

ANIMATE

A phase II study of nivolumab monotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for autologous stem cell transplant, who fail to reach complete metabolic remission after first or second line salvage therapy

DISEASE PROGRESSION URGENT EVENT FORM FAX

Number of pages (including cover):
Date:
Name of sender:
Site Name:
Contact telephone number:
Contact email address:

**Report due within 72 hours of becoming
aware of event**

Please fax to **020 7679 9861** or email to **ctc.animate@ucl.ac.uk**

General enquires: 020 7679 9860

E-mail: ctc.animate@ucl.ac.uk

FOR UCL CTC USE ONLY:

SAE number: _____

Incident report number: _____



Cancer Research UK and UCL Cancer Trials Centre



ANIMATE

Trial Number **A N M** –

Patient Initials

Disease Progression Form

Urgent Event

Progression / Relapse

Date of confirmed progression / relapse (DD/MM/YYYY)

Please complete the annual follow up form from now on even if the patient is less than 12 months post-treatment

Date site became aware of progression / relapse (DD/MM/YYYY)

Did the relapse occur at the site of prior disease (i.e. involved before initial salvage therapy)?

 Yes No

Was the relapse causally related to nivolumab?

 Yes *Please also submit an SAE form* No

Signature of clinician that assessed causality

If the patient has received treatment for relapsed disease, please complete a New Treatment Form

Biopsy

Was a biopsy taken?

 Yes No

Date sample taken (DD/MM/YYYY)

Date sample sent for central review (DD/MM/YYYY)

If biopsy not taken or sent for central review, please give reason:

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

Additional instructions for completing forms

Disease Progression Form

The Disease Progression Form should be completed when the cancer relapses/progresses.

Completing the form

- This form should be submitted when a patient relapses or has disease progression **within 72 hours of becoming aware of the event. This is an urgent event for this trial.**
- Patients diagnosed with disease progression should be followed up annually thereafter, even if they are less than 12 months post-treatment.

Specific Fields

- **Causal relationship with nivolumab:** This must be assessed by a clinician delegated the duty of assessing AE/SAE causality on the delegation log. If there is a reasonable possibility that nivolumab caused disease progression, an SAE report must be submitted to UCL CTC.
- A **biopsy** is to be performed at relapse if clinically indicated and the block is to be sent to HMDS for further analysis.

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