Registration of Clinical Trials

Background
In summer 2013, the HRA consulted upon the expectation that all clinical trials be registered in a publicly accessible register as part of its Transparency agenda. This document explains what this requirement means for research studies.

This condition will be applied and monitored as set out below.

What types of research does this apply to?
This requirement will apply to clinical trials which, for the purposes of registration, are defined as the first four categories on the Integrated Research Application System (IRAS) question 2:

- Clinical trial of an investigational medicinal product (CTIMP),
- Clinical investigation or other study of a medical device,
- Combined trial of an investigational medicinal product and an investigational medical device,
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

From 30 September 2013, all applications which receive a favourable ethical opinion from a Research Ethics Committee (REC) will, as a condition of that favourable opinion, be required to be registered in a publicly accessible trial register. Applications for exemption can be applied for and will be considered and reported by HRA. Plans for registration of other studies will continue to be reviewed by RECs.

Clinical trial research securing a favourable ethical opinion on /after 30 September 2013

Clinical Trial register
It is a condition of the favourable ethical opinion for all clinical trials to be registered on a publicly accessible clinical trial register. Failure to register will be regarded as a serious breach of good research practice, and will be managed by the HRA in accordance with the National Research Ethics Service Standard Operating Procedures (SOPs).

Applicants or sponsors who wish to make a case for an exception should contact Catherine Blewett via nres.queries@nhs.net using the subject line “Request for exception to registration requirements”. As a minimum, this request must include:
Details of the clinical trial, including full title and IRAS ID
- REC information (name of REC and REC reference number)
- Justification for request for exception
- Contact information for person making request and their role in relation to the clinical trial

Requests not meeting these minimum information requirements will not be processed. Such requests will be considered on a case by case basis and will be reported on the HRA website if exemption is agreed. Clinical trial registration is in line with the recent recommendations from the Science and Technology Select Committee, http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/130916-clinical-trials-report-published/

Timing
The expectation is that all studies are to be registered before the first participant is recruited. However, research awarded a favourable opinion from a REC after 30 September 2013 will not be considered to be in breach of the favourable ethical opinion if the study is registered within 6 weeks of the first participant having been recruited (or, for medical device studies, within the timeline determined by the current registration and publication decision trees).

The HRA does not expect trial registration at the time of REC application. Following application, researchers/sponsors should take the first formal point of communication with the REC Manager to formally confirm that registration has occurred, supplying the clinical trial register name and registration number. This may be when advising of a substantial amendment or other communication but should be undertaken in the first year annual report to the REC at the latest.

The HRA will be monitoring and reporting against compliance.

Accepted registers
These include:

- EU Clinical Trials Register (https://www.clinicaltrialsregister.eu). This register is linked to the EudraCT register, which is mandatory for all CTIMPs in patients authorised on or after 1 May 2004.
- International Standard Randomised Controlled Trials Number (ISRCTN) Register. This register accepts registration of randomised controlled trials and any other research study designed to assess the efficacy of health interventions in the human population.
ClinicalTrials.gov. This is a register of studies in the United States and around the world.

Detailed guidance about options for registration is provided in IRAS, through the green "i" buttons next to question A5 of the integrated dataset.

Clinical trial research securing a favourable ethical opinion prior to 30 September 2013

The HRA expects all studies given ethical approval before 30th September 2013 to be registered and that researchers and sponsors will wish to comply with best practice. Where clinical trials received a favourable opinion prior to 30 September 2013 and the clinical trial is still ongoing, details of registration should be provided with the next annual report or final report to the REC, whichever is sooner.

The HRA is looking at simple mechanisms to identify registration and publication rates in the UK. The HRA expects to update the applicant and sponsor declaration early in 2014 so that applicants and sponsors will need to declare to the REC that previous studies have been registered and published. The REC may seek further explanation where this is not the case.

A false declaration would be considered a breach of good research conduct.

Future developments

The HRA will consult with the devices industry with the intention of bringing the requirements for devices studies in line with other clinical trials by March 2014.

There is still work to do with regard to what constitutes acceptable standards for accessible registers for clinical trial registration, including how registers manage incomplete registration fields. In the interim, the HRA will accept any publicly accessible trial register in line with the guidance on IRAS. There may, however, be a refinement of these requirements at a later stage.