Distinguishing different types of monitoring and audit

Quality systems

Both monitoring and audit are based on standards. Quality assurance is about setting standards for an overall activity to achieve a specified output and putting systems in place to meet those standards. Audit is a quality assurance activity and is a retrospective check of those systems to ensure that they are achieving the standards set, including looking to see if there are any failures that haven't been picked up through quality control. Other quality assurance activities could include using policies and SOPs. Quality control is one of the systems put in place by quality assurance. Monitoring is a quality control activity which involves a system of ongoing checks to detect faults and failures in order to correct them, and prevent the failure occurring again, so that the specified output is produced consistently.

The overall activity may be hosting a portfolio of research or sponsoring a specific study. The standards set and the systems to ensure that they are met will be different. What the monitoring and auditing actually involves depends on whether the monitoring and auditing applies to organisation-wide systems, or to a specific study.

Monitoring and auditing organisation-wide systems

Under the research governance framework (RGF), care organisations hosting research are expected to ensure that research is conducted to the standards set out in the framework. This is so that the organisation can assure itself that it is meeting its duty of care to its patients/ service users, meeting its responsibility for the conduct of its staff and adhering to legislation (section 3.10.4 of RGF). Monitoring in this context involves checking on an ongoing basis that the processes put in place to: approve research, arrange contracts, be aware of amendments, ensure staff are adequately trained and supervised, ensure arrangements are in place to support research etc, are all working and that you are detecting and addressing failures in meeting research governance standards (section 4.11). So for studies where the PCT is simply hosting the research, your monitoring as part of the framework would be done through the ongoing work of the R&D office, e.g. progress reports. You may choose to audit a sample of studies, either randomly or on a risk-based decision, to check that the R&D offices' systems are in fact ensuring that the standards are being adhered to. Monitoring on an organisational basis would include, for example, keeping a record of research governance training of researchers to check that staff are receiving training on a regular basis. An audit might include obtaining a current CV and talking to a researcher to find out whether they have actually received training and whether they have an understanding of research governance. The terms monitoring and audit in this context are frequently used interchangeably although they are actually quite different. A figure of 10% is often quoted as being the mandatory minimum for monitoring/audit, although this figure is not in fact stipulated in the RGF.

Study-specific monitoring and audit

In relation to an individual study, it is the sponsor's responsibility to be satisfied with the arrangements for management and monitoring (section 3.8.3). If you are the sponsor for a study you should make these decisions for your site and all other sites. The first part is to set the standard – this may be ICH GCP or the UK Clinical Trials Regulations or the principles of GCP, depending on the study type. Whichever standards are set, it is important that all parties are aware of that standard, e.g. through study-specific procedures. The sponsor may delegate this activity to the R&D office of the host organisation or to others. In this situation it is for the sponsor to decide what the system for monitoring the study should be, what should be monitored, and at what frequency i.e. a monitoring plan. If monitoring is delegated to the site, this should be documented as part of the agreement between sponsor and site. This monitoring might include ensuring that the protocol is being adhered to, that the data collected is accurate and verifiable, that consent is being obtained in accordance with the process approved by the REC etc. The initiation of a study is the key point at which to ensure that all those conducting a study are aware of the standards that they should be following. As described above, this monitoring consists of ongoing checks during the progress of a study in order to correct issues as they arise - e.g. to avoid further non-adherence to the protocol. Monitoring should be documented – what was wrong, what was done to correct it, what will be done to prevent future occurrences. A sponsor may also select studies or sites to audit from all the studies sponsored on either a random or risk-based decision, to make sure that the monitoring system is working.

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Quality Assurance is the sum total of the organised arrangements made with the object of ensuring that products or services are of the quality required for their intended purpose.