# 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**

# POST-ALLOGENEIC TRANSPLANT 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:**

**Incident report number:** _____

ANIMATE

Trial Number A N M – | | |

Patient Initials | | |

# Post-Allogeneic Transplant Form (1/2)

*Urgent Event*

## Post-Allogeneic Transplant Event

Please see section 12.5.1 of the trial protocol for full details regarding post-allogeneic transplant events.

Date of transplant (DD/MM/YYYY) | | | | | | | | |

Date of event onset (DD/MM/YYYY) | | | | | | | | |

Date site became aware of event onset (DD/MM/YYYY) | | | | | | | | |

Date of assessment (DD/MM/YYYY) | | | | | | | | |

Did the patient experience Acute GvHD? Occurring from days 0 to 100 after date of transplant. N.B. Only grades 3-4 acute GvHD counts as an urgent event as per protocol section 12.5.1

☐ Yes ☐ No

Did the patient experience Hyperacute GvHD? occurring up to 14 days after date of transplant

☐ Yes ☐ No

Maximum overall aGvHD grade ☐ Grades 3-4 Please appendix 4 in protocol for guidance

Maximum skin grade ☐ Maximum liver grade ☐ Maximum gut grade ☐

GvHD assessment confirmed by treating clinician listed on delegation log (name): _____



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

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

# Post-Allogeneic Transplant Form (2/2)

*Urgent Event*

Has the patient experienced any off the following:

Sinusoidal obstruction ☐ Yes ☐ No

If yes, please confirm which two of the following criteria occurred within 20 days after stem cell infusion:

Bilirubin >17.1 µmol/L ☐ Hepatomegaly and/or tenderness or pain over the liver ☐ Weight gain >20% above baseline ☐

Any other non-infectious febrile episodes requiring steroid therapy (including steroid-responsive febrile syndrome)? ☐ Yes ☐ No

If yes, please confirm which of the following features the patient experienced:

Major Criteria for steroid-responsive febrile syndrome

Non-infectious fever ☐ Rash covering >25% of body surface area ☐ Non-cardiac pulmonary oedema ☐

Minor Criteria for steroid-responsive febrile syndrome

Bilirubin >17.1 µmol/L ☐ AST >2 x upper limit of normal ☐ Weight gain >2.5% above baseline ☐

Creatinine >2 x baseline ☐

Any other post-transplant immune complications?
*If yes, please specify:*

☐ Yes ☐ No

**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



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

# Additional instructions for completing forms

## Post-Allogeneic Transplant Form

The Post-Allogeneic Transplant Form should be completed if a patient experiences any Post-allogeneic transplant events.

### Completing the form

- This form should be submitted **within 72 hours of becoming aware of the event. This is an urgent event for this trial.**

### Specific Fields

- ***Please see section 12.5.1 of the trial protocol for full details regarding post-allogeneic transplant events.***

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