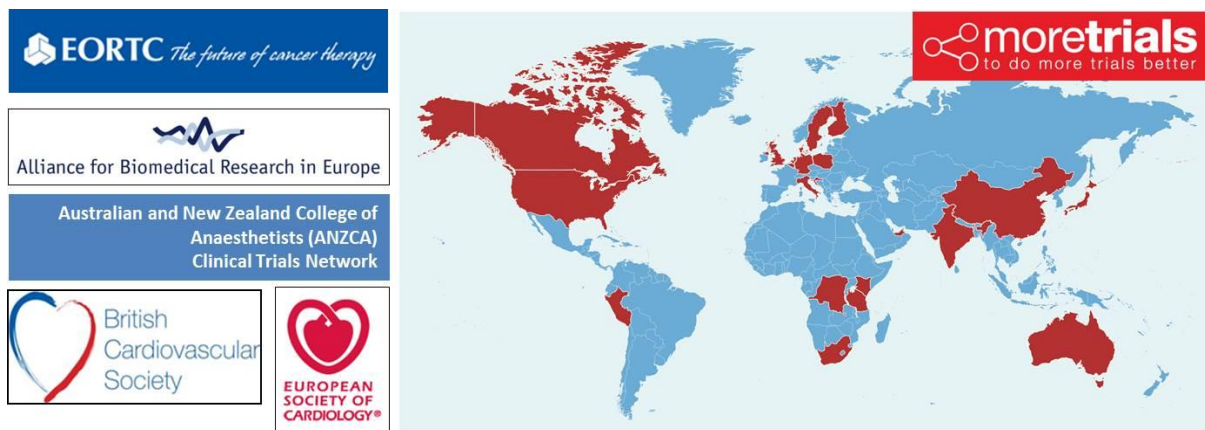


## Too little too late: ICH's proposed update of their Good Clinical Practice (GCP) guideline



### Problems with ICH-GCP

Along with leading trialists (119) from 22 countries, and with the support of five leading research organisations, we recently co-authored a letter that was deeply critical about the proposed update to ICH-GCP, and this letter has now been submitted to the European Medicines Agency (EMA) and the International Council on Harmonisation (ICH).

The letter, which is available [here](#), points out that longstanding concerns about the suitability of ICH-GCP guideline as a quality standard for conducting clinical trials have not been addressed in the proposed update. The ICH insists that the original text in their 20 year-old guideline “is still correct”, despite evidence to the contrary from trialists, industry and regulatory authorities. As a result of an unwillingness to make the extensive ‘root and branch’ changes that are needed to address the guideline’s many shortcomings, the update instead introduces contradictions between new text and the original guideline. This is likely to lead to even greater inconsistency in the way that ICH-GCP is interpreted and enforced, to the detriment of patients and public health.

### Structural problems with ICH

As well as drawing attention to problems with the updated ICH-GCP guideline, the letter outlines problems with the ICH itself. ICH was established by regulatory authorities and the pharmaceutical industry in the 1990s in order to harmonise the development of new drugs. But the ICH operates secretly, and the individuals responsible for producing the proposed update and for considering responses to it are inaccessible and unaccountable. ICH does not include representation from the wider community of academic trialists or research funders, and there is no meaningful involvement of trial participants or the wider public. We do not believe that this is acceptable.

### A better way forward

We believe that a new guideline is needed, one that properly addresses the current barriers to ensuring trial quality, and which is developed in an open and transparent process involving everybody interested in clinical trials. If you share this view, we invite you to visit the MoreTrials website [here](#) and to join us in our efforts to achieve real change in the way that trials are designed, conducted, analysed and reported.