RAMPART

Post-Treatment CRF - Form 08
Version 2.0 03 February 2020

Patient Initials | Date of Birth (d d / m m m / y y y y) | Trial Number R

Visit Date (d d / m m m / y y y y)

Visit Time Point: ☐ Week 52 ☐ Month 18 ☐ Month 24 ☐ Month 30 ☐ Month 36 ☐ Month 48 ☐ Month 60 ☐ Year 7 ☐ Year 9 ☐ Other:
☐ 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. If disease progression has been reported, the CRF is completed on an annual basis from the date of progression.

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 (d d / m m m / y y y y) **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")

ⓘ **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 for or receive non-trial treatment for RCC.

How many **nights** has the patient spent in:

1 ☐☐ **Intensive therapy/care units**

2 ☐☐ **HDU department**

3 ☐☐ **General/medical/surgical ward**

4 ☐☐ **Medical oncology**

How many **visits** has the patient made to/for:

5 ☐☐ **An outpatient clinic**

6 ☐☐ **Surgical day unit**

7 ☐☐ **Accident & emergency**

8 ☐☐ **Investigation or treatment as a day patient**

Signature	Printed Name	Date Completed (d d / m m m / y y y y)

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

For office use only

Date form received at CTU dd / mmm / yyyy

Date form entered onto database dd / mmm / yyyy

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Visit Date [d][d]/[m][m][m]/[y][y][y][y]

Visit Time Point ☐ Week 52 ☐ Month 18 ☐ Month 24 ☐ Month 30 ☐ Month 36 ☐ Month 48 ☐ Month 60 ☐ Year 7 ☐ Year 9 ☐ Other:
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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

ⓘ 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

ⓘ 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.

F. Non-Protocol Anti-Cancer Therapy

ⓘ If disease progression or a new primary cancer has been reported, please indicate below any anti-cancer therapy that has been given since the patient's last follow-up visit.

1 **Tyrosine Kinase Inhibitors (TKIs)**
☐ Axitinib
☐ Cabozantanib
☐ Everolimus
☐ Gefitinib
☐ Pazopanib
☐ Sorafenib
☐ Sunitinib
☐ Tivozanib

2 **Immune Checkpoint Inhibitors**
☐ Atezolizumab
☐ Avelumab
☐ Cemiplimab
☐ Durvalumab
☐ Ipilimumab
☐ Nivolumab
☐ Pembrolizumab
☐ Tremelimumab

3 **Non-Specific Immunotherapy**
☐ Fluorouracil (5FU)
☐ Interferon-alpha
☐ Interleukin-2 (IL-2)

4 **Radiotherapy**
☐ No
☐ Yes, please give details.....

5 **Surgery**
☐ No
☐ Yes, please give details.....

6 **Other Treatments**
☐ No
☐ Yes, please give details.....

Signature	Printed Name	Date Completed
		[d][d]/[m][m][m]/[y][y][y][y]

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