RAMPART

Treatment CRF - Form 05
Version 2.0 29 March 2019

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: ☐ Day 1 ☐ Week 2 ☐ Week 4 ☐ Week 6 ☐ Week 8 ☐ Week 12 ☐ Week 16 ☐ Week 20 ☐ Week 24 ☐ Week 28 ☐ Week 32 ☐ Week 36 ☐ Week 40 ☐ Week 44 ☐ Week 48 (tick one)

This CRF should be completed at weeks 16 and 32 for Arm A patients and at day 1, weeks 2, 4, 6, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48 for Arms B and C patients.

Some sections only need to be completed at particular visits, or for particular arms — please check the guidance text throughout the CRF.

If a decision is made to stop a patient's trial treatment early, they should still be followed up as per the treatment schedule during year 1. A Post-Treatment CRF (Form 08) should be completed instead of a Treatment CRF (Form 05) at each of these visits post cessation.

Treatment visits must take place **28 days** (+/- 3 days) from the date of last infusion. If unsure, please consult the trial protocol or contact a member of the RAMPART team prior to infusion.

A. Visit Status — ALL PATIENTS

1 **Did this treatment visit take place?**
☐ No, missed
☐ Yes

ⓘ Treatment visit must be 28 days +/- 3 days from the date of last infusion

2 **If no, why was the visit missed?**

.....

3 (d d / m m m / y y y y) **Date of last infusion**

ⓘ If the last infusion was missed, enter the date the last infusion was scheduled for.

B. Physical Exam — ALL PATIENTS

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

3 ☐☐☐.☐ kg **Weight**

C. Electrocardiogram — ARM B & C DAY 1 VISIT AND AS CLINICALLY REQUIRED

1 ☐☐☐ ms **QTcF** (must be < 450ms — if initial result is ≥ 450ms, repeat ECG two more times and record the average of the three)

2 **Any abnormalities noted on ECG?**
☐ No
☐ Yes - not clinically significant, please describe below
☐ Yes - clinically significant, please describe below

.....

.....

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

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D. Tremelimumab Administration — ALL PATIENTS

1 **Did patient receive tremelimumab infusion?**
☐ No — *please explain below*
☐ Yes

ⓘ The tremelimumab dose level is 75 mg.

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2 **State the dose that was administered.**

☐☐ mg

ⓘ As per protocol, dose should only be adjusted if patient's weight is below 30kg.

3 h h : m m 24 hr **Infusion start time**

4 h h : m m 24 hr **Infusion end time** (infusion period must be ≥55 minutes and ≤65 minutes)

5 **Were there any complications during infusion?**

Interruption	☐ No	☐ Yes
Reduction in flow rate	☐ No	☐ Yes
Suspended treatment	☐ No	☐ Yes
Other, please specify below	☐ No	☐ Yes

ⓘ Please provide any further information in the space provided below. Note that if 'Other' is ticked, further clarification is required.

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Vital Signs

ⓘ Patient should be supine for at least 5 minutes before vital signs are collected.

	6 **Pre-infusion**	7 **During infusion**	8 **Post-infusion**
Blood pressure (mmHg)	☐☐☐ / ☐☐☐ *systolic / diastolic*	☐☐☐ / ☐☐☐ *systolic / diastolic*	☐☐☐ / ☐☐☐ *systolic / diastolic*
Pulse (beats/min)	☐☐☐	☐☐☐	☐☐☐
Respiration rate (breaths/min)	☐☐	☐☐	☐☐
Temperature (°C)	☐☐.☐	☐☐.☐	☐☐.☐

E. Durvalumab Administration — ALL PATIENTS

1 **Did patient receive durvalumab infusion?**
☐ No — *please explain below*
☐ Yes

ⓘ The durvalumab dose level is 1,500 mg.

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E. Durvalumab Administration - continued — ALL PATIENTS

2 **State the dose that was administered**

mg

ⓘ As per protocol, dose should only be adjusted if patient's weight is below 30kg.

3 hh:mm 24 hr **Infusion start time**

4 hh:mm 24 hr **Infusion end time** (infusion period must be ≥55 minutes and ≤65 minutes)

5 **Were there any complications during infusion?**

Interruption	☐ No	☐ Yes
Reduction in flow rate	☐ No	☐ Yes
Suspended treatment	☐ No	☐ Yes
Other, please specify below	☐ No	☐ Yes

ⓘ Please provide any further information in the space provided below. Note that if 'Other' is ticked, further clarification is required.

.....

.....

Vital Signs

ⓘ Patient should be supine for at least 5 minutes before vital signs are collected.

	6 **Pre-infusion**	7 **During infusion**	8 **Post-infusion**
Blood pressure (mmHg)	___ / ___ (systolic / diastolic)	___ / ___ (systolic / diastolic)	___ / ___ (systolic / diastolic)
Pulse (beats/min)	___	___	___
Respiration rate (breaths/min)	___	___	___
Temperature (°C)	___.___	___.___	___.___

F. Laboratory Investigations — ALL PATIENTS

1 **Have pre-infusion laboratory investigations been carried out?** See protocol for further information on required lab investigations.
☐ No
☐ Yes

2 **Has the laboratory transcript been enclosed with this CRF?**
☐ No
☐ Yes

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F. Laboratory Investigations - continued — ALL PATIENTS

3 **Please indicate below the results for the following sub-set of required lab assessments:**

a	**ALP**	b	**ULN**	c	☐ U/L	☐ µkat/L		
d	**ALT**	e	**ULN**	f	☐ U/L	☐ µkat/L		
g	**AST**	h	**ULN**	i	☐ U/L	☐ µkat/L		
j	**Total Bilirubin**	k	**ULN**	l	☐ µmol/L	☐ mg/dL		
m	**Amylase**	n	**ULN**	o	☐ U/L	☐ µkat/L	☐ µmol/L	
p	**Lipase**	q	**ULN**	r	☐ U/L	☐ µkat/L	☐ µmol/L	
s	**Creatinine**	t	**ULN**	u	☐ µmol/L	☐ mg/dL		

ⓘ Any abnormal lab values should be reported in the AE log in accordance to the CTCAE 4.03 guidelines. This includes all laboratory investigations detailed in the study protocol.

Refer to the RAMPART protocol and the CTCAE 4.03 guidelines for further information.

G. Inpatient & Outpatient Visits (please record all visits since the last treatment visit, if no visits write "00") — ALL PATIENTS

ⓘ **Non-Trial Visits - since last reported trial visit** (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 **nights** has the patient spent in:

1 **Intensive therapy/care units**
2 **HDU department**
3 **General/medical/surgical ward**
4 **Medical oncology**

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

5 **An outpatient clinic**
6 **Surgical day unit**
7 **Accident & emergency**
8 **Investigation or treatment as a day patient**

ⓘ If the patient has been **admitted to hospital** (unless it was for a pre-planned treatment/procedure) a **SAE CRF (Form 13) should be completed** and faxed to the MRC CTU (0207 670 4653) **within 24 hours** of becoming aware of the event.

Please refer to the RAMPART Protocol for further guidance on safety reporting.

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H. Concomitant Medication — ALL PATIENTS

1 **Are you aware of any new concomitant medication since the last study visit?**
- ☐ No
- ☐ Yes - ☞ Enter details on Form04 - Concomitant Medications Log

I. Adverse Events — ALL PATIENTS

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

2 **Was current trial treatment interrupted due to an adverse event?**
- ☐ No
- ☐ Yes - ☞ Enter details on Form06 - Adverse Events Log

J. Pregnancy Outcome — ALL PATIENTS

1 **Was a pregnancy test completed for this study visit?**
- ☐ No
- ☐ Yes
- ☐ N/A (applicable to post-menopausal women only)

ⓘ For male patients, tick no.

2 **What was the result?**
- ☐ Negative
- ☐ Positive ☞ Enter details on Form14 - Pregnancy Monitoring CRF

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