

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

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In assessing the proposal, the Committee feels it desirable to seek to strike a balance between the need to: simplify red tape; respect the deadlines for commencement of the clinical trial; and the need to provide the utmost guarantees for trial subjects; coordinate findings so that the efficacy and safety of a new medicinal product can be rigorously assessed. However, the Committee thinks that forms of cooperation should be encouraged for the purpose of gradually moving towards a single EU procedure. Use should be made here of the scientific skills and knowhow available at the European Agency for the Evaluation of Medicinal Products (EMA), especially as regards "orphan" medicinal products and gene and cell therapy. In order to boost cooperation, it is essential that an EU database be provided as part of EudraNet (a telematic network linking the relevant national authorities, the EMA and the Commission). This would be used to coordinate and circulate information between the Member States involved in a multi-centre international trial, with an access key to guarantee the utmost confidentiality and the safeguarding of industrial protection. The goal must be a clear and simple legal framework which allows trials to be launched simultaneously in different countries. This presupposes respect for the deadlines laid down for the favourable opinion from the ethics committees and for the acceptance of any requests from the relevant authorities for modifications (these authorities have 30 days to notify their opinion to the sponsor). It is also essential that persons undergoing trials are guaranteed the best possible risks-benefits ratio. To this end, the Commission must obtain greater guarantees regarding the participation of third countries in multi-centre trials. The sponsor should be asked to ascertain that third countries involved in trials on a particular medicinal product are familiar with the Community guidelines and are therefore able to apply them properly.