main support)……..	0	1	2	3	4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box ☐ and go to the next section.					
I am satisfied with my sex life……..	0	1	2	3	4

Please circle or mark <u>one number per line</u> to indicate your response as it applies to the <u>past 7 days.</u>

EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
I feel sad……	0	1	2	3	4
I am satisfied with how I am coping with my illness……..	0	1	2	3	4
I am losing hope in the fight against my illness….	0	1	2	3	4
I feel nervous……	0	1	2	3	4
I worry about dying……..	0	1	2	3	4
I worry that my condition will get worse……..	0	1	2	3	4

FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
I am able to work (include work at home)……	0	1	2	3	4
My work (include work at home) is fulfilling……..	0	1	2	3	4
I am able to enjoy life……..	0	1	2	3	4
I have accepted my illness……..	0	1	2	3	4
I am sleeping well……..	0	1	2	3	4
I am enjoying the things I usually do for fun……..	0	1	2	3	4
I am content with the quality of my life right now……..	0	1	2	3	4

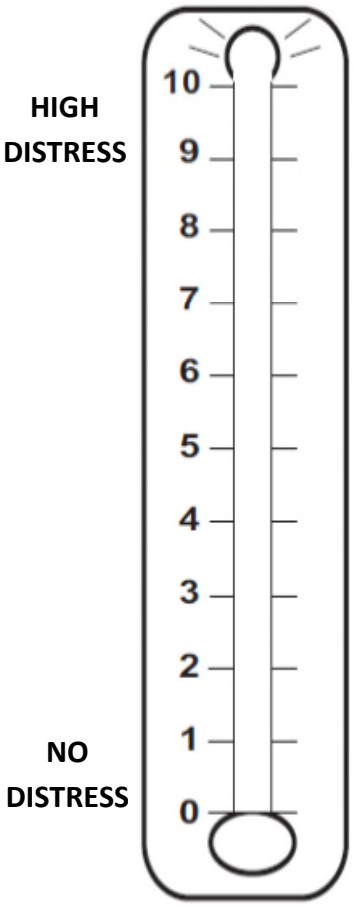
Please circle or mark <u>one number per line</u> to indicate your response as it applies to the <u>past 7 days.</u>

ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
I have been short of breath……..	0	1	2	3	4
I am self-conscious about the way I dress……	0	1	2	3	4
One or both of my arms are swollen or tender….	0	1	2	3	4
I feel sexually attractive……..	0	1	2	3	4
I am bothered by hair loss……	0	1	2	3	4
I worry that other members of my family might someday get the illness I have……..	0	1	2	3	4
I worry about the effect of stress on my illness…	0	1	2	3	4
I am bothered by a change in weight……..	0	1	2	3	4
I am able to feel like a woman……..	0	1	2	3	4
I have certain parts of my body where I experience pain……..	0	1	2	3	4

Distress Thermometer

1. Please circle the number below (0-10) that best describes in general how much distress you feel you have been experiencing over the past week, including today.

THERMOMETER



2. If any items below have been a cause of this distress for you over the past week, including today, please tick the box next to it. Please leave it blank if it does not apply to you.
3. Then rank (1st, 2nd, 3rd, 4th) your top 4 difficulties (1 would be the biggest problem, 4 would be your fourth biggest concern) and put this number beside the item in the RANKING column.

RANKING	Physical Problems	RANKING	Practical Problems
	☐ My appearance		☐ Caring responsibilities
	☐ Bathing or dressing		☐ Finance, work or housing
	☐ Breathing difficulties		☐ Transport or parking
	☐ Passing urine		☐ Questions about my illness / treatment
	☐ Constipation		☐ Communications with NHS staff
	☐ Diarrhoea		**Family Problems**
	☐ Eating or appetite		☐ Relationship with my children
	☐ Fatigue, exhaustion or extreme tiredness		☐ Relationship with my partner
	☐ Feeling swollen		☐ Relationship with other relatives/friends
	☐ High temperature or fever		**Emotional Problems**
	☐ Getting Around (e.g walking)		☐ Loneliness or isolation
	☐ Indigestion		☐ Sadness or depression
	☐ Sore or dry mouth		☐ Worry, fear or anxiety
	☐ Nausea or vomiting		☐ Anger or frustration
	☐ Pain		☐ Difficulty making plans
	☐ Dry, itchy or sore skin		☐ Guilt
	☐ Sleep problems and/or nightmares		☐ Hopelessness
	☐ Tingling in hands and/or feet		☐ Sexual Concerns
	☐ Changes in how things taste		**Spiritual/religious concerns**
	☐ Hot flushes		☐ Loss of faith or other spiritual concern
	☐ Memory or concentration		☐ Loss of meaning or purpose in life
	☐ Speech problems		☐ Not being at peace with or feeling regret about the past
	☐ Wound care after surgery		

Other concerns (e.g. other medical conditions, etc):……

……

Comments

We are very interested in patient reported experiences and would like to invite you to make any comments about your treatment or the study below, that you feel we or future patients should know about.

Please use the space below for these comments. You may wish to attach a separate sheet or use the final page for additional comments as necessary.

Employment and support

During the **last 3 months**:

Were you in employment before you started treatment? Yes ☐ No ☐

If yes, how much time have you taken off work due to your health? ☐ day(s)

If yes, how much earnings have you lost due to your health and its treatment? £ ☐

Have you received help or support from family or friends? Yes ☐ No ☐

If yes, how much time on average have they spent helping you? ☐ hours per week

If answered yes to receiving support from family or friends:

Did they take any time off work to help or support you? Yes ☐ No ☐

If yes, how much time in total did they take off? ☐ day(s)

Healthcare

Please record the **number** of services you have used over the **last 3 months** including those due to any health problems, not just your cancer and its treatment.

Hospital

This refers to any contacts you make with the hospital. This includes overnight stays in hospital, outpatient visits, telephone calls to hospital-based health professionals and physiotherapy for example. (You do not need to include chemotherapy or radiotherapy treatment visits.)

Type of service	**Have you used the service in the past 3 months?** *(tick if yes)*	**Total number of days**
Hospital inpatient stay (24 hours)		

Please specify all outpatient services that you have used.

Type of Outpatient service	**Have you used the service in the past 3 months?** *(tick if yes)*	**Total number of visits**	**Total number of contacts by telephone**
Hospital doctor			
Hospital nurse			
Physiotherapist			
Other:			

Please specify any tests or scans performed in the hospital (e.g. x-ray, CT-scan but not blood tests).

Description	Number
Mammogram	
X-ray	
CT-Scan	
Ultrasound	
MRI Scan	
Bone Scan	
Other:	

Community

This refers to all health care and social care that is **not** based in the hospital. This includes for example your GP, practice or community nurse, social worker, home help, or physiotherapist who is not based in the hospital.

Type of service	Have you used the service in the past 3 months? *(tick if yes)*	Total number of clinic visits	Total number of home visits	Total number of contacts by telephone
GP, surgery				
Nurse				
Psychiatrist or psychologist				
Physiotherapist				
Other:				

Travel

This section refers to how much in the **last 3 months** you spent on travel to attend hospital or other health and social care appointments, including any unplanned visits.

How many miles have you travelled by car? ☐ miles

How much have you spent on health-care related parking? £ ☐

How much have you spent on fares for public transport, taxis, etc.? £ ☐

Medications

What medications have you taken **this week** (last 7 days)? *(not including chemotherapy)*

Drug name	**Dose**	**Frequency**	**On prescription?** *(tick if yes)*
Example: Atenolol	*50mg*	*Once a day*	✓

Do you pay for your prescriptions? Yes ☐ No ☐

Other expenses

Have you personally incurred any other expenses due to your health or treatment over the **last 3 months?** (e.g. home adaptations, extra laundry, cleaning services)

Description	**Total cost (£)**

Additional Comments: Please use the space provided below to make any further comments on your study treatment or the study itself that you would like to tell us about:

End of questionnaire

Thank you for your time and effort

Hospital site use only:

Cross this box ☐ *if questionnaire was completed over the telephone.*