RAMPART

End of Durvalumab Treatment CRF - Form 07B
Version 1.0 25 June 2018

Patient Initials [ ][ ][ ][ ] Date of Birth [d d]/[m m m]/[y y y y] Trial Number [R][ ][ ][ ][ ][ ][ ][ ][ ]

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 (please tick)

This CRF should be completed once the last cycle of Durvalumab has been administered — i.e. at Week 48 for Durvalumab or earlier if the patient stops treatment prematurely.

A. End of Durvalumab Treatment — Arms B and C Patients Only

1 [d d]/[m m m]/[y y y y] **Date of last Durvalumab infusion**

2 **Reason for ending trial treatment—***(Tick one only)*
- ☐ Protocol treatment completed
- ☐ Excessive toxicity
- ☐ Patient refusal
- ☐ Disease progression — ✍ *please complete a Progression CRF (Form 10)*
- ☐ New primary cancer — ✍ *please complete an SAE CRF (Form 13) and update the AE Log (Form 6)*
- ☐ Death — ✍ *please complete a Death CRF (Form 12)*
- ☐ Pregnancy — ✍ *please complete a Pregnancy Monitoring CRF (Form 14) and fax to the MRC CTU (0207 670 4653) within one working day*
- ☐ Intercurrent illness or change in patient's condition that justifies discontinuation of treatment in clinician's opinion
- ☐ Patient found to not be eligible for trial — *please discuss with the trial team (mrcctu.rampart@ucl.ac.uk)*
- ☐ Other, please specify:

.....

.....

3 **Did Durvalumab treatment end due to an AE?**
- ☐ No
- ☐ Yes — ✍ *enter details on AE log (Form 06)*

4 **If treatment was ended due to an AE, state AE number.**

[ ][ ]

ⓘ The **Adverse Events Log** must be completed up to **120 days** after the **Date of Last Infusion**.

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 _____ Initials of data enterer [ ][ ][ ][ ]