

**Please complete this form every 4 months for 2 years, then 6 monthly until 5 years and annually thereafter.**

Keep a photocopy for your records and return the original to your trials unit:

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

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

**Patient's initials**      
F M I

**Date of birth**        
d m y

**MRC Patient ID No.**

NCIC CTG Patient ID No. 

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Responsible investigator: .....

Institution: .....

Please complete this form with information for the period between the last follow-up and now.

**Which Follow-up Report:** months / years (please delete as appropriate)

whichfur

1a ☐ Please confirm follow-up type:


1 = Seen in clinic  
2 = Telephone follow-up  
3 = Missed visit  
4 = Other, please specify

visit1

—redacted—

***If the patient was seen in clinic or had a telephone follow-up, please provide the visit date (question 1b).***

**If not, please provide the date last known alive (question 1c).**

1b  Date of follow-up visit

<sup>2</sup> Please provide all PSA values since last follow-up

(If there are more than 4 PSA values since the last follow-up, please provide approximately 3 monthly values where possible)

PSA value ng/ml

		psafup1			
		psafup2			
		psafup3			
		psafup4			

Date PSA value taken

		dpsafup_d			
		dpsafup2_d			
		dpsafup3_d			
		dpsafup4_d			

d m y

## DISEASE EVENTS

- Castration resistant disease progression
- Biochemical progression
- Clinical progression
- Metastases
- Death
- Second primary cancer

For definitions, please see RADICALS website and  
CRF Completion Guidelines

3 ☐ Was there a "disease event" since last follow-up?  
0 = No eventfu  
1 = Yes – please complete a Disease Event Form (CRF7)

4 ☐ **Please confirm the setting in which HT since last follow-up has been given**

0 = N/A; no HT has been given since last follow-up- **skip to question 11**      **consent**

1 = RADICALS-HD - 6 months or 2 years HT as per protocol

2 = RADICALS-RT - adjuvant HT given as standard-of-care

3 = HT given as treatment for relapse post radiotherapy - **skip to question 11** and provide details

**Please complete questions 5-10 to give details of :**

◆ **Hormone therapy (HT) for patients in RADICALS-HD allocated to 6 months or 2 years HT**

◆ *HT for patients in RADICALS-RT receiving adjuvant HT as part of standard-of-care*

**LHRH agonists/antagonists since last follow-up;** if this is the **first** follow-up visit, please give **start date**

0 = No  
1 = Started  
2 = Continuing  
3 = Stopped - give date last treatment administered

**lhrhc1**

**Date (if s**

d m y

6 

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**Date (if started or stopped)**  
d m y

7 ☐ If HT has stopped, please confirm the duration of the last treatment administered (for hormone injections)  
 1 = 1 month  
 3 = 3 months  
 6 = 6 months  
 9 = Other; please specify: —redacted—

8 ☐ **Anti-androgens since last follow-up (excluding for disease flare); if this is the first follow-up visit, please give start date**  
 0 = No ☐ **aachange**  
 1 = Started ☐  
 2 = Continuing ☐  
 3 = Stopped - give date that treatment course will have completed  **9**       **Date (if started or stopped)**  
 d m y

9 d m y **Date (if started or stopped)**

10 ☐ If HT has stopped early, please provide a reason why **htsto1**

1 = Toxicity  
2 = Patient choice  
3 = Progressive disease  
4 = Other: please specify: —redacted—

*Please continue on next page* ➔

Which follow-up report : whichfur months / years

MRC Patient ID No.

Date of follow-up

NCIC CTG Patient ID No.

11 ☐ Orchidectomy since last follow-up?0 = No  
1 = Yes12 ☐ Date of orchidectomy

d m y

## RTOG TOXICITY GRADING

Please give the RTOG toxicity grading for each of the following symptoms over the past 4 weeks:

13 ☐ Diarrhoea diar14 ☐ Proctitis proct115 ☐ Cystitis cys16 ☐ Haematuria haem17 ☐ Urethral stricture ure

## RTOG TOXICITY GRADING SYSTEM

Grade Symptoms

0 No Symptoms

1 Minor symptoms requiring no treatment

2 Symptoms responding to simple outpatient management, lifestyle (performance status)

3 Distressing symptoms altering patient's lifestyle (performance status). Hospitalisation for diagnosis or minor surgical intervention (such as urethral dilation) may be required

4 Major surgical intervention (such as laparotomy colostomy, cystectomy) or prolonged hospitalisation required

5 Fatal complications

## CTCAE v3.0 TOXICITY GRADING

Please give the CTCAE v3.0 toxicity grading for each of the following symptoms over the past 4 weeks:

18 ☐ Diarrhoea diarr1

0 = None

1 = Increase of &lt;4 stools per day over baseline; mild increase in ostomy compared to baseline

2 = Increase of 4-6 stools per day over baseline; IV fluids indicated &lt;24 hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL

3 = Increase of &gt;7 stools per day over baseline; incontinence; IV fluids &gt;24 hrs; hospitalisation; severe increase in ostomy output compared to baseline; interfering with ADL

4 = Life-threatening consequences (e.g. haemodynamic collapse)

5 = Not assessable, please give reason: —redacted—

19 ☐ Haemorrhage, GI (rectal)

0 = None

1 = Mild, intervention (other than iron supplements) not indicated

2 = Symptomatic and medical intervention or minor cauterisation indicated

3 = Transfusion, interventional radiology, endoscopic, or operative intervention indicated; radiation therapy (i.e. haemostasis of bleeding site)

4 = Life-threatening consequences, major urgent intervention indicated

5 = Not assessable, please give reason: —redacted—

20 ☐ Any days spent as an in-patient due to prostate cancer since the last follow-up report?

0 = No

1 = Yes - if yes, please provide the number of days of in-patient treatment

noinpt

21 ☐ Any unscheduled out-patient visits due to prostate cancer since the last follow-up report?

0 = No

1 = Yes - if yes, please provide the number of out-patient visits

novout

22 ☐ Please give a reason for visit(s) stated in question(s) 20 and/or 21

(Only answer this question if the answer to question 20 and/or 21 is 1 = Yes)

1 = Assessment of toxicity

2 = Treatment of toxicity

3 = Assessment of recurrence

4 = Treatment of recurrence

5 = Other or combination of above; please specify: —redacted—

23 ☐ Any elective hospitalisation to simplify treatment or procedures since last follow-up report?

0 = No 1 = Yes

elect1

24 ☐ Any elective hospitalisation for pre-existing conditions that, in the investigator's opinion, have not been exacerbated by trial treatment since last follow-up report?

0 = No 1 = Yes

elech1

Signed by

(Only MRC authorised person or NCIC CTG investigator)

Date

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