16.1 Adverse Event Reporting

Principal Investigators at each participating institution have an obligation to report relevant Serious Adverse Events (SUSARs and SAEs) that occur in this trial to HCTU, in a timely manner.

Reports should be faxed to the Trials Office at the number below:

HCTU Fax Number: 029 2074 2289

It is recognised that adverse events that may be life-threatening, are a normal consequence of acute myeloid leukaemia or its effective treatment, and many clinical changes in the patient's condition are expected. Within the trial, any event that occurs within 28 days of the patient's treatment, and meets the criteria laid out in Section 16.2 of the protocol, should be reported as an SAE. Beyond this period, any event which is felt to be causally linked to the medication received on the trial, and meets the criteria laid out in the protocol, should also be reported. Also, any patient deaths in CR require reporting as an SAE as per section 16.2 of the protocol.

16.2 Definitions

For the purpose of this trial a **Serious Adverse Event (SAE)** is defined as:

- Development of a non-haematological toxicity of grade 3 as defined in the NCI Common Toxicity Criteria, which does not resolve to grade 2 or less within **7 days**.
- Development of any grade 4 non-haematological toxicity (excluding alopecia).
- Development of neutropenia (<1.0 x 10^9/L) or thrombocytopenia (<50 x 10^9/L) for longer than 42 days after the end of chemotherapy in the absence of significant disease in the bone marrow (>5% blasts).
- Any event which is unrelated to the expected consequences of AML or its treatment which results in hospital admission or prolongation. Any event which results in persistent or significant disability or incapacity.
- Any event which results in a congenital abnormality or birth defect.
- Death in the absence of persistent or progressive disease.

The following **do not** require to be reported as **SAEs**:

- Patients may present with some pre-existing toxicities which meet the criteria set out above, but it is only the *development* of these toxicities after entering the trial which should be reported.
- Neutropenic fever is an expected severe adverse event which may occur as a result of the disease or the treatment. This *or its consequences* do not have to be reported unless fulfilling the criteria set out above
- Deaths from persistent or progressive disease.

SAE Reporting

What to include in report within 24 hours:

- Patient identifiers (Trial No, DoB, Initials, Sex) *
- Associated Drugs and treatment dates *
- Category of event (hospitalisation/death/life threatening etc.) *
- SAE start date *
- Details of event *
- Causality assessment for each individual associated drug *
- Details of person reporting
- PI signature

*once these details are available the reporting clock has started

What NOT to report (see section 16.2):

- Pre-existing toxicities (only *development* of these toxicities requires reporting)
- Neutropenic fever and its consequences (unless >42 days post chemo)
- Death due or associated with persistent or progressive disease (although this should still be recorded, see Section 16.5)
- **Unrelated SAEs 28 days or more after last dose of treatment**

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CANCER RESEARCH UK

NCRI National Cancer Research Institute

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Ved alle SAE'er og/eller indlæggelser der falder ind under 24 timers rapportering skal projektsygeplejersken kontaktes.
Dectt: 5-0508