ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Treatment Summary Form (1/1)

Treatment Summary

Number of cycles given

Date of last nivolumab administration (DD/MM/YYYY)

Date of decision to stop treatment (DD/MM/YYYY)

Please submit the Nivolumab patient accountability logs with this form

Specify the reason for stopping trial treatment
Tick one box only

- ☐ Completed 8 cycles
- ☐ PET negative after 4 cycles
- ☐ Disease Progression *please complete disease progression form*
- ☐ Serious Adverse Event (SAE) *including autoimmune events and death, Please complete SAE report form and/or death form if applicable*
- ☐ Unacceptable Non-Serious Adverse Event(s) *please specify event name, Grade and report on adverse event form, see CTCAE v5 for guidance*
  - Event term(s) ____ Grade ☐
- ☐ Intercurrent illness preventing further treatment
  - Event term ____ Grade ☐
- ☐ Clinician decision (not Adverse Event related)
- ☐ Patient decision
  - Has the patient withdrawn consent for follow up? ☐ Yes ☐ No
  - *If so, please complete Lost to Follow Up Form*
- ☐ Other *please specify reason:* ____

Completed by:

Signature:

CRFs should only be completed by appropriately qualified personnel detailed on the site delegation log

Date completed: D D M M Y Y Y Y

For UCL CTC use only: Date Checked: _____ Initials: _____ Date entered: _____ Initials: _____

Additional instructions for completing forms

Treatment Summary Form

The Treatment Summary Form is used to capture a summary of the treatment administered to a patient.

Completing the form

- This form should be submitted within two weeks of the decision to stop treatment (with the Treatment CRF for the last cycle given).
- If the patient stopped trial treatment early for any reason, details should be recorded on this form.
- If a patient withdraws consent to follow up please complete the Lost to Follow Up Form in addition to the Treatment Summary Form
- Please submit the Nivolumab patient accountability logs with this form.

Specific Fields

- *Specify the reason for Withdrawal (if applicable)*- only one box should be ticked
  - *Unacceptable Adverse Event*

    - Grade should be entered where applicable (ensure all AEs are entered on the Adverse Event form and if an SAE is observed fax through and SAE Report Form to the CTC). Please see CTCAE v5 for guidance.

If you have any questions about how to complete this form please contact the ANIMATE Trial Coordinator on:
020 7679 9860