

# PlaNeT-2 - Form 14a

Trial Number

Neonate Initials

If multiple births; birth order  of

**SERIOUS ADVERSE EVENT (SAE)**  
(Do NOT include major bleed)  
To record SAEs occurring from Randomisation to End of Study

**Type of report:** (Please tick box)  Initial  Follow-up 1  Follow-up 2  Follow-up 3  Follow-up 4

SAE definitions opposite

**Serious Adverse Event Name** .....

**Date and time of SAE onset**

Date  2 0   
D D M M Y Y Y Y

Time (24 hour clock)   
H H M M

**Why was the event serious?**  
(Please tick one box only)

- |   |  |
|---|--|
| <input type="checkbox"/> Death            | <input type="checkbox"/> Requires re-hospitalisation or prolongation of existing hospital stay |
| <input type="checkbox"/> Life-threatening | <input type="checkbox"/> Likelihood of persistent or significant disability or incapacity      |

**Please classify SAE under one of the following:**  
(Please tick one box only)

- |                                 |   |
|---------------------------------|---|
| <input type="checkbox"/> NEC    | <input type="checkbox"/> Platelet transfusion reaction<br>(Also complete Serious Platelet Transfusion Related AE Form 15) |
| <input type="checkbox"/> Sepsis | <input type="checkbox"/> Other,<br>Specify:.....  |

**Status of SAE:**

(Please tick one box only)

- |  |                                    |
|--|------------------------------------|
| <input type="checkbox"/> Resolved*               | <input type="checkbox"/> Worsening |
| <input type="checkbox"/> Resolved with sequelae* | <input type="checkbox"/> Fatal*    |
| <input type="checkbox"/> Ongoing                 |                                    |

**\*Date and time of SAE resolution**

Date  2 0   
D D M M Y Y Y Y

Time (24 hour clock)   
H H M M

**Was the platelet transfusion regimen altered as a result of this SAE?** NO  YES

**If 'Yes', is the treatment allocation being discontinued?** NO  YES

If 'Yes', complete the Discontinuation of Treatment Allocation Form 10

**Completed SAE Form 14a must be sent to the NHSBT CSU within 24 hours of identification of the event. Fax: 01223 588 136 Email: planet2@nhsbt.nhs.uk**

Principal Investigator Name (Print)

Principal Investigator Signature

Date  2 0   
D D M M Y Y Y Y

**PROCEED TO SAE NARRATIVE FORM** CSU use only: SAE Number .....

**Send Form 14a within 24 hours**