ANIMATE

Trial Number A N M – | | | |

Patient Initials | | |

Treatment Form (1/5)

Cycle No. |

Pre-treatment assessment

Pregnancy Test *(to be performed within 3 days prior to starting nivolumab at cycles 1, 3 , 5 and 7)*

N/A this cycle |

	Yes	No	N/A
Negative pregnancy test in females of child bearing potential			

If Yes enter date (DD/MM/YYYY) | | | | | | | | |

If N/A please state reason:

Post menopausal for 12 consecutive months |

Total abdominal hysterectomy and/ or bilateral oophorectomy |

Male |

Other Specify below |

Haematology *(to be performed within 3 days prior to starting each cycle)*

Date of Haematology (DD/MM/YYYY) | | | | | | | | |

Haemoglobin g/L | | | | . | | |

Platelets x 10^9/L | | | | |

Absolute Neutrophil Count (ANC) x10^9/L | | . | | |

Absolute Lymphocyte Count (ALC) x10^9/L | | . | | |

White Blood Cell (WBC) Count x10^9/L | | | . | | |

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

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (2/5)

Cycle No. ☐

Biochemistry *(to be performed within 3 days prior to the start of each cycle)*

Date of Biochemistry (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

U&Es	Test Result		Test Result
Sodium mmol/L	☐☐☐☐	Magnesium mmol/L	☐☐.☐☐
Potassium mmol/L	☐☐.☐☐	Calcium mmol/L	☐☐.☐☐
Urea mmol/L	☐☐.☐☐	Urate mmol/L	☐☐.☐☐
Creatinine µmol/L	☐☐☐.☐		

Liver Function Tests	Test Result
Albumin g/L	☐☐☐
Bilirubin µmol/L	☐☐☐
Alk. Phosphatase IU/L	☐☐☐☐
Aspartate Transaminase (AST) IU/L	☐☐☐☐
OR	
Alanine Transaminase (ALT) IU/L	☐☐☐☐
Lactate dehydrogenase (LDH) IU/L	☐☐☐☐
Glucose mmol/L	☐☐.☐☐

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

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (3/5)

Cycle No. ☐

Autoimmune tests *(to be performed within 3 days prior to the start of cycle 1 and 5)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Amylase IU/L ☐☐☐ **OR** Lipase U/L ☐☐☐

ACTH ng/L ☐☐☐

Thyroid function tests *(to be performed within 3 days prior to the start of cycles 1, 3, 5 and 7)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐ N/A this cycle ☐

TSH mIU/L ☐☐•☐☐

Free T4 pmol/L ☐☐•☐☐

Free T3 pmol/L ☐☐•☐☐ To be taken if TSH / T4 abnormal otherwise please tick this box for N/A ☐

Oxygen saturation *(to be carried out each cycle on the day of nivolumab administration)*

Date of Assessment (DD/MM/YYYY) ☐☐☐☐☐☐☐☐

Oxygen Saturation % ☐☐☐

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

ANIMATE

Trial Number A N M – ☐☐☐ Patient Initials ☐☐☐

Treatment Form (4/5)

Cycle No. ☐

Trial Treatment

Drug	Date given (DD/MM/YYYY)	Dose given	Units	Route	Days	Was there a dose delay ? 1 = Yes 0 = No If yes, please specify below
Nivolumab			**mg**	**IV**	**1**	

If dose was not 240mg, please specify reason:

Drug	Reason for Delay (use code, see below)	How many days was treatment delayed for?	Specify AE/SAE Terms/Other reason (applicable for codes 1, 2, & 5 - use box below if more space needed)
Nivolumab			

1= Adverse event
2= Serious adverse event
3= Patient decision
4= Withdrawal of consent
5= Other (specify)

If patient has stopped treatment completely, please fill in the Treatment Summary form and/or if patient has experienced an SAE, please submit an SAE report form.

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

Treatment Form (5/5)

Cycle No. |

Blood sample for translational research *(to be taken at the beginning of cycles 1, 2, 4, 6 and 8)*

Date sample taken (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date sample sent to central laboratory (DD/MM/YYYY) | | | | | | | | |

Sample not taken |

Please give reason for not taking sample:

PET- CT Scan

(to be carried out on days 11-13 of cycles 4 and 8. If patient stops treatment during cycles 5-7, scan must be carried out at least 11-13 days after last treatment)

Date of scan (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date scan sent for central review (DD/MM/YYYY) | | | | | | | | |

Contrast-enhanced CT Scan

(if feasible, to be performed at same imaging session as PET-CT scan)

Date of scan (DD/MM/YYYY) | | | | | | | | |

N/A this cycle |

Date scan sent for central review (DD/MM/YYYY) | | | | | | | | |

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 Form

The Treatment Form is used to record all trial treatment chemotherapy administered to the patient. Each Patient may receive up to 8 cycles of nivolumab (each cycle being 14 days in length)

Completing the form

- This form should be submitted within 2 weeks of the end of each cycle.
- Please remember to review the **Rolling Adverse Event Form** at the end of each cycle and send updates as necessary. The cover page must be completed and sent each cycle even if there have been no new AEs.

Specific Fields

- *Treatment doses (page 4)*
  - *Dose* — the patient is to be administered a flat dose of 240mg on day 1 of each cycle.
  - *Was there a dose delay? - Y = 1 / N = 0* – If there was a delay enter 1 for Yes in the box, if the drug was administered as planned enter N

- *Was the full dose given? (page 4)*
  - A flat dose of 240mg is to be administered. However, it is possible that an infusion may be stopped prematurely due to an adverse reaction. Please specify in the box provided when this occurs and record the dose received by the patient during infusion.

- *Delays/Omission (page 4)*
  - *Drug*– Nivolumab is the only IMP on this trial.
  - *Reason for delay*– the appropriate code should be entered. Further detail should be provided as required (see below)
  - *Treatment delay*—please specify number of days treatment was delayed where applicable.
  - *Specify Adverse Event/SAE Term(s) / Other Reason-* this should be completed where codes 1,2 or 5 have been entered in the 'reason for delay' column. If more than one AE/SAE contributed to the delay, please enter all relevant terms as a list. If you need more space, please use the box at the bottom of the page.

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