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European Commission
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8TH January 2010

Dear Sirs,

## AMRC response to the European Commission public consultation paper on 'Assessment of the functioning of the 'Clinical Trials Directive' 2001/20/EC.

The UK Association of Medical Research Charities (AMRC) is pleased to respond to the public consultation paper.

### AMRC

AMRC is a stakeholder association of the leading medical and health research charities in the UK. Working with our member charities and external partners, we aim to support the sector's effectiveness and advance medical research by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government and policy-making.

Established in 1987, AMRC now has 120 member charities that contributed approximately £1 billion[1] to research in 2008-2009 aimed at tackling diseases such as heart disease, cancer and diabetes, as well as rarer conditions like cystic fibrosis and motor neurone disease. The principal focus of this funding is in the UK. However, many of our members now support and contribute to international research networks, collaborations and activity.

The UK medical research charity sector is perhaps unique in the EU in that it is both a significant funder of clinical trials but also plays an important role in informing and recruiting patients, and in ensuring appropriate public and patient involvement in the conduct of trials. A rising concern for our members in recent years has been the regulatory burden and associated costs of conducting clinical trials and the extent to which this now stands in the way of research aimed at improving patient health and well-being. We welcome the fact that these concerns have been openly captured in the appraisal of the current situation included in the consultation paper

For perspective, AMRC member charities funded 166 clinical trials at a cost of almost £69 million in 2008-2009 and our members are seen as full partners in the systems and infrastructure recently developed by the UK Government to deliver clinical trials. They are also actively involved in a range of initiatives aimed at improving public awareness and understanding of the importance of clinical trials to developing new treatments, therapies and interventions.

AMRC's submission to the public consultation necessarily focuses on key issues and consistent themes expressed to us by our members. A number of our members have, in addition, submitted

[1] Based on AMRC subscription data collected 2008/09

their own more detailed responses to the consultation based on their direct operational experience of the implementation of Clinical Trials Directive.

- AMRC's members strongly support the stated aims of the Clinical Trials Directive with regard to ensuring patient safety and achieving greater harmonisation and simplification of processes. We recognise that the Directive has resulted in some improvements in each of these areas. Of particular note is the way in which the Directive has improved patient safety and protection through more consistent and thorough application of good clinical practice (GCP) across Member States.

- Nonetheless the overall experience of our member charities is that the Directive has resulted in increasing levels of bureaucracy and associated negative impacts in terms of costs and time-lag. These have had a disproportionate impact on academic trials as noted in the Impact on Clinical Research of European Legislation (ICREL) Report[2]. They also represent a significant barrier to the efficient promotion and advancement of clinical trials and, ultimately and most importantly, to future improvements in patient care.

- AMRC supports proposals to streamline the National Competent Authority (NCA) and Research Ethics Committee (REC) authorisation processes and ensure greater consistency in the application of rules by Member States. Notwithstanding the different preferences that may be expressed by our members as regards how the current system should be improved, it is clear that they are committed to a common goal of seeing more practicable and efficient processes established. We believe this provides a solid foundation for future dialogue with the European Commission, other funders and partners, on the proposals as set out.

- AMRC would welcome more detailed guidance to accompany the Directive aimed at reducing inconsistencies in interpretation (i.e. what constitutes a 'substantial amendment', definitions of 'Suspected Unexpected Severe Adverse Reactions (SUSARs) and interpretations of interventional and non-interventional trials). At this juncture in the lifetime of the current Directive we would propose that modified and improved guidance is preferable to adopting the Directive's text in the form of a Regulation.

- The operation of the Directive would be considerably improved by the inclusion of a risk-based approach to assessing and regulating clinical trials which recognises the different levels of risk associated with different types of trials with the objective of reducing the regulatory burden on low-risk trials. Such an amendment should be accompanied by appropriate guidelines.

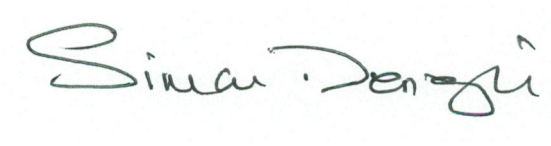
- AMRC and its members are opposed to proposals for differential treatment of commercial vs non-commercial/academic trials under the Directive. Indeed, we believe that such a move would undermine progress made to date in ensuring greater consistency in approach and the promotion of best practice. We believe it would also negatively impact on the culture of collaboration around trials that has developed in recent years, particularly in the UK.

- We hope that the European Commission will also use the review of the Directive as an opportunity to examine other initiatives it might support and promote to advance clinical trials activity in the interests of patients. We would draw your attention to the recent PatientPartner workshop series (www.patientpartner-europe.eu) which has been helpful in identifying of EU-wide challenges in getting good information in front of patients and patient groups about clinical trials as well as work that remains to be done to bring

[2] http://www.efgcp.be/downloads/icrel_docs/Final_report_ICREL.pdf

charities, industry and academia together behind a common agenda. The European Commission may like to further note the work the Association has done in partnership with commercial and non-commercial partners under the auspices of the UK Clinical Research Collaboration (UKCRC) to improve public understanding and awareness of the importance clinical trials http://www.ukcrc.org/information-resources-on-clinical-trials-launched/ .

Once again, AMRC welcomes the opportunity to respond to the consultation paper. We would be happy to expand on any of the above comments where necessary and look forward to further engagement with the European Commission about the Directive in the coming months.



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