CANCER RESEARCH UK

UCL

ANIMATE

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

New Treatment Form (1/2)

This form should be sent with the next due Follow Up Form.

Is this the first round of new treatment post nivolumab? ☐ Yes ☐ No

If no, indicate line of new treatment following nivolumab i.e. 2nd, 3rd etc. ☐

Systemic treatment for lymphoma

Did the patient receive systemic treatment? ☐ Yes ☐ No

Start date of new treatment (DD/MM/YYYY) ☐☐ ☐☐ ☐☐☐☐

End date of new treatment (DD/MM/YYYY) ☐☐ ☐☐ ☐☐☐☐

What kind of regimen did the patient receive?

Chemotherapy ☐

Chemotherapy + monoclonal antibody ☐

Monoclonal antibody therapy alone ☐

Other
Please specify: ☐

Please specify the drugs used in the regimen given:

Number of cycles given ☐   **If excessive toxicity is observed that is considered to be potentially due to nivolumab treatment, please submit an SAE form.**

Radiotherapy

Did the patient receive radiotherapy? ☐ Yes ☐ No

Start date of new treatment (DD/MM/YYYY) ☐☐ ☐☐ ☐☐☐☐

End date of new treatment (DD/MM/YYYY) ☐☐ ☐☐ ☐☐☐☐

Please specify site(s) irradiated:

Radiotherapy dose: _____ Gy   _____ Fractions

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 23.08.2021, v2.0

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

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Trial Number | **A** **N** **M** — ☐ ☐ ☐   Patient Initials ☐ ☐ ☐

New Treatment Form (2/2)

Transplant

For first transplants only, please **also** complete and submit the Transplant form.

Did the patient receive a transplant? ☐ Yes ☐ No

Tick box if second or subsequent transplant, and complete question below ☐

For second and subsequent transplants, please indicate type of transplant:

☐ Autograft ☐ Allograft

Response to new treatment

Not due yet ☐ *Please remember to send in an updated report once response assessment has been performed*

Date of response assessment (DD/MM/YYYY) ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Please specify response to treatment by ticking the relevant boxes below:

PET-CT

☐ Complete Metabolic Response (CMR)   ☐ Partial Metabolic Response (PMR)

☐ No Metabolic Response (NMR)   ☐ Progressive Metabolic Disease (PMD)

Please see appendix 3 of the trial protocol for guidance

CT

☐ Complete Response (CR)   ☐ Partial Response (PR)

☐ Stable Disease (SD)   ☐ Progressive Disease (PD)

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 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Please return to: **ANIMATE** Trial Coordinator, CR UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London, W1T 4TJ

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

Additional instructions for completing forms

New Treatment Form

The New Treatment Form should be completed if a patient receives any further treatment for Hodgkin Lymphoma post-trial treatment.

Completing the form
- The form should be submitted as necessary with the next due follow up form.
- If the patient has received second and subsequent treatment for their Hodgkin Lymphoma then please complete this form as appropriate.

Specific Fields
- **Systemic treatment for Lymphoma** — Please answer *yes* or *no* for 'did the patient receive systemic treatment?'. If answered yes, please complete this section stating the start and end date of treatment, what regimen and how many cycles were given. If excessive toxicity is observed that is considered to be potentially due to nivolumab treatment, please submit an SAE form.

- **Radiotherapy** — Please answer *yes* or *no* for 'did the patient receive radiotherapy?' If answered yes, please complete this section stating the start and end date of treatment, what sites were irradiated and the dose given.

- **Transplant** — Please answer *yes* or *no* for 'did the patient receive a transplant?' If answered yes, please complete and submit the Transplant form (only required for first transplant).

- **Response to new treatment**— Please give the response to new treatment and the date of this assessment, or tick the box for *not yet due* if treatment is still ongoing. ~~An update report should then be sent with a subsequent follow up form.~~ If response assessment has not yet been performed, please ensure the New Treatment form is updated with the response once it becomes available and sent to the CTC.

  Please see appendix 3 of the trial protocol for further guidance on PET-CT based response assessment.

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