

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

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

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

--	--	--	--	--	--	--	--

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

--

Please indicate if this is the
first, second or a subsequent
progression
(post ANIMATE treatment)

--

Use coding:
1 = 1st, 2 = 2nd, 3 = 3rd etc.

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

Biopsy— only required for first progression (post ANIMATE treatment)

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:

--

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

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.**
- Please complete form for second and any subsequent progressions after ANIMATE treatment. The form may be completed multiple times depending on number of progressions observed, add the number of progressions seen i.e. second progression, third progression etc.
- 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 (for first progression after ANIMATE treatment only) 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