LRF CLL4 TRIAL: ADVERSE EVENTS - Definitions July 2004

Serious adverse event

Any adverse event that

- results in death,
- is life-threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- is a congenital anomaly or birth defect

All such events should be reported to CTSU or the chief investigator (Prof. Catovsky) within 24 hours.

Expected adverse drug reaction or event

See section 16 and form B in the protocol, in addition to the summary of product characteristics for each protocol drug.

In summary:
Chlorambucil may be associated with neutropenia, thrombocytopenia, nausea and mucositis. It may also be associated with haemolytic anaemia.
Fludarabine may be associated with neutropenia, thrombocytopenia, lymphopenia, pneumonia, nausea, diarrhoea, mucositis and autoimmune complications (haemolytic anaemia).
Fludarabine plus cyclophosphamide, in addition to the above, may be associated with vomiting and fatigue.

Suspected unexpected serious adverse reaction (SUSAR)

Any serious adverse event which is not listed as expected and which is judged as having a reasonable suspected causal relationship with a protocol drug.