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Guidance on Training Requirements for Laboratories Processing Research Samples



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This guidance document has been developed by the UKCRC Registered CTUs Laboratory work stream (as part of the Quality Assurance operational group) and provides general guidance to CTUs on appropriate levels of training required by laboratory staff processing research samples. The laboratory work stream comprises both QA representatives and laboratory leads and has been developing templates and guidance on CTU oversight of laboratories, laboratory staff training and CTU training for auditing laboratories.

Background

Laboratory sample analysis contributes significantly to research data, including essential safety information and primary or secondary outcomes. It is therefore essential that research samples are processed correctly, by trained and qualified laboratory staff. The laboratory may receive, prepare and store samples prior to shipping to a central laboratory for analysis, or may perform the analysis themselves. Training should be appropriate to ensure every laboratory activity performed on research samples is completed in accordance with the study protocol, GCP¹, applicable legislation and guidance, and best laboratory practice

The processing of research samples in accordance with Good Clinical Practice is described in detail in a number of guidance documents. For the purposes of guidance for UKCRC CTUs, the EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012) and the MHRA Good Clinical Practice Guide, Chapter 13 (2012) have been used as the primary sources of information (if applicable, refer to guidance documents from other countries for international trials).

Due to the variety of sample processing, in terms of both purpose and laboratory facilities, the level and style of training will vary, but in all cases must be sufficient for each individual to perform their allocated role. This guidance document therefore describes reasonable levels of assay, protocol and GCP training for different types of sample involvement.

1. The processing and analysis of research samples collected as part of clinical trials or other research studies must comply with Good Clinical Practice. Laboratories may also work to other guidelines such as Good Laboratory Practice (GLP), Good Clinical Laboratory Practice (GCLP) and ISO 15189:2012, however, when processing and analysing clinical research samples, it is GCP that applies.

GCP Training

According to SI2004/1031 'Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his task'. All laboratory staff processing research samples must therefore have a level of understanding of the research process sufficient to allow them to process the sample according to the protocol. However, this will depend on the sample processed. For example:

- Many research samples will be processed by local pathology laboratories to determine eligibility, monitor ongoing safety or to identify study endpoints, using standard assays that are also used to analyse non-research samples, as part of routine clinical care.

There are specific elements of sample processing that may differ from routine clinical sample processing, such as sample identifiers and data reporting. Clinical laboratories should have approved procedures for the processing of research samples. Provided that laboratory staff are trained in these procedures, no additional GCP training should be required although a level of research awareness is suggested.

However, there must be senior/coordinating staff within each laboratory that do understand the role of the research sample (its role in determining patient safety and eligibility, and in endpoint analysis) to ensure that samples are processed in accordance with GCP, applicable legislation and guidance, and best laboratory practice. Staff with responsibility for overseeing the processing of research samples should receive applicable GCP training, preferably training that has a laboratory perspective.

- Where research samples are contributing to study endpoints and the assays performed are specific to the research environment (i.e. typically in academic or central laboratories and not also used as a routine clinical test), laboratory staff processing these samples must have appropriate GCP training to perform their delegated role. In most cases laboratory specific GCP training would be preferable and would include the chapters covered in the EMA Reflection paper (see references).

Protocol and other Study Specific Training

All laboratory staff processing research samples should have study specific training proportionate to their role in sample processing. Using the examples above:

- Most pathology laboratory staff should have additional training in those aspects of the study that differ from their daily role in processing routine, clinical samples. This may include specific requirements for sample labelling/identification, reporting of results, adaptation of a specific assay and storage of the sample/data or may be adjustments to existing laboratory procedures which might otherwise compromise compliance with the protocol (for example; phoning results may be a standard procedure, but for a clinical trial sample, may result in unblinding of the study team). As above, this information may be included in laboratory procedures or a study specific laboratory manual, and these can provide the framework for training. Evidence of training may be in the form of study specific SOP or laboratory manual records.

The sponsor/CTU should work with senior staff within the laboratory to ensure that they have sufficient training/understanding of the research project to allow full compliance with the protocol.

- Central/academic laboratory staff should receive protocol training proportionate to their role. Laboratory leads should attend site initiation meetings or Investigator meetings, where appropriate and contribute to the protocol training of laboratory staff. If needed, the laboratory should provide training for site staff e.g. in obtaining a sample, special handling requirements such as light protection and specific sample transport conditions.

Training Records

Sponsors/CTUs and the laboratory should ensure that all staff processing research samples are qualified and trained to do so and all laboratory staff should maintain a record of research training. Using the examples above:

- Most pathology laboratory staff would not be expected to provide a copy of their CV or evidence of GCP training to the sponsor/CTU, however, the key contacts within the laboratory responsible for the overall management of research samples should be able to provide evidence of training of all staff if required and should be prepared to provide a copy of their own CV and associated training to illustrate the knowledge required for the management and oversight of research samples within the laboratory.

Evidence of competency to conduct the required test /operate particular instruments should be available for all staff.

Training for all staff in procedures specific to research samples must be recorded. This can be done within existing systems if SOPs for processing of research samples are used.

- Central/academic laboratory staff must maintain a training record sufficiently detailed to demonstrate their ability to perform their delegated role. This is likely to include current CV, recent GCP training, job description, assay competency assessments and protocol specific training.

Summary

The CTU must have confidence that staff are appropriately trained and experienced when processing research samples, so that processing has been in accordance with the study protocol, good clinical practice and applicable regulations and guidance. Performance and recording of training to process research samples depends on the reason for sampling and on the type of laboratory performing the work.

Routine pathology laboratories that process research samples to the same standard as for clinical care should maintain systems for training that will have been subjected to review by audit and inspection. There should be no requirement to obtain CVs and GCP certificates in this situation unless there is a specific reason to do so. However, where specific requirements for processing research samples exist, these should be subject to documented training.

However, it is important that there is good communication with the laboratory and a laboratory contact should be identified that is familiar with the requirements of the protocol and GCP and is in a position to ensure appropriate actions are taken and oversight obtained in order to deliver the trial requirements.

Laboratory staff whose role is solely to process research samples that define study endpoints should be trained to the same degree as other research staff conducting the study, with training (including GCP training) proportionate to their role.

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References

Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (Ref. EMA/INS/GCP/532137/2010, EMA, 2012)

Good Clinical Practice Guide (Chapter 13, MHRA, 2012)