RAMPART

Randomisation CRF - Form 01

Version 2.0 29 March 2019

Patient Initials [ ][ ][ ][ ] Date of Birth [d d]/[m m m]/[y y y y] Randomising Centre .....

This CRF should be completed prior to randomisation.

A. Eligibility Criteria (see protocol for full details)

ⓘ Ensure informed consent has been obtained.

1 **Is the patient eligible for this trial?** (i.e. do they meet all of the inclusion criteria and none of the exclusion criteria as detailed in the protocol and Form 02?)
- ☐ No
- ☐ Yes

2 **Does the patient have histologically proven renal cell carcinoma?**
- ☐ No
- ☐ Yes

3 [ ][ ] **Leibovich score** (must be between 3 and 11 to be eligible)

4a [d d]/[m m m]/[y y y y] **Date of nephrectomy** (must be ≥ 28 days and ≤ 91 days prior to randomisation)

4b [d d]/[m m m]/[y y y y] **Date of CT scan**

5 **Histology**
- ☐ Conventional/clear cell
- ☐ Papillary type 1
- ☐ Papillary type 2
- ☐ Chromophobe
- ☐ Other, please specify: .....

ⓘ A copy of the patient's pathology report confirming histology should be enclosed with this CRF. The patient's Trial Number should be transcribed onto the report.
Patients with pure oncocytoma, collecting duct, medullary and transitional cell cancer (TCC) are not eligible.

6 **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

7 **The patient must have archival pathology tissue available, please confirm**
- ☐ No, unavailable
- ☐ Yes, available

8 [ ][ ].[ ] g/dL **Haemoglobin** (must be ≥ 9.0 g/dL)

ⓘ To convert from g/L to g/dL, divide figure by 10.

9 [ ][ ][ ] 10^9/L **Platelets** (must be ≥ 100 x 10^9/L)

10 [ ][ ].[ ] 10^9/L **Neutrophils** (must be ≥ 1.5 x 10^9/L)

11 [ ][ ][ ].[ ][ ] **AST or ALT** (must be ≤ 2.5 x ULN)

12 [ ][ ].[ ][ ] **AST/ALT ULN value used**

13 **Is the value given for question A11 in regards to AST or ALT?**
- ☐ AST
- ☐ ALT

14 **What is the unit used for AST/ALT?**
- ☐ IU/L
- ☐ µkat/L

15 [ ][ ].[ ][ ] **Bilirubin** (must be ≤ 1.5 x ULN)

16 [ ][ ].[ ][ ] **Bilirubin ULN value used**

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 data entry checked dd / mmm / yyyy

Initials of data entry checker [ ][ ][ ][ ]

Patient Initials [ ][ ][ ][ ] Date of Birth [d d]/[m m m]/[y y y y] Randomising Centre .....

A. Eligibility Criteria — continued

17 **What is the unit used for Bilirubin?**
- ☐ µmol/L
- ☐ mg/dL

18a [ ][ ][ ].[ ] mL/min **Creatinine clearance** (must be ≥ 40 mL/min)

ⓘ Creatinine clearance must be calculated using the Cockcroft Gault formula (using actual body weight) detailed in the RAMPART protocol.

18b [d d]/[m m m]/[y y y y] **Date of earliest blood test used to confirm eligibility**

ⓘ A copy of the full laboratory transcript (with all screening laboratory investigations) should be enclosed with this CRF. The Trial number should be present on the transcript.

19 [d d]/[m m m]/[y y y y] **Date of electrocardiogram** (must be no more than 28 days prior to randomisation)

20 [ ][ ][ ] ms **QTcF** (must be < 450 ms — if initial result is ≥450 ms, repeat the ECG two more times and record the average)

21a **The patient must not be pregnant, please confirm** (serum HCG pregnancy test must be carried out within 7 days prior to randomisation)
- ☐ No, the patient is not pregnant
- ☐ Yes, the patient is pregnant

21b [d d]/[m m m]/[y y y y] **Date of pregnancy test**

☐ N/A (Tick for male patients or female patients who are post-menopausal as described in Form02 question A12.

22 **The patient has agreed to use contraception as per the patient information sheet, please confirm**
- ☐ No, not agreed
- ☐ Yes, agreed

23 **The patient must not be taking any medication that is prohibited as detailed in the protocol, please confirm**
- ☐ No, the patient is not taking any prohibited medication
- ☐ Yes, the patient is taking prohibited medication

24 [d d]/[m m m]/[y y y y] **Date of informed consent**

25 [d d]/[m m m]/[y y y y] **Planned start date of treatment** (must be no more than 14 days after randomisation)

B. Randomisation (please call the MRC CTU Randomisation line (020 7670 4777) to fill in these details)

1 [d d]/[m m m]/[y y y y] **Date of randomisation**

2 **Treatment arm patient assigned to**
- ☐ A — active monitoring for 1 year
- ☐ B — durvalumab every 4 weeks for 1 year + active monitoring for 1 year
- ☐ C — durvalumab every 4 weeks for 1 year + tremelimumab at day 1 and week 4 + active monitoring for 1 year

3 **R**[ ][ ][ ][ ][ ][ ][ ][ ] **Trial number**

ⓘ Now ✍ please **complete the Eligibility Criteria CRF (Form 02)** and remember to **send the Consent Form, the histology report and the laboratory transcript** to the MRC CTU.

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 data entry checked dd / mmm / yyyy

Initials of data entry checker [ ][ ][ ][ ]