

Patient Initials     Date of Birth   /    /     Trial Number **R**

Visit Date   /    /

Visit Time  Week 52  Month 18  Month 24  Month 30  Month 36  Month 48  Month 60  Year 7  Year 9  Other:  
Point  Month 15  Month 21  Month 27  Month 33  Month 42  Month 54  Year 6  Year 8  Year 10 .....

*This CRF should be completed at visits after treatment has finished i.e. at Week 52, Months 15, 18, 21, 24, 27, 30, 33, 36, 42, 48, 54, and 60, and yearly from Month 60/Year 5 for as long as possible; or possibly at visits in the first year if the patient stops treatment prematurely. The 'Other' visit time point should only be used if patient stops treatment early and post treatment visit(s) occurs before week 52.*

**A. Visit Attendance**

1 **Did the patient attend the visit?**  
 No, missed visit. Please specify reason.....  
 Yes, in person  
 Yes, telephone consultation  
 Other, please specify .....

2   /    /     **Date the patient was last known to be alive**

**B. Physical Exam**

1 **Was the full physical exam completed?**  
 No  
 Yes

2 **WHO performance status**  
 0 – Able to carry out normal activity  
 1 – Restricted in physical strenuous activity but ambulatory and able to carry out light work  
 2 – Ambulatory and capable of self-care but unable to carry out any work; up more than 50% of waking hours  
 3 – Capable only of limited self-care; confined to bed or chair for more than 50% of waking hours  
 4 – Completely disabled; cannot carry out any self-care; totally confined to bed or chair

**C. Inpatient & Outpatient Visits** (please record all visits since the last post-treatment visit, if no visits write "00")

① **Non-Trial Visits - since last reported trial follow-up** (only include visits related to patient's renal cell carcinoma)  
 ✓ **Report:**  
 GP visits, outpatient visits, any hospital visits or admissions related to patient's RCC.  
 ✗ **Do not report:**  
 Any GP visits, outpatient visits, hospital visits or admissions that do not relate to patient's RCC.  
 Any visits where patients are prepared or receive non-trial treatment for RCC.

How many <b>nights</b> has the patient spent in:	How many <b>days</b> has the patient spent in:
1 <input type="text"/> <input type="text"/> <b>Intensive therapy/care units</b>	5 <input type="text"/> <input type="text"/> <b>An outpatient clinic</b>
2 <input type="text"/> <input type="text"/> <b>HDU department</b>	6 <input type="text"/> <input type="text"/> <b>Surgical day unit</b>
3 <input type="text"/> <input type="text"/> <b>General/medical/surgical ward</b>	7 <input type="text"/> <input type="text"/> <b>Accident &amp; emergency</b>
4 <input type="text"/> <input type="text"/> <b>Medical oncology</b>	8 <input type="text"/> <input type="text"/> <b>Investigation or treatment as a day patient</b>

Signature  Printed Name  Date Completed   /    /

Please return a copy to RAMPART Trial, MRC Clinical Trials Unit at UCL, 90 High Holborn, 2<sup>nd</sup> Floor, London WC1V 6LJ

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 Date form received at CTU   /    /     Date form entered onto database   /     /     Initials of data enterer


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#### D. Concomitant Medication

1 **Are you aware of any new concomitant medication since the last study visit?**

- No  
 Yes—  Enter details on Form04 - Concomitant Medications CRF

① The concomitant log on Form 04 would need to be updated up to month 15 or, if treatment ends early, 120 days after the last treatment. Ensure any concomitant medication(s) taken within this frame are entered on Form 04 - Concomitant Medications.

#### E. Adverse Events

1 **Are you aware of any adverse events or change in adverse event status (eg. worsening) since the last study visit?**

- No  
 Yes—  Enter details on Form06 - Adverse Events Log CRF

① Adverse events should be reported up to and including 120 days after last protocol treatment (Arms B and C) and up to month 15 for Arm A patients, or until disease progression (all arms), whichever is sooner. SARs and SUSARs should be reported for the duration of the trial.

Signature

Printed Name

Date Completed

/    /

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Date form received at CTU      dd /      mmm /      yyyy

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