AML17 **Serious Adverse Event Report Form** Type of report: Initial ☐ Follow Up ☐ Final ☐

Patient Identification

Patient's initials: _____ Trial Number: _____ Date of Birth: ___/___/_____

Sex: Male / Female delete as appropriate Course Number: _____ Responsible Doctor:_____

Centre: _____ Status: ☐ CR ☐ Relapsed disease ☐ Persistent disease

Associated Drug (please tick all that apply)

☐ Daunorubicin	☐ Ara-C	☐ Clofarabine	☐ Mylotarg	☐ Etoposide
☐ Trisenox	☐ CEP 701	☐ ATRA	☐ Fludarabine	☐ Idarubicin
☐ G-CSF	☐ RAD 001	☐ Amsacrine	☐ Mitoxantrone	

Other (please Specify): _____

Treatment start date: ___/___/_____ Treatment stop date: ___/___/_____ or continuing ☐

Adverse event description why was the event serious?

☐ Death	☐ Life-threatening	☐ Hospitalisation or prolongation of existing hospitalisation	☐ Persistent or significant Disability / incapacity
☐ Congenital anomaly	☐ Resulting in cancer	☐ Grade 3/4 non-haematological toxicity	☐ Neutropenia for more than 42 days

☐ Other please specify: _____

Date SAE started: ___/___/_____ Date SAE resolved: ___/___/_____ or persisting: ☐

Outcome: ☐ Fatal if so, date of death: ___/___/_____ Cause of death: _____

☐ Recovered Number of days spent in hospital as a result of the SAE: _____

Details of adverse event: please attach copies of relevant reports marking each sheet with the appropriate patient trial number

SAE name ..... (using CTCAE version 3.0)

Event Description.....

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Causality Assessment: Do you consider the relationship between the suspected drug and the serious adverse event to be:

Please specify each associated drug:	Very likely	Probable	Possible	Unlikely	Unrelated
1. _____	☐	☐	☐	☐	☐
2. _____	☐	☐	☐	☐	☐
3. _____	☐	☐	☐	☐	☐

Concomitant medications: Please specify for each associated drug which is pertinent to this SAE.

Drug name:		Dose	Start date	End date	Relationship to the SAE	Expected or Unexpected
1.						
2.						
3.						
4.						
5.						

Details of person reporting: please print

Name:_____ Address: _____

Telephone: _____ Fax:_____ Email: _____

Signed: _____ Date: ___/___/_____

Please send fax to the HAEMATOLOGY CLINICAL TRIALS UNIT within 24 hours of event to: 029 2074 2289