ARIA Policy on Clinical Trials

Scope

This policy sets out ARIA's requirements in respect of clinical trials. It is designed to be consistent with the requirements of other major funders of clinical trials across the UK.

A clinical trial, as defined by the World Health Organisation, is "*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*".

A broad range of interventions are tested under clinical trials, including (but not limited to) drugs, surgical procedures, radiologic procedures, devices, behavioural treatments, therapeutic products, and more.

Understanding the regulatory regime

It is important for applicants planning to include a clinical trial as part of their proposal to be aware of the regulatory requirements that might apply to their work.

Applicants who may be uncertain as to whether (or where) their proposed activity falls within the scope of the UK regulations should look at the guidance published by the Medicines and Healthcare products Regulatory Agency ("**MHRA**"). Applicants can contact the MHRA to seek clarity at clinicaltrialhelpline@mhra.gov.

If a clinical trial will be conducted outside of the UK, applicants should include details of the location of a proposed trial and demonstrate their understanding of the applicable regulatory requirements for its conduct.

Regulatory Approvals

Applicants for ARIA funding are not required to have regulatory approval for their trials prior to submitting an application to ARIA.

However, applicants will be required to provide information describing any regulatory and ethics approvals which are reasonably likely to be required in respect of their proposed activities, a clear articulation of the steps required for approval, and the estimated timelines for securing such approvals.

Successful applicants will be required to ensure that all relevant regulatory and ethical approvals and licences are in place before a trial can begin. Appropriate insurance arrangements should also be implemented.

Where a trial is to be subcontracted (in whole or in part), the relevant subcontract must be in place before a trial can begin.

ARIA may require evidence that any required approvals and licences have been secured before releasing funding.

Sponsors

The sponsor of a clinical trial is the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

ARIA does not sponsor clinical trials.

All applications to ARIA for funding involving clinical trials that are likely to require a sponsor must include the names of the intended sponsors and details of the steps required to formalise the sponsorship arrangement (including associated timings).

If the proposed sponsorship position is unclear or inappropriate, ARIA may require applicants to revisit the position and may ultimately refuse to fund the trial.

Trial Conduct

It is a requirement of ARIA funding for successful applicants to conduct any clinical trials in accordance with all applicable legislation and regulations.

Successful applicants must ensure that trials follow best clinical practice and implement technical and organisational measures appropriate to the level of risk.

Research which is to be performed outside the UK must be conducted responsibly and supported by regulatory approval and an independent ethics review.

All trials, wherever undertaken, must comply with the latest Good Clinical Practice guidelines as published by the International Council for Harmonisation. In addition, all clinical trials must be designed and managed to comply with the requirements for ethical principles under the Declaration of Helsinki.

Publication of results

While respecting possible constraints in respect of the protection of intellectual property rights, confidentiality and commercial sensitivity, it is a requirement of ARIA funding for successful applicants to publish the results of a clinical trial funded by ARIA no later than 12 months from the end of the trial (unless a deferral is agreed with the relevant regulator) and otherwise in accordance with all applicable legislation and regulations.