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A model clinical trials agreement

The Department of Health's new model agreement raises questions about the NHS's relation with industry

Good clinical research is hard to do at the best of times, and there is a growing perception that the regulatory environment is making it increasingly difficult to plan and carry out clinical trials within a realistic time frame. A recent editorial in the *BMJ* claimed that the 2004 European Union clinical trials directive has hindered this process.[1] Anyone who has tried to carry out a clinical trial, particularly a multicentre one, knows only too well the frustrations of seemingly endless negotiations at the review process. While research may be a moral duty[w1] in our search for better ways of caring, we must always be on guard against using patients and volunteers as a means to an end, as the TGN1412 tragedy recently emphasised.[2]

On 30 October 2006, the Department of Health announced that a model clinical trials agreement had been finalised—a remarkable achievement that should be welcomed by all stakeholders in clinical research in the United Kingdom.[3] This provides a template that can be used by all National Health Service trusts for any clinical trial, without modification.

The press release contained acclamation from leaders of industry and academia for what health minister Andy Burnham stated would "mean patients getting faster access to effective drugs and treatments," a laudable goal. The benefits of not having to renegotiate many of the elements within clinical trials agreements for every sponsor, study, and centre are clear. Before embracing this agreement with open arms, however, we should examine what it actually says and what the deeper implications might be.

This agreement is not completely new, but a revision of a 2003 document,[4] and a concept that has now been examined in many jurisdictions.[5] It applies only to contract research, defined as "commercial, industry sponsored trials of investigational medicinal products, involving NHS patients, undertaken in NHS hospitals, usually directed towards pharmaceutical product licensing." It does not apply to phase I testing with healthy volunteers (as in TGN1412), to studies initiated by investigators, to trials in which the sponsor merely provides funding, or to research in non-NHS institutions. The announcement has received little comment to date, although links have appeared on some NHS trust websites. This lack of interest is surprising as the agreement is the product of a unique consortium of industry, government, and academia—the UK Clinical Research Collaboration (www.ukcrc.org).

In addition to industry, the collaboration lists an impressive collection of entities—referred to as partners—on its website, including government departments (Health, Trade and Industry), the NHS, the Medicines and Healthcare Products Regulatory Agency, the Academy of Medical Sciences, the Academy of Medical Royal Colleges, charities such as Cancer Research UK, the Medical Research Council, and the National Institute for Health and Clinical Excellence. The implication is that these bodies are equally committed to the agreement. Equally importantly, other organisations, such as the Central Office for Research Ethics Committees (www.corec.org.uk), are not mentioned. Research ethics committees are responsible for protecting human subjects[w2] and are central to many issues covered in the agreement, such as budgets, financial disclosures, potential conflict of interest,[w3] [w4] compensation for research related injury, data protection, research publication, and research integrity[w5]; the role of the committees is mentioned many times in the text of the agreement.

While collaboration is admirable, we must realise that the development of a business model for research is a primary motivation behind this initiative. The title of the collaboration's press release refers to saving money and is therefore consistent with current NHS priorities.[6] However, efficiency is not the same thing as effectiveness. It seems that the Department of Health[w6] and the NHS (www.rdforum.nhs.uk/) are fast turning into a business, as their current emphasis on research and development is in keeping with the chancellor's prebudget statement.[w7] As the guidance document expresses it, the NHS is being "harnessed" in what is essentially a competitive model.[w8] [w9]

A surprising and disturbing element of the agreement relates to the crucial principles of transparency and accountability in research. Rather than incorporating and upholding the new and widely supported[7] standards for an open research culture[w10] developed by the World Health Organization earlier this year,[8] the clinical trials agreement has embedded an older and more problematic industry standard.[w11]

This model agreement appears at a time when public trust in the drug industry has never been lower.[w12] The industry has recently been described as extraordinarily ineffective,[w13] and the *BMJ* (among others) has been urging that a firewall be set up between sponsors and research.[9] The likelihood of guilt by association is therefore appreciable. For instance, were the royal colleges aware of this deviation from the international standard in transparency and accountability when they lent their name to the collaboration?

The concept of harnessing the NHS became even more problematic last month when the chief executive of the collaboration wrote to an assistant director general of WHO (WHO, personal communication); the support of all the partners was implied as their logos were attached. This letter complained about the scope of the WHO initiative on transparency and the alleged lack of consultation with stakeholders.

The removal of counterproductive roadblocks in research regulations is generally a good thing. Research is far more than just a business though. Regulatory review was created for compelling reasons and, no matter how important the research is, thoughtful analysis cannot be bypassed for the sake of convenience. The real benefits of contract research with investigational medicinal products should not be overstated.[w13] Association with money unfortunately erodes trust,[10] [w3] however, and government and academia would be well advised to maintain a respectable distance from sources of funding.[11] The NHS is not for sale.

Extra references w1-w13 are on bmj.com

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