Response of the European Society of Radiology (ESR) to the European Commission consultation on the Clinical Trials EU Directive (Directive 2001/20/EC)

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The European Society of Radiology is the European body representing the radiology profession with over 44,000 individual members and acts as an umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology. With medical imaging playing a key role in numerous clinical trials, the ESR kindly requests being considered a stakeholder in the assessment of the functioning of the Clinical Trials Directive 2001/20/EC and looks forward to being included in the future process.
The ESR is registered in the Commission's Register for Interest Representatives. For more information on ESR, please visit www.myesr.org

This document is based on an internal ESR consultation that was carried out using a questionnaire of multiple choice questions and free text answers. This document contains a summary of ESR's view of how to improve the European legal framework for clinical trials. The detailed evaluation of the questionnaire can be made available to the European Commission as soon as finalised.

The European Society of Radiology considers the following ten action points essential to achieve a better European legal framework for clinical trials:

1. Eliminate the differences between Ethics Committees in views and requirements;
2. Counteract the high costs for increased labour-intensive administrative procedures;
3. Allow for a unique clinical trial authorisation from each country involved in a multinational trial;
4. Make the EMEA responsible for performing assessments and awarding multinational clinical trial authorisations valid across the whole EU;
5. Amend the Clinical Trials EU Directive in order to reduce/eliminate the possibility of inconsistent application;

6. Make lower-risk trials easier to be authorised and performed (typically when a diagnostic procedure or a contrast agent at usual dose is proposed in a trial for an off-label indication);
7. Make the borderline between interventional trials (under the Clinical Trials EU Directive legal framework) and non-interventional (outside the Clinical Trials EU Directive legal framework) more defined and precise;
8. Facilitate non-commercial organisations in being sponsors of clinical trials;
9. Provide specific rules for performing clinical trials on incapacitated/vulnerable patients in order not to negate the advantages of clinical research to those categories of patients;
10. Support third countries where regulation of clinical trials is currently weak (e.g. partnership projects).

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