MRC Clinical Trials Unit

Canadian Cancer Trials Group | Groupe canadien des essais sur le cancer

RADICALS - CRF 8
SERIOUS ADVERSE REPORTING FORM ✻

EudraCT Number: 2006-000205-34

MRC PR10
CCTG PR13

Please fax to 020 7670 4818 within 1 working day of identification of event for the attention of : RADICALS Trial Manager

1. Patient's initials: [f][m][l]

2. Date of birth: [d][d][m][m][y][y][y][y]

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 .....

9. Trial Arm
[ ] 1 = RT + no HT
2 = RT + 6 mo HT
3 = RT + 2yr HT
4 = Salvage RT policy

10. Sex
[1] 1=Male
2=Female

11. Height [ ][N/A][ ] cm

12. Weight [ ][N/A][ ]

13. Body Surface [ ] • [N/A][ ] m²

14. Was the event serious?
[ ] 0 = No
1 = Yes

15. Why was the event serious?
[ ] 1 = Resulted in Death
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 .....

16. Where did SAE take place?
[ ] 1 = Hospital
2 = Out-patient clinic
3 = Home
4 = Nursing Home
5 = Other, specify:.....

Details of SAE

17. Main diagnosis/symptom (Enter the MAIN EVENT in the first row, followed by any associated symptoms)	**18. Grade** (<CTCAE v3.0> or <DAIDS> or <see protocol>)	**19. Date of onset** *dd/mm/yyyy*	**20. SAE Status** 1= Resolved 2= Resolved with sequelae 3= Ongoing 4= Worsened 5= Fatal	**21. Date resolved** *dd/mm/yyyy*
Associated symptoms:				

Trial Medications **22. Cycle Number** [N/A]

23. Trial Drug	**24. Date of first administration** *dd/mm/yyyy*	**25. Actual dose given at most recent administration**	**26. Date of most recent administration** *dd/mm/yyyy*	**27. Route** 1= Oral 2= Intravenous 3= Subcutaneous 4= Other	**28. Causal relationship to SAE** 1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6= Administration	**29. Expected-ness*** 1= Expected 2= Unexpected	**30. Action taken due to SAE** 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

* Was the event one of the recognised undesirable effects of the trial medication ?

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)

31. Treatment Give generic name	**32. Total Daily Dose**	**33. Route** 1= Oral 2= Intravenous 3= Subcutaneous 4= Other	**34. Start Date** *dd/mm/yyyy*	**35. Ongoing** 0=No 1=Yes	**36. End Date** *dd/mm/yyyy*	**37. Causal relationship to SAE** 1= Definitely 2= Probably 3= Possibly 4= Unlikely 5= Not related 6= Administration	**38. Action taken due to SAE** 0=None 1=Dose reduction 2=Treatment delayed 3=Treatment reduction & delayed 4= Treatment stopped

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

Date Completed: [d][d][m][m][y][y][y][y]

39. 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).

Diagnostic Tests:

40. Test name					
41. Date					
42. Normal range					
43. Result (+ units)					

44. 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)

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 y

CTU Clinical Reviewer Use ONLY

SAE ☐ **SAR** ☐ **SUSAR: 7 day** ☐ **15 day** ☐

Comments:

Body system:

Clinical Reviewer Signature:

Date checked by Clinical Reviewer d d m m m y y y y

MRC CTU Staff Use ONLY

Event No | | | | | | | | |

If SUSAR, date sent to MHRA & MREC d d m m m y y y y

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

MRC CTU Staff Signature: