

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

This CRF should be completed once disease progression has been confirmed. If the first progression is a local progression, please update and re-send the form once the patient has their first metastasis. Please also complete an **End of Treatment CRF (Form 07A and/or Form 07B)** at the same time if progression has occurred during the treatment phase.

### A. First Progression


1 **Date of first progression**

/    /

2 **Method of assessment**

- CT Scan  
 MRI Scan  
 X-ray  
 Biopsy  
 Other, please specify .....


3 **Is the first progression a local progression?**

- No -  go to question A5  
 Yes

4 **Location of local progression**

- Renal bed  
 Remnant kidney  
 Local node

5 **Is the first progression a distant metastasis?**

- No -  go to question A7  
 Yes

6 **Location of distant metastasis?**

- Contralateral kidney  
 Distant Node  
 Lung  
 Bone  
 Liver  
 Other, please specify .....

7 **Did the first progression event meet the criteria for an SAE?**

- No  
 Yes

**i** Disease progression should only be reported after thorough investigation and evidence such unequivocal radiological progression or biopsy. Patients with equivocal radiological changes should continue on the trial and be re-imaged at the next planned time or earlier if clinically indicated. If progression is then confirmed, the date of first progression should be the date of the scan where equivocal changes were first described.

**i** If the patient is found to have progressed in multiple locations at the time of their first progression, please indicate each location.

**i** Please note that if the patient is found to have a new primary cancer, either in the contralateral kidney or another organ, this should be reported on the New Primary Cancer CRF (Form 20). New primary cancers should not be detailed on this Progression CRF, which is for local progression or metastases only.

**i** Please refer to section 7.1 of the RAMPART Protocol for full details of SAE criteria. Progression events that meet the SAE criteria should be noted here, but **do not** need to be reported on an SAE CRF as they are exempt from expedited reporting.

**i** If this is a report of a local progression only, please complete section B when the patient has a first metastasis. If the first progression includes a metastasis you do not need to complete section 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   /    /

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**B. First Metastasis**

**1 Date of first metastasis**

/    /

**i** This section should only be completed if the first progression was a local progression.

**2 Method of assessment**

- CT Scan
- MRI Scan
- X-ray
- Biopsy
- Other, please specify .....

**i** If the patient is found to have metastases in multiple locations at the time of their first metastasis, please indicate each location.

**3 Location of first metastasis?**

- Contralateral kidney
- Distant Node
- Lung
- Bone
- Liver
- Other, please specify .....

Signature

Printed Name

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