

Medicinal products for human use: implementation of good clinical practice in the conduct of clinical trials

1997/0197(COD) - 03/09/1997 - Legislative proposal

OBJECTIVE: approximation of legislative provisions relating to the conduct of clinical trials on medicinal products for human use. **SUBSTANCE:** the proposal for a directive seeks to provide the same level of protection for patients taking part in a clinical trial and to harmonize technical standards and also rationalize documentary and administrative procedures involved in multi-centre clinical trials, whilst taking account of experience acquired by the Member States. The proposal contains a number of internationally approved definitions codifying the terms used in the Member States, facilitating an international exchange of data relating to clinical trials within the European Union. In addition, the proposal harmonizes the procedures to be followed with regard to information to facilitate ongoing safety monitoring and introduces monitoring in the form of inspections. It is important to note that this proposal is in fact a rationalization of legislation, since overall the administrative and bureaucratic requirements will be reduced in line with a 'risk-based' approach, thus allowing new medicines to be made available in a timely manner. It is also intended to simplify the regulatory burden for small and medium companies (e.g. companies starting up in biotechnology) for which the current complexity of national requirements makes it almost impossible to conduct trials in more than one Member State.