EUROPEAN CANCER ORGANISATION

European Commission
Directorate General for Enterprise and Industry
Unit ENTR/ F/2
BREY 10/ 114
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**ECCO supports a revision of the EU Clinical Trials Directive (2001/20/EC)**

ECCO – the European CanCer Organisation – welcomes the opportunity by interested parties to respond to the EU Clinical Trials Directive (CTD) consultation and is supporting proposals by its member societies to adapt the Directive requirements to reflect practical necessities in cancer research and treatment.

ECCO – the European CanCer Organisation – exists to uphold the right of all European cancer patients to the best possible treatment and care and to promote interaction between all organisations involved in cancer research, education, treatment and care at the European level.

Representing the interests of their respective professions/groups from a truly multidisciplinary perspective, ECCO's 24 member organisations - representing over 50,000 professionals - span the entire spectrum from basic, applied and translational research to practice, treatment, care, prevention and advocacy. Therefore, ECCO is uniquely positioned to provide the voice of consensus of the European oncology professionals and engage with policymakers to ensure that cancer stays at the top of the EU health and research agenda.

ECCO and its member societies have been concerned about the detrimental effect the implementation of the Directive has had since its implementation in 2004, particularly on international clinical trials and those that are headed by hospitals, universities, cancer networks and other non-commercial institutions. Lack of harmonisation between European countries in the implementation of the Directive and the increased costs and workload of setting up and running trials has meant that many international trials not aiming at registration of a compound have taken much longer to get started, or, in some cases, have had to be abandoned before start up because of the insurmountable hurdles they faced. At the same time, the Directive does not appear to have improved patient safety in clinical trials nor the competitiveness of European research.

**ECCO supports its member societies, the European Organisation for Research and Treatment of Cancer (EORTC) and SIOP Europe, the European Society for Paediatric Oncology (SIOPE), in their appeal to review the Directive, taking into account their proposals, such as:**

- Minimise the bureaucracy, workload, and, therefore, the costs, of setting up and running clinical trials by harmonising procedures across all Member States
- Refine the definitions of what is a "clinical trial" and an "investigational medicinal product" as well as the role of the clinical trial sponsor (and co-sponsor): the need for a single, pan-European sponsor is interpreted differently by national regulatory authorities and has caused huge delays in launching new protocols by long-established European collaborative groups, such as those involved in paediatric oncology;
- Harmonise the interpretation of rules to avoid confusion over the interpretation of "local rules" by competent authorities and Ethic Committees in different Member States;
- Ensure a single Clinical Trial Authorisation (CTA) irrespective of the numbers of participating countries, either by the development of a single CTA application across Europe or a mutual recognition process;
- Streamline the process of gaining ethical approval, possibly by having a single Ethics Committee per Member State, rather than the several in existence currently;
- Simplify the process of making amendments to trials;
- Improve and harmonise the way risk in a clinical trial is assessed so that it takes account of occasions when an investigated treatment is already considered "standard of care" and therefore should be "zero-rated" for the purposes of the clinical trial;
- Improve and harmonise the way in which insurance for a trial is calculated according to medically sound evaluation of risks;
- Streamline and harmonise the way suspected unexpected serious adverse reactions (SUSARs) are reported;
- Take into account the special needs of groups of patients with rare cancers or particular needs, such as children and the elderly;

ECCO is wholeheartedly endorsing the individual submissions of our member organisations to the Commission's Consultation, and refers to EORTC and SIOPE individual submissions for further information on any of the above. We hope that the Commission's consideration of all the submissions made will result in a revision of the Directive that really does lead to an improvement in patient health and safety across Europe, without compromising investigators' abilities to conduct research into important questions in cancer treatment.