



MRC PR10
CCTG PR13

RADICALS

Quality of Life Form

For patients in RADICALS-RT (Radiotherapy Timing Comparison) only

Guidance

1. We are interested in some things about you and your health. Please answer all of the questions **yourself**.
2. **Circle the number** or **tick the box** that best applies to you.
3. There are no “right” and “wrong” answers.
4. The information that you provide will remain **strictly confidential**.
5. One completed, return to the nurse or study doctor.
6. The nurse or study doctor must post to:

UK: RADICALS Data Manager, MRC Clinical Trials Unit, Institute of Clinical Trials & Methodology, 90 High Holborn 2nd Floor, London, WC1V 6LJ

Canada: Clinical Trials Assistant, NCIC CTG, Queen’s University, 10 Stuart Street, Kingston, Ontario, K7L 3N6, Canada

“Clinical trials, such as RADICALS, are essential to determine the best treatment for a disease. In a trial, **it is vital that patients are able to report the impact of treatment on their quality of life**. For this reason, you are being asked to complete the questions below. **Your feedback is a very important part of the trial**. If you have any difficulties with this, please discuss them with your study doctor or nurse specialist”

- Jim Stansfeld, PCaSO and patient member of the RADICALS team

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Patient's initials

Date of birth

d

m

y

MRC Patient ID No.

NCIC CTG Patient ID No.

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Quality of Life Time point (please circle) : **Baseline** | 1yr | 5yr | 10yr

Date of completion:

d

m

y

¹Question Group 1: SF12

Excellent

Very Good

Good

Fair

Poor

In general, would you say health is:

healthis 1

2

3

4

5

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

²**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf

1 limmo1 2

3

³Climbing several flights of stairs

1 limcl1 2

3

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 you physical health?

All of the time

Most of the time

Some of the time

A little of the time

None of the time

⁴Accomplished less than you would like

1 physa1 2

3

4

5

⁵Were limited in the kind of work or other activities

1 physwork 2

3

4

5

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
⁶ Accomplished less than you would like	1 emoaccom 2		3	4	5
⁷ Did work or activities less carefully than usual	1 emocare 2		3	4	5
	Not at all	A little bit	Moderately	Quite a bit	Extremely
⁸ During the <u>past 4 weeks</u> , how much did pain interfere with your normal work (including both work, outside the home and housework)	1 painint 2		3	4	5

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
⁹ Have you felt calm and peaceful?	1 calmpea 2		3	4	5
¹⁰ Did you have a lot of energy?	1 loten1 2		3	4	5
¹¹ Have you felt downhearted and depressed?	1 downdep 2		3	4	5
¹² During the <u>past 4 weeks</u> , how much of your time has your physical health or emotional problems interfered with your social activities (like visiting friends, relative, etc.)?	1 intsoc 2		3	4	5

Question Group 2: EQ - 5D

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Describing your own health today:

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

- | | | | |
|---|---|--------|--------------------------|
| 1 | Mobility | mob | |
| | I have no problems walking about | | <input type="checkbox"/> |
| | I have some problems walking about | | <input type="checkbox"/> |
| | I am confined to bed | | <input type="checkbox"/> |
| 2 | Self care | seca | |
| | I have no problems with self care | | <input type="checkbox"/> |
| | I have some problems washing or dressing myself | | <input type="checkbox"/> |
| | I am unable to wash or dress myself | | <input type="checkbox"/> |
| 3 | Usual activities (e.g. work, study, housework, family or leisure activities) | usact | |
| | I have no problems with performing my usual activities | | <input type="checkbox"/> |
| | I have some problems with performing my usual activities | | <input type="checkbox"/> |
| | I am unable to perform my usual activities | | <input type="checkbox"/> |
| 4 | Pain/discomfort | padis | |
| | I have no pain or discomfort | | <input type="checkbox"/> |
| | I have moderate pain or discomfort | | <input type="checkbox"/> |
| | I have extreme pain or discomfort | | <input type="checkbox"/> |
| 5 | Anxiety/Depression | anxdep | |
| | I am not anxious or depressed | | <input type="checkbox"/> |
| | I am moderately anxious or depressed | | <input type="checkbox"/> |
| | I am extremely anxious or depressed | | <input type="checkbox"/> |

⁶How would you rate your overall **health** today? rateheal

1 2 3 4 5 6 7 8 9 10
Very Poor Excellent

Question Group 3: ICSMALESF

	Never	Occasionally	Sometimes	Most of the time	All of the time
¹ Is there a delay before you can start to urinate?	1	uridelay 2	3	4	5
² Do you have to strain to continue urinating?	1	urist1 2	3	4	5
	Normal	Occasionally reduced	Sometimes reduced	Reduced most of the time	Reduced all of the time
³ Would you say that the strength of your urinary stream is.....	1	urist2 2	3	4	5
	Never	Occasionally	Sometimes	Most of the time	All of the time
⁴ Do you stop and start more than once when you urinate?	1	urist3 2	3	4	5
⁵ How often do you feel that your bladder has not emptied properly after you have urinated?	1	bladempt 2	3	4	5
⁶ Do you have to rush to the toilet to urinate?	1	rushuri 2	3	4	5
⁷ Does urine leak before you can get to the toilet?	1	urileak 2	3	4	5
⁸ Does urine leak when you cough or sneeze?	1	cough1 2	3	4	5
⁹ Do you ever leak for no obvious reason and without feeling that you want to go?	1	norea1 2	3	4	5
¹⁰ Do you leak urine when you are asleep?	1	sleep1 2	3	4	5
¹¹ How often have you had a slight wetting of your pants a few minutes after you had finished urinating and had dressed yourself?	1	uriafter 2	3	4	5

	Hourly	Every 2 hours	Every 3 hours	Every 4 hours
¹² How often do you pass urine during the day?	1	urioften 2	3	4
	None	One	Two	Three
		Four or more		
¹³ During the night, how many times do you have to get up to urinate on average?	1	urinight 2	3	4
	None	One	Two	Three
		Four or more		
¹⁴ Overall, how much do your urinary symptoms interfere with your life?	1	urinterf 2	3	4
	Not at all	A little	Somewhat	A lot
¹⁵ Do you take medication for your bladder?	No	Yes		
	1	2	medbladd	
Please specify the type of medication.....	—redacted—			
	No	Yes		
¹⁶ Have you had previous surgery for incontinence?	1	2	incon1	

Question Group 4: Vaizey

	Never	Rarely	Sometimes	Weekly	Daily
¹ Incontinence for solid stool	1 incsolid	2	3	4	5
² Incontinence for liquid stool	1 incliq	2	3	4	5
³ Incontinence for gas	1 incgas	2	3	4	5
⁴ Alteration to lifestyle	1 altlife	2	3	4	5
	No	Yes			
⁵ Need to wear a pad or plug	1	2	padplug		
⁶ Taking constipation medicines	1	2	consmed		
⁷ Lack of ability to defer defecation for 15 minutes	1	2	lackdef		

Key

Never	No episodes in the past 4 weeks
Rarely	1 episode in the past 4 weeks
Sometimes	More than 1 episode in the past 4 weeks but less than 1 per week
Weekly	1 or more episodes a week but less than 1 per day
Daily	1 or more episodes per day

Question Group 5: IIEF5

		Very low	Low	Moderate	High	Very high
1 Over the past 4 weeks how do you rate your confidence that you can get and keep your erection?		1 erecc1	2	3	4	5
2 Over the past 4 weeks when you had erections with sexual stimulation, how often were your erections hard enough for penetration?	No Sexual activity	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
	1	2 erecpec	3	4	5	6
3 Over the past 4 weeks during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	Did not attempt intercourse	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
	1	2 erecmain	3	4	5	6
4 Over the past 4 weeks during sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Did not attempt intercourse	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
	1	2 maincomp	3	4	5	6
5 Over the past 4 weeks when you attempted sexual intercourse, how often was it satisfactory for you?	No Sexual activity	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
	1	2 satisfac	3	4	5	6
6 Do you use any sexual support (please circle)	No	Yes	sexsupp			
7 If yes, please specify the type of support (please circle)	Medication	Yes	No suppmcd			
	Pump	Yes	No suppump			
	Implant	Yes	No suppimp			
	Other	Yes	No suppoth			
	If other, please specify..... —redacted—					