

<u>A</u> phase II study of <u>ni</u>volumab <u>m</u>onotherapy in patients with relapsed/refractory Hodgkin lymphoma, fit for <u>a</u>utologous s<u>te</u>m 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: <u>ctc.animate@ucl.ac.uk</u>

FOR UCL CTC USE ONLY:

Incident report number: \_\_\_\_\_



Cancer Research UK and UCL Cancer Trials Centre



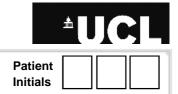


**ANIMATE** 

Cancer Research UK and UCL Cancer Trials Centre

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## **Post-Allogeneic Transplant Form (1/2)**

Trial

Number

Α

Urgent Event

ost-Allogeneic Transp	Dlant 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 e (DD/MM/YYYY)	event onset
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 confirn clinician listed on delegatio	

RESEARCH UK	Cancer Research UK and UCL Cancer Trials Centre	<b>UC</b>
NIMATE	Trial N M - Patient Number A N M - Initials	
Post-Allogeneic	Transplant Form (2/2) Urgent Event	
Has the patient experienced	d any off the following:	
Sinusoidal obstruction	Yes No	
If yes, please confirm which	n two of the following criteria occurred within 20 days after stem cell infusion:	:
Bilirubin >17.1 µmol/L	Hepatomegaly and/or tenderness Weight gain >20% ab or pain over the liver baseline	ove
Any other non-infectious febrile episodes requiring steroid therapy (including steroid-responsive febrile syndrome)?	Yes No	
If yes, please confirm which	n of the following features the patient experienced:	
Г	responsive febrile syndrome	
Non-infectious fever	Rash covering >25% of body Non-cardiac pulmona surface area oedema	ry
Minor Criteria for steroid-r	responsive febrile syndrome	
<u>Minor Criteria for steroid-r</u> Bilirubin >17.1 μmol/L	AST >2 x upper limit of normal Weight gain >2.5% at baseline	ove
Г	AST >2 x upper limit of normal Weight gain >2.5% at	bove
Bilirubin >17.1 µmol/L	AST >2 x upper limit of normal Weight gain >2.5% at	bove
Bilirubin >17.1 µmol/L Creatinine >2 x baseline	AST >2 x upper limit of normal Weight gain >2.5% at	bove
Bilirubin >17.1 µmol/L Creatinine >2 x baseline Any other post-transplant immune complications? <i>If yes, please specify:</i>	AST >2 x upper limit of normal Weight gain >2.5% at baseline	





## 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 postallogeneic transplant events.

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