R&D Consultation



Trial Planning Phase

R&D Consultation follows the Pharmacovigilance station and occurs in parallel to Protocol Development. The station precedes the Funding Proposal station. R&D Consultation is good practice and is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Within NHS organisations (and some Higher Education Institutions) there are Research and Development (R&D) Departments or Clinical Research Offices. Organisations that work closely together, for example an NHS Trust and a local university may have joint R&D offices. These offices act on behalf of the organisation(s) to facilitate the local management of all research within that organisation.

An NHS R&D Office must ensure all relevant approvals are in place (see <u>R&D</u> <u>Submission station</u>) before a research project can take place within their organisation:

- When acting as the sponsor, NHS R&D offices will be involved in the oversight of the trial by guiding the Chief Investigator and managing the risks associated with any trial initiated.
- When acting as a host organisation, NHS R&D offices facilitate the timely set up of externally sponsored trials and support the Principal Investigators participating in those trials

Whichever scenario applies, these offices need to be aware of all projects that involve their organisation's staff or resources.

Researchers are advised to contact their local R&D Office in the early stages of study development so that they can help identify facilities that can provide valuable support.

It will be important when consulting R&D to define how costs are allocated by differentiating between research costs, NHS service support costs and treatment costs in relation to activities specified in the protocol. The Department of Health's AcoRD guidance should be referred to in this activity.

Organisations and individuals that have responsibilities for clinical trials (or other types of study) in the NHS should ensure that research is conducted in accordance with principles of good practice in the management and conduct. The Health Research Authority and the health departments in Northern Ireland, Scotland and Wales have developed the UK Policy Framework for Health and Social Care Research (2017) which has replaced the separate Research Governance Frameworks in each country.

The NHS R&D Forum website has a list of <u>R&D contact details</u> and further resources on research governance.

Further reading:

- R&D Submission station
- Contract & Agreements station
- UKCRC Information page Research Passport.