



Road Map Initiative for Clinical Research in Europe

The First in a series of 5 Workshops

Brussels, 2 July 2009 – In view of the European Commission’s plans to review the Clinical Trials Directive (DIR 2001/20/EC) in 2010, academic institutions/investigators, sponsors, ethics committees, competent authorities and patients representatives are joining forces on 7 July in a first of a series of five workshops with the aim of arriving at a united position – a component missing during the original development of the Directive. The ultimate objective of this workshop being a more efficient CTA process that stimulates rather than stifles research and innovation.

The Road Map Initiative’s partners came together during a CLINT Project workshop at the EBMT 35th Annual Congress in Gothenburg this year, where consensus was reached on the need to promote a single CTA process with clear definitions of the respective roles of the competent authority (e.g. assessment of the IMPD, the Investigational Medicinal Product Dossier, at the EU level) and the ethics committees (e.g. protection of participants at the national level). The objective of next week’s workshop is to discuss how the CTA process could become more efficient without increasing the risk for trial participants. A single CTA for multi-national clinical trials would reduce the complexity of the process and the resources required to run them, however, any such development would have to satisfy the diverse needs of the stakeholders involved. Tuesday’s workshop aims to provide a forum for all key players to air their views and articulate their needs which will feed into a future recommendation to the Commission.

The primary aims of Directive 2001/20/EC were not only to protect patients and improve standards but also to encourage competition and to harmonize administrative procedures. However, it introduced the concept of a Clinical Trial Authorisation (CTA) by a competent authority and a favourable opinion from a lead or central research ethics committee as a prerequisite for the performance of a clinical trial. In multi-national clinical trials this authorisation process has to be followed in each country where the clinical trial is supposed to be performed. The content of the CTA application dossier is defined by each Member State in a different way, and the review processes result in different additional requirements, which results in a longer trial preparation period for multi-national trials and increased administrative cost.

The results of ICREL (Impact on Clinical Research of European Legislation), a one year project funded by FP7, to produce hard data to measure change in the performance of clinical trials in Europe between 2003 and 2007, pointed out the following:

- o An increase of the study preparation time
- o A shift from academic research to commercial trials
- o An increase in costs, administrative burden and timeframes without clearly improving the involvement and safety of patients in clinical trials.

The CTA workshop is just the first of 5 workshops which will be organised by the initiative's partners over the next 9 months in order to explore with all the relevant stakeholders a number of possible solutions to improve clinical research in Europe:

- To require only one Clinical Trials Authorisation (CTA) irrespective of the numbers of participating nations, either by the development of a single CTA application across Europe or the mutual recognition of authorisations by Competent Authorities
- To simplify and harmonise the procedures for clinical trial approval (e.g. the EudraCT forms as a single set of forms to be completed) and safety reporting (Eudravigilance and reporting rules).
- To define better and harmonise the roles of the ethics committees (achieve the so-called single-opinion) and of the competent authorities
- To adopt a risk-based approach: adaptation of the regulatory requirements considering the risk associated with the trial with regard to the safety reporting (e.g. limited safety reporting for commercially approved drugs), data monitoring, insurance, application dossiers, substantial amendments, free-of-charge supply of drug (e.g. not in case of market approval)
- To allow co-sponsorship in the case of multinational trial with the aim of facilitating collaboration between research groups
- To better define terms and concepts (IMP, interventional study, substantial amendment, etc.)
- To increase public financial support to investigator-led clinical trials
- To harmonise insurances requirements e.g. uniform costs per country, minimum and maximum
- Indemnity payments, total duration of coverage, time to permit claims etc

The series of workshops will culminate in a stakeholder Conference in April 2010 to which representatives of, DG Enterprise, DG Research and DG SANCO will be invited to participate.

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Contacts:

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