MRC Clinical Trials Unit

National Cancer Institute of Canada | Institut national du cancer du Canada

RADICALS - CRF 8
SERIOUS ADVERSE EVENT REPORTING FORM ✱

EudraCT Number: *2006-000205-34*

MRC PR10
NCIC CTG PR13

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

1 *Patient's initials* [ ][ ][ ] (F M L)

2 *Date of birth* [ ][ ] d [ ][ ] m [ ][ ][ ][ ] y

3 *MRC Patient ID No.* [ ][ ][ ][ ][ ][ ]

NCIC CTG Patient ID No. [ ][ ][ ][ ][ ][ ][ ][ ]

4 *Hospital No.* .....

5 *Responsible clinician* .....

6 *Country* .....

7 *Institution* .....

Type of report

8 [ ] 1 = First
2 = Follow-up, number .....

Trial arm

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

Sex

10 [1] 1 = Male
2 = Female

Height

11 [ ] N/A [ ] cm

Weight

12 [ ] N/A [ ] kg

Body Surface Area

13 [ ] . N/A [ ] m^2

Was the event serious?

14 [ ] 0 = No
1 = Yes

Why was the event serious?

15 [ ] 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.....

Where did SAE take place?

16 [ ] 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 **Expectedness*** 1 = Expected 2 = Unexpected	30 **Action taken due to SAE** 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Treatment reduced & delayed 4 = Treatment stopped

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

Radiotherapy and other treatments

(Include concomitant medication, radiotherapy, 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** 1 = Definitely 2 = Probably 3 = Possibly 4 = Unlikely 5 = Not related 6 = Administration	38 **Action taken** 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Treatment reduced and delayed 4 = Treatment stopped

Signed by Clinician

(only MRC authorised person / NCIC CTG investigator) _____

Date of completion [ ][ ] d [ ][ ] m [ ][ ][ ][ ] y

EudraCT Number: 2006-000205-34

MRC Patient ID No. | | | | | | |

NCIC CTG Patient ID No. | | | | | | | | |

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

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Diagnostic Tests:

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

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

44 ☐ 0 = No
1 = Yes If Yes, specify: (include: medical history, drug or alcohol abuse, family history, findings from special investigation)

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Signed by Clinician *(only MRC authorised person / NCIC CTG investigator)* _____

Print name _____

Contact telephone no. / email address _____

Date of completion | | | | | | | | | d m y

CTU Clinical Reviewer Use ONLY

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

Comments:

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Clinical Reviewer Signature

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

MRC CTU Staff Use ONLY

Event No. | | | | | | | | |

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

Form checked and ready to file: | | | | | | | | | d m y

MRC CTU Staff Signature

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