A Road Map Initiative for Clinical Research in Europe

This Initiative brings together representatives of academic and not-for-profit organisations who have been involved in EU-funded projects to investigate different aspects of the clinical trials environment in Europe following implementation of the Clinical Trials Directive (DIR 2001/20/EC) and/or to promote academic clinical trials.

The various groups first came together in October 2008 at a meeting organised by the CLINT project to discuss the main recommendations arising from each project with a view to developing joint recommendations to the EU. Having identified a number of topics of common concern, the partners agreed to collaborate in exploring these issues further through a series of stakeholder workshops aimed at developing a body of recommendations to feed into a review of DIR 2001/20/EC planned by the European institutions in 2010. The series of workshops aims to bring together all of the relevant stakeholders (commercial and non-commercial sponsors, investigators, ethics committees, competent authorities and patients) and the outcomes of the workshop will culminate in a Stakeholder Conference in March 2010 to which representatives of DG SANCO, DG Enterprise and DG Research will be invited to participate.

The main goal of the Road Map Initiative is to work towards suggestions for improvement in potential new legislation with the aim of facilitating the performance of clinical research for the benefit of patients and to increase the competitiveness of clinical research on a European level. In order to be heard It is essential to have a united academic voice, which was missing during the development of the Directive. The Initiative is open to representatives from all stakeholder groups with an interest in supporting the development of broadly agreed elements for improved clinical trials legislation.

Key partners in this initiative have undertaken to take the lead in organising one or more of the workshops aimed at exploring possible solutions to the most critical obstacles to clinical trials in Europe:

Schedule of workshops:

Month	Venue	Topic	Organised by
7 July 2009	Brussels	Single Clinical Trial Approval (CTA) Process	EFGCP
21 September 2009	London	Co-sponsorship and contractual issues	CLINT/EBMT
18 January 2010	Barcelona	Risk-based approach	ECRIN
19 January 2010	Barcelona	Ethics Committees	ECRIN
8 February 2010	Brussels	Pharmacovigilance	EORTC
17 March 2010	Brussels	Final Workshop with EU: Designing the Future Conditions for Clinical Research in Europe	EFGCP

Possible solutions identified for exploration with stakeholders through these workshops:

- 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

Collaborating organisations and projects behind this initiative:

CLINT: Facilitating international prospective clinical trials in stem cell transplantation (EU funded project)
EBMT: European Group for Blood and Marrow Transplantation
ECRIN: European Clinical Research Infrastructures Network
EFGCP: European Forum for Good Clinical Practice
EORTC: European Organisation for Research and Treatment of Cancer
ELN: European Leukaemia Net (EU funded project)
ICREL: Impact on Clinical Research of European Legislation (EU funded project – ended in Jan 2009)
UCLAN: University of Central Lancashire, Centre for Professional Ethics

Contact for information:

For further information about how to join this initiative or how to register for the final Workshop:

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