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Research in Europe at Stake

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Concerns voiced before the EU Clinical Trials Directive (2001/20/EC) came into force are rising regarding the potential threat the Directive poses to non-commercial clinical trials.

Introduction

In May 2001 the EU Directive 2001/20/EC implementing Good Clinical Practice (GCP) for clinical trials was published, requiring full translation into EU member states' national legislation by 01 May 2004. Concerns against the provisions of this directive were voiced before it came into force and groups such as the European Organisation for Research and Treatment of Cancer (EORTC) are still working hard to avoid the disappearance of non-commercial clinical trials. The aim of the Directive is to unify the regulation of clinical trials across the European Union, whether sponsored by charitable organisations, industry or universities. Administrative provisions governing all interventional clinical trials have been simplified and harmonised, by establishing a transparent procedure, and creating conditions conducive to the effective co-ordination of clinical trials in the European Union by the authorities concerned. No distinction is made between commercial and non-commercial clinical trials. The Directive intends to facilitate the internal market in medicinal products, while at the same time maintaining appropriate levels of protection for publichealth. However, the Directive poses a number of important legal and financial problems for academic research.

Petition

Problems posed by the Directive are related to sponsorship, the manufacture of marketed drugs, fees for ethics committees and authorities, provision of free drugs, onsite monitoring and increased administration.

For example, the Directive defines a "sponsor" as an individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial. This model seems to be based on the industry context, where a company taking an innovative compound through its development programme is self evidently the sponsor. Non commercial trials usually operate differently. The principal investigator, the employer (i.e. a university), a funding body and a clinical host collectively take responsibility for various aspects of the trial.

Out of concern for the future of academic and investigator led European research, a petition against the Directive was initially launched from a cancer platform, but gained momentum in cardiology, dermatology, and psychiatry. To date, more than 3000 people from Europe and beyond have raised their voices against the new regulations through this petition. In a next step, feedback will be collated from all the signatories on problems encountered due to the implementation of the Directive. In Ireland, for example, new clinical trial applications have reduced by 50% in the first five months since implementation. Examples will be listed in a new section on the website of the body organising the petition (www.saveeuropeanresearch.org). The list will eventually be forwarded to the European Commission to invite a response.

Outlook

EORTC undertook a snapshot review of all EORTC trials either recently closed, currently open or about to begin, and projected the consequences of the Directive on this set of 127 clinical trials. In the worst case, approximately 60% of all the academic drug trials would not have taken place.

At this stage, it is too late to repeal the Directive; however the "detailed notes for guidance" produced by the Commission, which address the practical implementation of the Directive, can be amended at any time and national authorities have some flexibility in implementation of the text.

The Directive moreover provides that all clinical trials must be conducted in accordance with GCP, for which the Commission has published a separate Directive laying down the standards. EORTC is currently discussing a text dedicated to specific modalities related to the new GCP Directive and the implementation of non commercial research with the European Commission.

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