Sponsorship and Funding in Research

Sponsorship

The UK Policy Framework for Health and Social Care Research (2017) defines a sponsor as “the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements to set up, run and report a research project”.

Sponsorship falls broadly into two main categories: commercial and non-commercial. Commercial sponsors are commercial companies and non-commercial sponsors are typically NHS organisations or Universities.

There are a few differences between the two categories are allowed to operate within the NHS namely; commercially sponsored projects must be fully funded by the sponsor including overheads (e.g. estate costs), contracting arrangements and indemnity.

The main responsibilities of the Sponsor include:

- Obtain required authorisations to commence the trial e.g. Research Ethics Committee (REC) Favourable Opinion or MHRA authorisation (if applicable).
- Keep records of all amendments and obtain approval where required.
- Have a robust and maintain a Quality Management System (QMS)
- Ensure compliance with all applicable legislation
- Notify all relevant bodies of the conclusion or termination of the trial within specified timeframes.
- Ensure that the conditions of Good Clinical Practice (GCP) are satisfied or adhered to.
- Ensure that the trial is conducted in accordance with the protocol and subsequent amendments.
- Notify any serious breaches of GCP or the protocol, or any urgent safety measures taken to the appropriate authorities.
- Ensure investigational medicinal products and relevant devices are available to subjects free of charge.
- Keep a trial master file to hold all documents relating to that trial.
- Appoint named individuals responsible for archiving the trial essential documents
- Ensure an investigator’s brochure exists (where needed) and is validated and updated at least annually.
- Keep records of all adverse events relating to that trial which are reported by investigators
- Recording and reporting suspected unexpected serious adverse reactions to appropriate authorities within specified timelines
- Ensure investigators are informed of suspected unexpected serious adverse reactions (SUSARs).
- Ensuring all SUSARs are entered into the European database
- Provide annual list of SUSARs and a safety report to the appropriate authorities.

- Meet the requirements for the authorisation to manufacture and import investigational medicinal product (IMP).
- Certification of the IMP by a Qualified Person
- Two step release of IMP ('technical release' and 'regulatory release')
- Ensure IMP is labelled in accordance with Article 15 of Commission Directive 2003/94/EC
- Identify and train person/persons to upload data to CPMS (registration/login details can be found here https://cpms.nihr.ac.uk/). CPMS online training course and the guidance document found here https://learn.nihr.ac.uk/course/view.php?id=128

The sponsor may also delegate some of their activities to third parties. Within commercial research some these responsibilities are often delegated to Contract Research Organisation (CRO), whereas in non-commercial research duties are often delegated to the Chief Investigator (CI) and/or a Clinical Trials Unit (CTU).

Funding

Just as with sponsorship, funding fall into the 2 broad categories of commercial and non-commercial. However, just because a research project is commercially funded does not mean that it will have a commercial sponsor. An example of a commercially funded project with a non-commercial sponsor is an Investigator Initiated Trial (IIT), where individual investigators apply for funding for their study from commercial organisations and the study is then managed through employer.

Non-commercial funding can come from a range of organisations and schemes, for instance; charities, research councils, National Institutes of Health in USA (NIH), the European Commission, internal schemes, the National Institute for Health Research (NIHR) and other UK government agencies are all examples of non-commercial research funders.

The UK Policy Framework for Health and Social Care Research (2017) states that the main responsibilities of the funder include:

- Assessing (or arranging for assessment of) the scientific quality, the relevance of the research to the target population and, if appropriate, the value for money of the research as proposed, involving patients, service users and the public where appropriate in funding decisions.
- Reviewing information about the attribution of costs to confirm that costs to all parties (including excess treatment costs) have been identified and described in accordance with national guidance where applicable, and that the costs are not disproportionate compared to the value of the output.
- Considering (with advice if necessary) whether the research is really achievable within the settings as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health and social care if the research will have an impact on care provision.
- Making ongoing funding conditional on a sponsor and relevant approvals being in place before the research begins (but not before initial funding is released, as some funding may be needed in order to put these in place).

- Using contracts and conditions of funding to promote compliance with the policy framework, in particular to encourage arrangements for making information about research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee) and for retaining and making accurate findings, data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished.

Useful Links

1. UK Policy Framework for Health and Social Care Research (2017)
2. HRA list of example funders
3. HRA list of roles and responsibilities
4. Clinical Trials Toolkit Routemap - Sponsorship