RAMPART

Randomisation CRF - Form 01

Version 1.0 25 June 2018

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)

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

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.

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**

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

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

18 [ ][ ][ ].[ ] 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.

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

21 **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

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 pathology report and the laboratory transcript** to the MRC CTU.

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

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