Clinical trials on medicinal products for human use

2012/0192(COD) - 19/12/2012 - Document attached to the procedure

Opinion of the European Data Protection Supervisor (EDPS)

The EDPS welcomes the fact that the Commission has made an effort to guarantee the correct application of EU rules concerning the protection of personal data in the proposed Regulation on clinical trials on medicinal products for human use.

The EDPS considers, however, that **clarifications are necessary** with regard to where **sensitive data** regarding health might be processed and stored, regarding the authorisation procedure in the EU Portal and database and the reporting of adverse effects in the European Medicines Agency (EMA) database.

The EDPS recommends in particular, that the proposal:

- explicitly refers to Article 8 of Directive 95/46/EC and Article 10 of Regulation (EC) No 45/2001 regarding the processing of personal data concerning health;
- clarifies whether personal data concerning health will be processed in the EU database, and if so, for what purpose;
- refers to the right of the data subjects to block their personal data;
- ensures, for the EMA database, a provision which more clearly defines in what situations and subject to what safeguards information containing patient data will be processed and stored;
- explicitly mentions that the annual reports should only be using anonymous data;
- replaces or complements the minimum retention period of 5 years by a maximum retention period.