



Press Release

Future of Clinical Trials in Europe: Biotech industry's keys for change

London, 4 October 2007

EuropaBio – the European association for bioindustries congratulates the European Commission and European Medicines Agency (EMA) for the first comprehensive event on the status of clinical development in Europe and on the evaluation of the Clinical Trials Directive in practice in the member states.

Contributions from stakeholders (Patient groups; National Competent Authorities (NCAs); Researchers; CROs; Investigators and Industry) led to a broad understanding of the issues and helped to identify hurdles making Europe less attractive for clinical trials, .

The general consensus among EuropaBio members is that the Clinical Trials Directive fails to bring the necessary harmonisation across Member States. EuropaBio continues therefore to call for the review of this Directive and its implementation into national laws. Our aim is to achieve an effective harmonization as well as transparency and consistency in the approval and conduct of clinical trials across Europe.

EuropaBio's four points to be addressed within the current legislative framework:

- To reduce the current disharmonisation through a better specification of provisions and definitions (e.g. of Investigational Medicinal Products) and limit substantial amendments.
- Establish a single submission point for clinical trials applications (CTAs)
- Set up a centralized safety reporting system
- Streamline the role and responsibilities of the Ethical Committees at both local and national level

The following significant improvements can be achieved by modifying the existing framework legislation.

A mutual recognition of assessments to be carried out by National Competent Authorities (NCAs) as well as strengthening the remit of the Clinical Trial Facilitation Group (CTFG) are also important. This can be achieved through active contribution of the EMA and the support and coordination of CTFG by them.

Looking towards the future, industry calls for a parallel legislative path to cover clinical trial developments for the new generations of innovative therapies and products covered

by the Advanced Therapies Regulation. Also in such case, industry considers it to be key to have a robust and effective coordination by the EMEA.

“We strongly believe in a step-wise approach to ensure stability and continuity in the legislative framework for clinical trials on innovative medicines in Europe while at the same time allowing the introduction of corrective actions which are urgently needed to ensure that Europe retains its strength, its leadership and its excellence in Good Clinical Practices,” says Andrea Rappagliosi, Chairman of EuropaBio’s Healthcare Council.

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For Editors

The Clinical Trials Directive

EU Directive 2001/20/EC concerns the creation of laws, regulations and administrative provisions of Member States relating to clinical trials on medicinal products for human use. It aims to facilitate the internal market in medicinal products within the EU, while continuing to protect of public health. It seeks to simplify and harmonise the administrative provisions governing clinical trials carried out in the European Community, by establishing a clear, transparent procedure.

To read the Directive:

http://eudract.emea.europa.eu/docs/Dir2001-20_en.pdf

To read the implementing texts on the Directive:

<http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/dir200120ec.htm>

EuropaBio/BIA White Paper on the Clinical Trials Directive (October 2006):

<http://www.europabio.org/documents/BIAEBioWP-Directive181006.pdf>

About EuropaBio

EuropaBio, the sole and unique European Association for Bioindustries, has 85 direct members operating Worldwide, 12 associate members and 5 bioregions as well as 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research and development, testing, manufacturing and distribution of biotechnology products. <http://www.europabio.org>