ANNEX IV

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL E.ADVERSE EVENTS:

1. Adverse events information;
2. Adverse event reporting group;
3. Serious adverse event;
4. Non-serious adverse event.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Division E..