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The Case for a UK National Clinical Trial Audit System

The problem

- The results of clinical trials are often reported slowly, inaccurately or not at all. As a consequence, patients are harmed, public health agencies (such as NICE) cannot make informed decisions, public health funds are wasted, medical progress is slowed down, and shareholders are exposed to substantial risks. The problem has been known since the 1980s and its negative impacts are well documented. For example, the NHS arguably misspent £424 million on Tamiflu based on incomplete evidence (the results of eight trials had remained hidden). More details here.

The solution

- **Health Research Authority (HRA) to monitor whether clinical trials conducted in the UK are registered and report their results.** (At present, the UK has no such monitoring system.)
- Every clinical trial conducted in the UK requires approval from one of Britain's 68 regional Research Ethics Committees. The Health Research Authority (HRA) already holds all ethics approvals on file. Using these documents, the HRA can centrally check whether trials have (1) registered, (2) posted summary results on registries, and (3) accurately published results in journals.
- A successful pilot has proven the feasibility of monitoring all trials at very low cost. This would not impose additional red tape or delays on medical researchers, as the HRA already holds all necessary records. More details here.

Key benefits

- Substantial NHS budget savings
- Better care for patients and improved drug safety (harms are currently under-reported)
- Acceleration of medical progress
- Better-informed decision-making by the NHS, NICE, and individual doctors

Legal and regulatory framework

- Under UK regulations, all clinical trials have to be registered in order to obtain ethics approval. Under EU regulations, some types of clinical trials ("CTIMPs") have to post results on registries within 12 months maximum.
- The HRA is responsible for implementing both regulations within the UK, but currently does not monitor compliance due to capacity constraints.
- Non-compliance is widespread. At present, no penalties are being imposed on non-compliant institutions. More details here.

Support for a National Clinical Trial Audit System

SciTech Committee submissions explicitly supporting this policy proposal

1. Joint submission by HealthWatch UK, Universities Allied for Essential Medicines UK, and TranspariMED
2. Submission by the AllTrials campaign (representing 734 health groups)
3. Submission by Dr Simon Kolstoe et al.
4. Submission by Dr Ben Goldacre

In addition, NIHR, MRC, DfID and the Wellcome Trust have recently pledged to conduct internal trial audits.

Support for getting all trials registered and reported

- **Health Research Authority (HRA)**

  "[We] have long endorsed the registration of research and subsequent publication of research results… which is entirely consistent with our remit to protect and promote the interests of patients and the public in health research."

- **The National Institute for Health and Care Excellence (NICE)**

  "[A]ll clinical trial data should be made available so that those with responsibility for developing guidance and making treatment decisions have all the necessary information to hand to help them do so safely and efficiently."

- **The Medical Research Council (MRC)**

  "[We have] for many years, strongly supported the position that clinical trial results must be published in a timely manner".

- **Association of Medical Research Charities (AMRC)**

  "Medical research charities support the registration of clinical trials and the publication of findings… Patients want to take part in clinical trials so that the data generated can be used to improve treatment for others in the future as well as hoping treatments will benefit them personally. And for clinical research to benefit patients, the findings must be made available for others to learn from them. Supporters of charities have a right to expect that their donations will fund research that will benefit patients and the public. Charities have a duty to put useful research findings into the public domain and our longstanding advice to all AMRC members is to include a requirement to publish (within a reasonable time frame) in the terms and conditions of their awards. Our members are increasingly developing research evaluation systems which will allow them to audit compliance with this."

- **Cancer Research UK**

  "As the largest UK funder of academic clinical studies on cancer, we're absolutely committed to making sure the results of our trials are properly reported, and to ensuring that the people who matter most to us – cancer patients – can derive the greatest possible benefit from the data collected. We believe that information from clinical studies should be published as soon as the results are shown to be reliable… This is a vital issue, both for researchers, patients and the public."

- **The British Medical Association (BMA)**

  "Doctors need accurate and unbiased information on the efficacy and safety of different treatments to help them prescribe properly, safely and most effectively for their patients. If data from clinical trials are withheld or otherwise not available, doctors cannot be sure of the risks and benefits of using particular drugs thus risking avoidable harm to patients and wasting scarce NHS resources."

- **Over 700 other organisations** that have signed up to the AllTrials campaign.