

Please fax to 020 7670 4818 or send via secure email to [mrctu.radicals@ucl.ac.uk](mailto:mrctu.radicals@ucl.ac.uk) within 1 working day of identification of event

1. Patient's initials:  2. Date of birth:  3. MRC Patient ID no:

4. Responsible Clinician:  5. CCTG Patient ID no:

6. Country:  7. Institution:

8. Type of report ☐ 1 = First ☐ 2 = Follow-up, number ..... **tyrep**  
9. Trial Arm ☐ 1 = RT + no HT ☐ 2 = RT + 6 mo HT\* ☐ 3 = RT + 2yr HT\* ☐ 4 = Salvage RT policy  
\*complete Trial Medications (Q22—Q29)  
10. Sex ☒ 1 = Male ☐ 2 = Female  
11. Height  cm  
12. Weight  kg  
13. Body Surface  m<sup>2</sup>

14. Was the event serious? ☐ 0 = No ☐ 1 = Yes **esea**  
15. ☐ 1 = Resulted in Death - Please complete a Death Form (CRF9) **ysae**  
☐ 2 = Life-threatening  
☐ 3 = Required inpatient hospitalisation or prolongation of existing hospitalisation  
☐ 4 = Persistent or significant disability/incapacity  
☐ 5 = Congenital anomaly/birth defect  
☐ 6 = Other important medical condition, specify ..... **—redacted—**  
16. Where did SAE take place? ☐ 1 = Hospital ☐ 2 = Out-patient clinic ☐ 3 = Home ☐ 4 = Nursing Home ☐ 5 = Other, specify ..... **whrsae**  
**—redacted—**

**Details of SAE**

17. Main diagnosis/symptom (Enter the MAIN EVENT in the first row, followed by any associated symptoms. If the main diagnosis changes after investigation then please update on a follow up SAE CRF) **saenam**  
18. Grade (<CTCAE v3.0> or <DAIDS> or <see protocol>) **saegr**  
19. Date of onset **dons\_d**  
  
20. SAE Status ☐ 1 = Resolved ☐ 2 = Resolved with sequelae ☐ 3 = Ongoing ☐ 4 = Worsened ☐ 5 = Fatal **saesta**  
21. Date resolved **dores\_d**

Associated symptoms: **—redacted—**

**Trial Medications - Hormone Therapies** 22. Cycle Number Please complete the table below if participant was randomised to 6mo or 2yr HT (Q9)

22. Trial Drug (e.g. Zoladex—please only record protocol hormone therapy treatment)	23. Date of first administration	24. Actual dose given at most recent administration	25. Date of most recent administration	26. Route 1= Oral 2= Intravenous 3= Subcutaneous 4= Other-specify	27. Causal relationship to SAE 1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6= Administration	28. Expected-ness** 1= Expected 2= Unexpected Only required if Q27 is 1, 2 or 3	29. Action taken due to SAE 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped
<b>tdrug</b>	<b>dost_d</b> <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yyyy"/>	<b>tdose</b>	<b>dorcnt_d</b> <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yyyy"/>	<b>drou</b>	<b>crlgd</b>	<b>expd</b>	<b>act</b>

\*\*Was the event one of the recognised undesirable effects of the trial medication as listed in the trial reference safety information? (<http://www.radicals-trial.org/>)

**Trial Radiotherapy or other treatments** (Include concomitant medication, surgery and palliative care; exclude any therapy given for management of SAE. Continue on a separate sheet if necessary)

30. Treatment Give generic name	31. Total Daily Dose	32. Route 1= Oral 2= Intravenous 3= Subcutaneous 4= Other - specify	33. Start Date	34. Ongoing 0=No 1=Yes	35. End Date	36. Causal relationship to SAE 1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6= Administration	37. Action taken due to SAE 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped
<b>m_otr1</b>	<b>odose</b>	<b>orou</b>	<b>odost_d</b> <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yyyy"/>	<b>ongt</b>	<b>odend_d</b> <input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yyyy"/>	<b>ocaut</b>	<b>oact</b>

Signed by Clinician:  (Only MRC authorised person/ CCTG investigator)

Date Completed:

EudraCT Number: 2006-000205-34

MRC Patient  
ID no:

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CCTG Patient:  
ID no:

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**38. Describe serious adverse event** (include manifestation & progression of event, any treatments given in response to the event and any relevant tests carried out e.g. WBC, neutrophil count. Continue on a separate sheet if necessary).

— redacted —

**Diagnostic Tests:**

39. Test name	test			
40. Date	dotest_d			
41. Normal range	testnr			
42. Result (+ units)	trslt			

**43. Do you consider this event likely to have been caused by anything other than the treatment listed previously on this form?**

☐ 0= No  
☐ 1= Yes

If Yes specify (include medical history, drug or alcohol abuse, family history, findings from special investigation)

evtexp

— redacted —

**Signed by Clinician :**(only MRC authorised person/  
CCTG investigator)**Contact telephone no.  
/email address****Print name****Date of completion**

d	d	m	m	y	y	y
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**CTU Clinical Reviewer Use ONLY**

satype

SAE ☐ SAR ☐ SUSAR: 7 day ☐ 15 day ☐

Not SAE ☐ event unrelated to trial treatment and occurred >30 days since last trial treatment administration

Body system: saesys

System Organ Class: sysor1

Preferred term: prefe1

Lower level term: lowte1

MedDRA code: MedDR1

**Comments:**

— redacted —

**Clinical Reviewer Signature:**Date checked by  
Clinical Reviewer

d	d	m	m	y	y	y
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**MRC CTU Staff Use ONLY**

Event No

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If SUSAR, date sent  
to MHRA & MREC

d	d	m	m	y	y	y
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Form checked and  
Ready to file

d	d	m	m	m	y	y	y	y
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**MRC CTU Staff Signature:**