

**ANIMATE**

Trial Number **A** **N** **M** –

Patient Initials

**Follow Up Form (1/5)** (for patients who received nivolumab) Month    
To be used at months 1-12

**Pregnancy Test** (at follow up months 1, 2 and 3)

Yes	No	N/A
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Negative pregnancy test in females of child bearing potential

If Yes enter date

       

N/A this visit

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 at 1, 2, 3, 6, 9 & 12 months post treatment visits)

Date of Haematology (DD/MM/YYYY)

       

Haemoglobin g/L

   .  

Platelets x 10<sup>9</sup>/L

   

Absolute Neutrophil Count (ANC) x10<sup>9</sup>/L

  .  

Absolute Lymphocyte Count (ALC) x10<sup>9</sup>/L

  .  

White Blood Cell (WBC) Count x10<sup>9</sup>/L

   .  

**Completed by:**

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

**Signature:**

**Date completed:**

D	D	M	M	Y	Y	Y	Y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**ANIMATE**

Trial Number **A N M** –

Patient Initials

**Follow Up Form (2/5)** (for patients who received nivolumab) To be used at months 1-12   **Month**

**Biochemistry** (to be performed at 1,2, 3, 6, 9 & 12 months post treatment visits)

Date of Biochemistry (DD/MM/YYYY)

**U&Es**

**Test Result**

Sodium mmol/L	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Magnesium mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>
Potassium mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	Calcium mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>
Urea mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	Urate mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>
Creatinine µmol/L	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>		

**Liver Function Tests**

**Test Result**

Albumin g/L	<input type="text"/> <input type="text"/> <input type="text"/>
Bilirubin µmol/L	<input type="text"/> <input type="text"/> <input type="text"/>
Alk. Phosphatase IU/L	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Aspartate Transaminase (AST)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<b>OR</b>	
Alanine Transaminase (ALT) IU/L	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Lactate dehydrogenase (LDH) IU/L	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Glucose mmol/L	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>

**Completed by:**

**Signature:**

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**Date completed:**

D	D	M	M	Y	Y	Y	Y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**ANIMATE**

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**Follow Up Form (3/5)** (for patients who received nivolumab) Month   To be used at months 1-12

**Autoimmune tests** (to be performed at 1, 2 and 3 months post-treatment follow up visits)

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

Amylase IU/L    OR Lipase U/L

ACTH ng/L

**Thyroid function tests** (to be performed at 1, 2 and 3 months post-treatment follow up visits)

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

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

**Lung function tests** (to be performed 10 (±2) days and 12 months post-treatment)

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

**Spirometry**

FEV1/FVC%    FEV1% of normal

**Diffusion Capacity (DLCO/TLCO)**

DLCO ml/min/mmHg   .   Tick if not done

or

TLCO mmol/kPA/min   .   Tick if not done  % of normal

Completed by:

Signature:

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Date completed:

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**Follow Up Form (4/5)** (for patients who received nivolumab) Month   To be used at months 1-12

**Further Treatment**

Has the patient started new treatment for Hodgkin  Yes  No

*Please complete and send a New Treatment form*

**Adverse Event Assessment** (complete at months 1, 2 and 3 unless patient has started a new treatment for Hodgkin lymphoma)

Date of assessment (DD/MM/YYYY)         N/A this visit

Has the rolling AE form been updated and submitted to UCL CTC?  Yes  No

**Assessment for late toxicity of nivolumab**

(complete at follow up months 6, 9 and 12)

Date of assessment (DD/MM/YYYY)         N/A this visit

Has the patient experienced any late toxicity attributed to nivolumab?  Yes  No

*If yes, please specify below, including any treatment:*

**Please continue to report AESI/SAEs up to 5 months post nivolumab treatment, or later if considered a late effect of nivolumab (see protocol section 12.2.2 for guidance)**

**FOR UCL CTC USE ONLY:**

SAE number: \_\_\_\_\_

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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**ANIMATE**

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**Follow Up Form (5/5)** (for patients who received nivolumab) To be used at months 1-12

**Remission status**

Date of assessment (DD/MM/YYYY)

Has the patient relapsed or progressed?  
*If yes, please complete a disease progression form and send biopsy sample if taken. Details of the biopsy should be recorded on the disease progression form.*

Yes  No

**Biopsy—patients who are PET positive after 8 cycles**  
*(To be performed at end of treatment if PET positive after 8 cycles and patient has consented)*

Date of biopsy (DD/MM/YYYY)   N/A  
*(tick if: - <8 cycles given - Patient is PET negative after 8 cycles - Patient has not consented for repeat biopsy)*

Date biopsy sent to central laboratory (DD/MM/YYYY)

**Blood sample for translational research** *(to be taken 1 month after treatment)*

Date sample taken (DD/MM/YYYY)   N/A  
*(tick if not applicable at this visit)*

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

Sample not taken

Please give reason for not taking sample:

Completed by:

Signature:

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Date completed:   
D D M M Y Y Y Y

**ANIMATE**

Trial Number **A** **N** **M** –

Patient Initials

**Follow Up Form** (for patients who received nivolumab)

The Follow Up Form is used for all patients who received nivolumab treatment, this form should be used after the decision has been made to stop treatment. Month

**Completing the form**

- This form should be completed at the end of months 1, 2, 3, 6, 9 and 12 in the first year after stopping trial treatment. The Annual Follow Up form should then be used.
- The form should be submitted to UCL CTC within 4 weeks of the patient being seen

**Specific Fields**

- Not all investigations are due at each visit. Each question outlines when that investigation is required. If it does not need answering at this visit then please tick the N/A box to the right of the question.
- A quick reference guide to patients outlining what is required at each visit is included in the trial protocol as appendix 2, please consult for further clarification.
- For late toxicity assessment, please see CTCAE v5 for guidance on event terms and grading.
- Please see section 12.2.2 of the protocol to see if the event meets the criteria for an AESI/SAE and submission of an SAE report form.

Completed by:

Signature:

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Date completed:

D	D	M	M	Y	Y	Y	Y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please return to: **ANIMATE** Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ  
 CRF Template V3 06/Jan/2017 Modified for **ANIMATE** on 17.12.2019, v2.0

For UCL CTC use only: Date Checked: \_\_\_\_\_ Initials: \_\_\_\_\_ Date entered: \_\_\_\_\_ Initials: \_\_\_\_\_