MRC Clinical Trials Unit

Smarter studies
Global impact
Better health

RAMPART

PI Sign Off CRF - Form 11

Version 1.0 03 September 2019

UCL

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

Date of Randomisation | d | d | / | m | m | m | / | y | y | y | y |

This CRF can only be signed by the PI. A signed declaration confirms that the PI has had oversight, takes responsibility for the data and to the best of their knowledge trial procedures have been carried out in accordance to the RAMPART protocol. This CRF should be signed off at randomisation, end of treatment, progression and death.

A. Declaration at Randomisation

I confirm that I have had oversight over the eligibility assessments carried out for this patient. To the best of my knowledge all procedures required before randomisation have been carried out in accordance with the RAMPART Protocol and the data recorded in CRFs is accurate. All trial related tasks and CRFs have been completed by myself or an appropriately trained individual on the RAMPART Delegation Log.

1 **Principal Investigator sign-off** .....

2 **Date of sign-off** | | | / | | | | / | | | | |

B. Declaration at End of Treatment

I confirm that treatment was ended in accordance with the RAMPART Protocol. To the best of my knowledge, all procedures required during the treatment phase have been carried out in accordance with the RAMPART Protocol and the data provided is accurate. All trial related tasks and CRFs have been completed by myself or an appropriately trained individual on the RAMPART Delegation Log.

1 **Principal Investigator sign-off** .....

2 **Date of sign-off** | | | / | | | | / | | | | |

ⓘ For arm A patients, sign off should be at the end of treatment visits (end of year 1), for arm B patients after Durvalumab treatment has ended and for arm C patients after both Tremelimumab and Durvalumab has ended.

C. Declaration at Progression

I confirm that this patient has disease progression, which has been confirmed as per the criteria detailed in the RAMPART Protocol. To the best of my knowledge, all procedures required up to the date of progression have been carried out in accordance with the RAMPART Protocol and the data provided is accurate. All trial related tasks and CRFs have been completed by myself or an appropriately trained individual on the RAMPART Delegation Log.

1 **Principal Investigator sign-off** .....

2 **Date of sign-off** | | | / | | | | / | | | | |

D. Declaration at Death

To the best of my knowledge, all procedures required up to the date of death have been carried out in accordance with the RAMPART Protocol and the data provided is accurate. All trial related tasks and CRFs have been completed by myself or an appropriately trained individual on the RAMPART Delegation Log.

1 **Principal Investigator sign-off** .....

2 **Date of sign-off** | | | / | | | | / | | | | |

For office use only

Date form dd / mmm / yyyy Date data dd / mmm / yyyy Initials of data | | | | |