

Consultation item no. 10, Do you agree with the appraisal “Rather than limiting the scope of the Clinical Trials Directive, it would be better to come up with harmonised and proportionate requirements for clinical trials. These proportionate requirements would apply independently of the nature of the sponsor ('commercial' or 'academic/non-commercial').” Please comment.

Comment from the Spanish Society of Medical Oncology (SEOM):

We agree that “harmonised and proportionate requirements for clinical trials” should be applied independently of the nature of the sponsor.

We do not agree with the part of the sentence that reads: “the nature of the sponsor ('commercial' or 'academic/non-commercial’)”. The nature of the sponsors defined in the Preliminary appraisal fails to recognize a third type of sponsor of very high relevance in European clinical research: the Cooperative Groups. Nowadays, Cooperative groups in Europe sponsor clinical research (in the field of cancer, and also in other medical areas) that is academic in origin but almost always has commercial interest both from the point of view of national and European Health Systems and of the pharmaceutical industry. This is therefore a type of sponsor that, if excluded from the definition of “type of sponsor”, would leave out of the Clinical Trials Directive a major type of sponsor of European research, which is of the utmost relevance both for the national and the European health policy systems. This fact must be specifically contemplated in the text, in order to complete the definition of “sponsors” and avoid exclusion of a major stakeholder.

The appraisal no. 10 should therefore read: “Rather than limiting the scope of the Clinical Trials Directive, it would be better to come up with harmonised and proportionate requirements for clinical trials. These proportionate requirements would apply independently of the nature of the sponsor ('commercial', 'academic/non-commercial' or 'clinical research cooperative groups').”

Supporting information

A. List of the Spanish Cancer Cooperative Groups (<http://www.seom.org/apoyo-a-la-investigacion/ayudas-proyectos-investigacion-clinica/que-son-los-grupos-cooperativos>)

1. Grupo Español para el Tratamiento de Tumores Digestivos (**TTD**)
2. Grupo Español de Cáncer de Pulmón (**GECP**)
3. Grupo Español de Estudio y Tratamiento de Intensificación y otras estrategias experimentales en Tumores Sólidos (**SOLTI**)
4. Grupo Español de Investigación en Sarcomas (**GEIS**)
5. Grupo Español de Tumores Germinales (**GG**)
6. Grupo Español de Investigación en Cáncer de Mama (**GEICAM**)
7. Grupo Español para el Estudio del Cáncer Urológico (**SOGUG**)
8. Grupo Español de Cáncer de Ovario (**GEICO**)
9. Grupo de Investigación en Cáncer de Mama y Ovario (**PSAMOMA**)
10. Grupo Español de Neuroncología Médica (**GENOM**)
11. Grupo Español para el Tratamiento de Tumores de Cabeza y Cuello (**TTCC**)
12. Grupo Oncológico para el Tratamiento y Estudio de los Linfomas (**GOTEL**)
13. Grupo para el Estudio de la Astenia (**Grupo ASTHENOS**)
14. Grupo Español de Tumores Neuroendocrinos (**GETNE**)
15. Grupo Cooperativo **ONCOSUR**
16. Grupo Español Multidisciplinar en Cáncer Digestivo (**GEMCAD**)

B. Relevant European Cooperative Groups

(<http://www.eortc.be/Groups/default.asp>)

- [EORTC Brain Tumor Group](#)
- [EORTC Breast Cancer Group](#)
- [EORTC Cancer in Elderly Task Force](#)
- [EORTC Children's Leukemia Group](#)
- [EORTC Cutaneous Lymphoma Task Force](#)
- [EORTC Gastrointestinal Tract Cancer Group](#)
- [EORTC Genito-Urinary Cancers Group](#)
- [EORTC Gynecological Cancer Group](#)

- [EORTC Head and Neck Cancer Group](#)
- [EORTC Imaging Group](#)
- [EORTC Infectious Diseases Group](#)
- [EORTC Leukemia Group](#)
- [EORTC Lung Cancer Group](#)
- [EORTC Lymphoma Group](#)
- [EORTC Melanoma Group](#)
- [EORTC Pathobiology Group](#)
- [EORTC Pharmacology & Molecular Mechanisms Group](#)
- [EORTC Quality of Life Group](#)
- [EORTC Radiation Oncology Group](#)
- [EORTC Soft Tissue and Bone Sarcoma Group](#)

3. Additional Suggestion.

For the future, we suggest to undertake an European Initiative, that parallels the US NCI's Clinical Trials Cooperative Group Program (<http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group>), as follows:

Create the European Clinical Trials Cooperative Group Program

Key Points

- The [European Clinical Trials Cooperative Group Program](#) should be designed to promote and support clinical trials (research studies) of new cancer treatments, explore methods of cancer [prevention](#) and early detection, and study [quality-of-life](#) and [rehabilitation](#) issues.
- Cooperative groups include researchers, cancer centers, and community physicians throughout Europe, and can be national or European.

The European Clinical Trials Cooperative Group Program, which should be regulated by a specific directive after the approval of the “revised Clinical Trials Directive 2001/20/EC”, should be designed to promote and support clinical trials (research studies) of new cancer treatments, explore methods of cancer prevention and early detection, and study quality-of-life issues and rehabilitation during and after treatment. Cooperative Groups include researchers, cancer centers, and community physicians throughout Europe, both at the national and European levels. They should work with the EC to identify important questions in cancer research and to design clinical trials to answer these questions.