



The Clinical Trials Directive 2001/20/EC

What EuropaBio is asking for

- To review the Clinical Trials Directive to improve harmonisation of procedures to approve and therefore facilitate the conduct of clinical trials in Europe.

Purpose of this meeting

EuropaBio has identified key areas for improving the Clinical Trials Directive as discussed in the written submission for the European Commission-EMEA Conference on the operation of the Clinical Trials Directive held on 3 October 2007. The main points arising from this were:

- Lack of harmonisation for applications for clinical trial authorisations as a result of different national dossier requirements
- Increased bureaucracy and uncertainty as a result of varying national requirements, particularly in respect of conducting clinical trials in two or more Member States
- Different interpretations of the definition of Investigational Medicinal Product
- Varying requirements for safety reporting across the Member States
- Good Management Practices related issues in some Member States

The administrative burden to identify and comply with additional local requirements is significant. As a result Europe is now regarded as a less attractive location to undertake clinical development. Indeed, some member companies have already decided not to conduct their clinical studies in the EU. If the current situation is not addressed and improved, it will be particularly damaging to the continued viability of the bioscience sector in the Community.

Introduction

The Clinical Trials Directive 2001/20/EC was an important first step towards harmonisation of the requirements and processes between EU Member States. However, differences in the way the Directive has been implemented by Member States have adversely impacted on the ability of companies to initiate and carry out multicentre and multinational trials across Europe. The impact on SMEs is particularly significant because they lack resources to cope with the additional administrative burden and consequent delays.

Recommendations

There is a need for legislative change in order to bring about better harmonisation, transparency and consistency in the approval and undertaking of clinical trials across the EU. This would have a direct benefit of improving patient access to innovative medicines as well as making the EU a more attractive prospect for investment in R&D as well as meeting the goals laid out in the Commission's Better Regulation initiative.

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