Thursday, 11 September 2014

A revision of the Clinical Trials Regulation has been adopted by European legislation makers. This revised framework will bring significant advances compared to todays' situation. However, the original objectives of this legislation should be remembered: these were to enhance efficiency of the overall clinical trials authorization process and, in turn, to boost the EU's competitiveness as a place to conduct research and make for more efficient patients access to new innovative treatments.
Especially the procedure for assessment and approval of multinational clinical trial authorisation applications will change: in future, each Member State will have to generate one single opinion and the competent authority of the "reporting Member State" will coordinate the assessment process until a common decision is reached. Ethics committees are supposed to be an essential part of this assessment process but it is left to the Member State to decide how this will be achieved.
Today, we are at a critical stage in the process where the new rules have to be integrated into the national systems in each Member State. When establishing procedures at national level, it is now essential that Ethics Committees find ways to ensure both a reliable independent ethical review delivered within the defined time frame as well as the relevant level of collaboration during the process with the national competent authority. This will require a re-thinking of ethical review processes and Ethics Committee infrastructure in most Member States. Early discussion with Ethics Committee members and competent authorities from other countries and with concerned stakeholders could help to define the optimal solutions and support the development of a streamlined and a more harmonised system for the European Union.
This workshop aims to facilitate an exchange of opinions on opportunities and threats of the new CTA assessment requirements for the ethical review. It will also be an opportunity for early feedback from some Member States on potential concepts and options for the successful collaboration between ethics committees and competent authorities. Learnings from real life experience over the past decade will be used to identify the most critical aspects for different stakeholders: ethic committees, competent authorities, patients, investigators, commercial and non-commercial sponsors. Specific national hurdles that need to be overcome in the Member States will be identified to enable Europe to emerge as an attractive place for conducting Clinical Research.

Last update: 1 July 2014