**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.