

ANIMATE

Trial Number **A** **N** **M** –

Patient Initials

Annual Follow Up Form (1/1) (for patients who received nivolumab) Year

Disease status

Date of assessment (DD/MM/YYYY)

Has the patient died? Yes No

If yes, please complete a death form

Has the patient relapsed or progressed? Yes No

*If yes, please complete a **disease progression form for initial and subsequent progressions (after nivolumab)***

Has the patient started a new treatment for Hodgkin lymphoma? Yes No

*Please complete a new treatment form for **all subsequent new treatments (after nivolumab)***

Assessment for late toxicity of nivolumab

Date of assessment (DD/MM/YYYY)

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

If yes, please specify, including any treatment given:

Please continue to report AESI/SAEs later than 5 months post trial treatment if the event is considered to be 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:

Additional instructions for completing forms

Annual Follow Up Form

The Annual Follow Up Form is used for all patients who received nivolumab treatment from the 2 year post-treatment visit onwards

Completing the form

- This form should be completed annually, starting at 2 years after post-treatment and then submitted annually thereafter until the end of trial is declared.
- The form should be submitted within 4 weeks of the patient being seen.
- **If patient has progressed please complete a Disease Progression form and send it in along with this form. A Disease Progression form is required for the initial and subsequent progressions (after nivolumab)**
- **If a patient has received new treatment please complete the New Treatment form and send in along with this form. A New Treatment form is required for any initial and subsequent New Treatment(s) following Nivolumab**
- Please continue to report AESI/SAEs later than 5 months post trial treatment if the event is considered to be a late effect of nivolumab (see protocol section 12.2.2 for guidance).

Specific Fields

- **Year** should reflect the number of years post-treatment, e.g. for the 2 years post-treatment follow up visit, please enter "2".
- 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.

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