

RETENTION OF STUDY DATA AND SUPPORTING RECORDS FOR INSPECTION PURPOSES

Background

With increasing frequency the GLPMA is encountering situations in which a member of the UK GLP Compliance Monitoring programme has conducted a GLP study, or part of a study, but has not retained the original raw data or copies of it.

When conducting a GLP compliance monitoring inspection of a UK test facility the Inspector will need to examine data from recently completed studies in order to assess:

- i. the quality of data, and
- ii. whether GLP was complied with during the generation of those data.

Without study data available for examination the Inspector is not able to determine the extent to which GLP was complied with during the conduct of that study or phase.

Requirement to retain study data

The GLP Principles, which constitute Schedule 1 of the UK GLP Regulations, require data "to be retained in archives for the period specified by the appropriate regulatory authorities." The GLPMA is itself an appropriate regulatory authority.

In order to ensure that there will be data from recently performed GLP work available for examination, the GLPMA expects that study data from all GLP requiring studies, or phases of studies, should be retained at the UK test facility or test site for sufficient time to allow its examination by GLPMA Inspectors during compliance monitoring inspections.

The GLPMA currently conducts compliance monitoring inspections of most test facilities at a frequency not exceeding 24 - 27 months. Therefore, if the original raw data from any study or phase is unlikely to still be held within the archives of the UK facility for this period of time, e.g. it will have been returned to the sponsor in accordance with study plan and/or contractual agreements, then copies of the data concerned should be made and retained for at least one inspection cycle (effectively 2 to 3 years).

It should be remembered that these copies of data will potentially be used by Inspectors to assess the GLP compliance of the studies themselves. Therefore, it is in the interest of the test facility to ensure that the copies are complete and accurate. However, these copies are not intended to replace the raw data itself and so their production does not necessarily need to have been subject to the same level of control and checking as they would if they were to assume the status of raw data.

After an appropriate period any copies of data produced to satisfy the above requirement may be destroyed in accordance with established documented procedures.

Summary

Members of the UK GLP Compliance Monitoring Programme should ensure that they hold the raw data from GLP studies, or copies thereof, for a sufficient period of time to ensure that they would be available for examination by the GLPMA.