



**MEDICAL ACADEMIC STAFF COMMITTEE, BRITISH MEDICAL ASSOCIATION
RESPONSE**

**Revision of the 'Clinical Trials Directive' 2001/20/EC
CONCEPT PAPER**

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors and medical students from all branches of medicine throughout the UK. With a membership of over 145,000 worldwide, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare. The BMA is registered on the European Commission register of interest representatives (ID: 59537502076-56).

The BMA's Medical Academic Staff Committee (MASC) welcomes the opportunity to contribute to the debate on the European Commission's concept paper on the revision of the Clinical Trials Directive.

The BMA supports the coordinated assessment procedure (CAP), but is concerned that local, national or cultural factors may lead to ethical issues being separated out from consideration under the CAP.

The BMA believes that given the disparity there is between the ways in which the different member states achieve approval of a clinical trial, particularly ethical approval, we must accept national interpretation of the Directive but with mutual recognition of what is done within other member states in which we have confidence.

The BMA believes that trying to achieve a single ethical approval would be almost impossible to achieve, or at the very least be time consuming. Recognising that such approval has been achieved nationally should be recognised as adequate for the multinational progress of such a study. The BMA does not support a single acceptance or approval for the whole of Europe, as this could lead to occasions when the UK would not find that ethically acceptable *for the UK*.

The BMA is concerned about the lack of coordination of research governance in the UK and cautions against any revision of the clinical trials directive that might be a further encumbrance.

The BMA positively advocates the introduction of an application system common to all member states. In particular, the BMA points to the Integrated Research Application System (IRAS) used in the UK as a dynamic and tested model, which could be rolled out across Europe.

A handwritten signature in black ink, appearing to read 'Michael Rees', with a horizontal line underneath.

Professor Michael Rees
Co-Chair, Medical Academic Staff Committee
British Medical Association

A handwritten signature in blue ink, appearing to read 'Peter Dangerfield', with a horizontal line underneath.

Dr. Peter Dangerfield
Co-Chair, Medical Academic Staff Committee
British Medical Association