

APPENDIX I

ADVERSE EVENT REPORTING

Definitions

Serious adverse event (SAE)

Any adverse event that

- results in death,
- is life-threatening
- requires unexpected hospitalisation or unexpected prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity

Except the following which should NOT be reported as SAEs:

Hospitalisation due to febrile neutropenia.

Death following relapse.

Expected serious adverse drug reaction or event (SSAR)

All complications as a result of severe bone marrow failure, the adverse reactions or events described in Appendix B, Appendix E, Appendix G and Appendix H of the protocol and those described in the summary of product characteristics for each protocol drug are 'expected', even if they result in death. These will therefore be categorised as SSARs

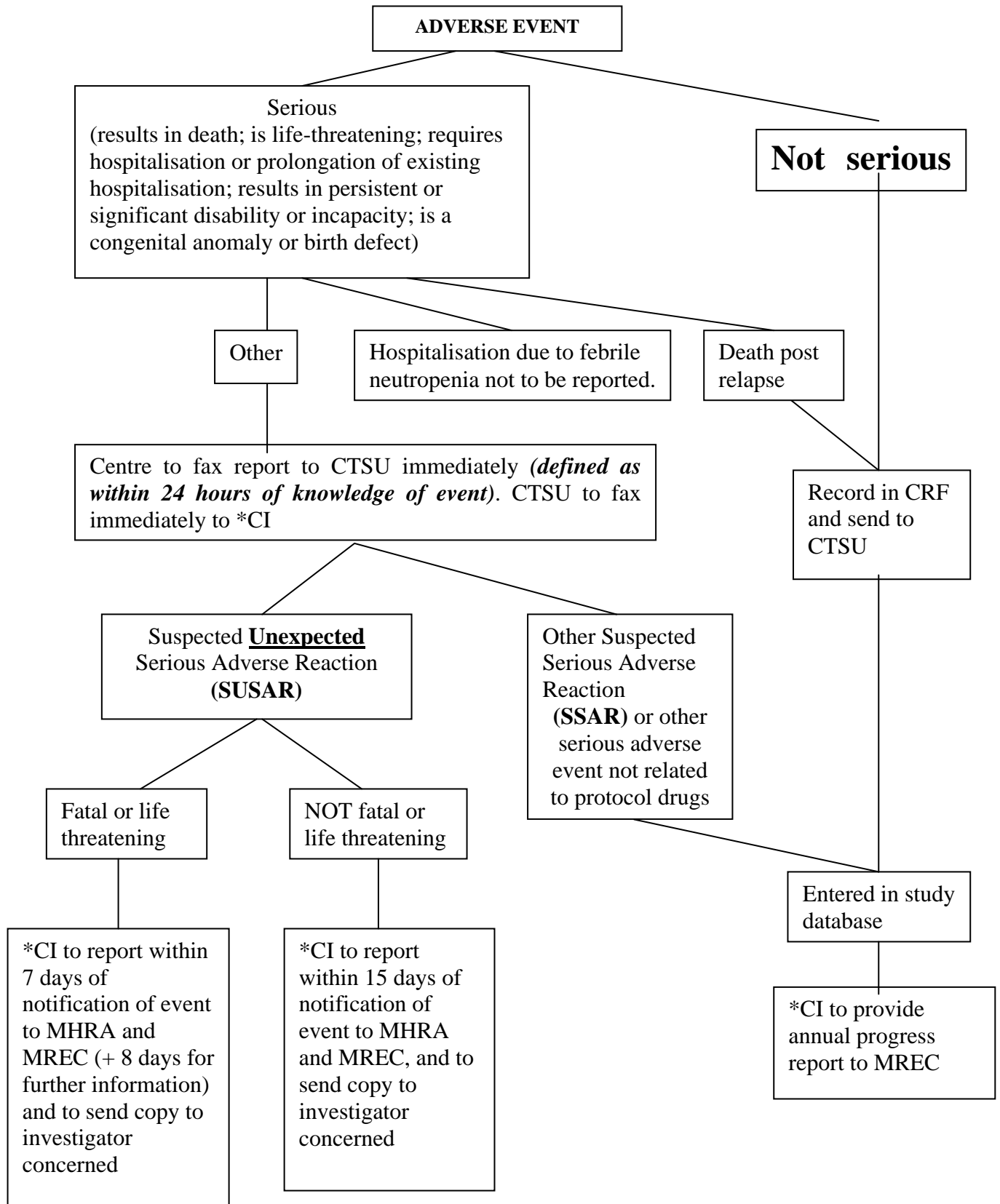
Suspected unexpected serious adverse reaction (SUSAR)

Any serious adverse event which is NOT a complication of bone marrow failure or an expected side effect of a drug as defined above, and which is judged as having a reasonable suspected causal relationship with a protocol drug will be considered a SUSAR. In addition, if a SSAR is encountered more frequently than seen in previous UK studies, or comparable studies elsewhere, it will be considered a SUSAR.

All such events should be reported to the CTSU within 24 hours.

Adverse Events (AE)

NCI Grade 3 or 4 toxicity should be reported on the toxicity form. There is no need to report Grade 1 and 2 toxicities.



*CI = Chief Investigator

MRC UKALL2003 SERIOUS ADVERSE EVENT REPORT

To be completed by local investigator and faxed to CTSU

A Serious Adverse Event is any adverse event that

- results in death,[#]
- is life-threatening
- requires unexpected hospitalisation or unexpected prolongation of existing hospitalisation[†]
- results in persistent or significant disability or incapacity

If death after relapse (i.e. off protocol treatment), report only on trial form 4.

† Hospitalisation due to febrile neutropenia alone should not be reported.

Fax to: 01865-743986

PATIENT NAME: _____ **AGE:** _____

TRIAL REFERENCE NUMBER: _____ **SEX:** M F

CONSULTANT: _____ **HOSPITAL:** _____

Date of Event ___/___/___ **Treatment:** A B C **Week of treatment:** _____

Brief description (Continue on separate page if necessary):

Was the event related to treatment?:

DEFINITELY PROBABLY POSSIBLY UNLIKELY NOT RELATED

If definitely, probably or possibly, name drug/course involved: _____

Did concomitant medication (non-protocol drug) contribute to event? If so, name drug involved:

Outcome:

Recovered Date recovered: ___/___/___ Died Date died: ___/___/___

Recovered with sequelae Date recovered: ___/___/___ Ongoing at ___/___/___

CTSU: Date original SAE form received: ___/___/___ Date faxed to chief investigator ___/___/___

To be completed by Chief Investigator (Trial Co-ordinator): Date original SAE form received ___/___/___

Signed: _____

Was the event related to treatment:

DEFINITELY PROBABLY POSSIBLY UNLIKELY NOT RELATED

If definitely, probably or possibly, name drug involved: _____

Classification: SUSAR SSAR Other serious adverse event

If SUSAR: Date informed MHRA ___/___/___ Date informed lead REC ___/___/___

(If fatal/life-threatening, to report within 7 days, (+8 for further info), otherwise within 15 days)

Copy of report sent to local investigator: ___/___/___