



Supplementary Criteria for GLP Registration **Management of Multi-site Studies**



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Supplementary Criteria for GLP Registration

Good Laboratory Practice Compliance Monitoring Programme

Management of Multi-site Studies

AS GLP C20.2

Second Edition July 2020

Published by:

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Edition Statement

Edition	Amendment	Date of Issue	ISBN No.
1	Initial issue	August 2000	090861172 2
2	Rebrand	July 2020	978-1-877531-95-8

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1 Introduction

The operation of and general requirements for registration under the International Accreditation New Zealand (IANZ) Good Laboratory Practice (GLP) Compliance Monitoring Programme are detailed in the IANZ publication “*Procedures and Conditions for GLP Registration*” (AS 2). In particular, Section 3.2 of that document specifies the registration standards for testing facilities – those being the *OECD Principles of Good Laboratory Practice* and associated consensus documents.

Where there is a need to expand upon or to provide a definitive interpretation of the requirements set out in these registration standards, IANZ will publish “Supplementary Criteria for GLP Registration” documents. This document, one in the series of “Supplementary Criteria for GLP Registration”, describes the preferred options for the organisation and management of multi-site studies.

2 Background

Many of the studies (or phases of studies) conducted in New Zealand for which GLP compliance is claimed are multi-site in nature. Whether for an agricultural chemical, a veterinary medicine, or any other compound/formulation, these studies generally involve a field phase at one or more sites and a laboratory phase at another. Common examples include:

- For agricultural chemicals in particular, the field phase is conducted at more than one site or location. These sites may be managed by the same GLP compliant facility or may be part of separate organisations. They are generally all within New Zealand but this may not necessarily be so.
- For many study types, the field phase may be at the “home” site or a remote site. The analytical or laboratory phase(s) may be at another site or sites which may be part of the GLP compliant facility or a separate subcontracted organisation.

This document sets out the preferred options of how such multi-site studies should be organised and managed.

3 General principles

The preferred philosophy for management of multi-site studies under GLP is “one study-plan - one Study Director” i.e. to encompass all phases of the study at the various sites. Other options are accepted (as detailed later in this document) as long as the underlying principle of GLP is maintained i.e. the study is organised and conducted in a planned and systematic manner.

Given the “one study plan - one Study Director” philosophy, the following common scenarios are discussed.

3.1 Multi-site studies within a single GLP compliant facility

Where there is more than one site in a study (including multi-site field phases or field and laboratory phases) that are all under the management of the GLP compliant facility, then there will generally be a Principal Investigator at each site reporting to a Study Director. The Principal Investigators are part of the same GLP compliant facility as the Study Director and will provide a Principal Investigator’s report to the Study Director for inclusion in the final report. The facility will also have its own quality assurance function which is responsible for quality assurance at each site.

3.2 Multi-site Studies using Sub-contractors

Where one or more of the test sites (whether they be a field site or a laboratory) is under the management of an organisation other than the GLP compliant facility where the Study Director resides (i.e. subcontracted), then the Study Plan should still list this site with a Principal Investigator (detailing his/her organisation and address, the phase(s) of the study and responsibilities delegated). This is in preference to the subcontracted facility having a study plan of its own.

In such instances, it is expected that subcontracted Principal Investigator(s) will have an input into the writing of the Study Plan and, in particular, for the phase(s) for which they will have responsibility. They will work directly from this external Study Plan.

Note: GLP Compliance for the sub-contracted phase(s) at this site(s) can be claimed only if the sub-contracted organisation is registered under the IANZ GLP Compliance Monitoring Programme (or

international equivalent). If this is not the case, then the Study Director's compliance statement must specifically exclude this phase (see Appendix 1 (c) in "Procedures and Conditions for GLP Registration").

Where the subcontracted facility is GLP compliant, it is noted that they should not need to write their own study plan or appoint a Study Director in accordance with their Standard Operating Procedures. However, it is recognised that some may choose to do so for their own internal management purposes. This is considered acceptable (and even desirable in some circumstances) as long as all extra documentation produced is consistent with the original study plan. The report from the sub-contracted facility (to the Study Director) should still be in accordance with the original Study Plan and written and signed by a "Principal Investigator" - who may also make a GLP compliance statement as appropriate.

3.3 Quality Assurance

The primary responsibility for quality assurance at all sites of a multi-site study lies with the management and quality assurance unit of the test facility where the Study Director resides. If a phase of the study is subcontracted to a GLP compliant facility, the responsibility still remains with the quality assurance function of the Study Director's test facility.

However, this quality assurance role may be delegated to the quality assurance unit of the subcontracted GLP compliant organisation.

This delegation must be documented and agreed by all parties - either in a contract for services or in the Study Plan itself.

It must be noted that all quality assurance inspections of the subcontracted facility (whether by the contractor's quality assurance personnel or the subcontractor's quality assurance personnel) must be reported to the:

- Principal Investigator
- management of the subcontracted facility
- Study Director (at the contractor facility), and
- management at the contractor facility.

(See Clause 2.2 (e) of the *OECD Principles of Good Laboratory Practice*).

4 Alternative options

In the case of Section 3.2 above, it is possible that the subcontracted facility write a formal Study Plan for their phase of the study. Instead of a Principal Investigator, a Study Director is appointed and the sponsor of this study is the Study Director of the parent study. In addition, the quality assurance function responsibility lies with the management/quality assurance of the subcontracted facility. The two study plans should make appropriate cross references to each other, and all study plans need to be available to all parties and maintained in the study records.

While this option is acceptable as long as it is demonstrated to be managed properly, it is not the preferred option, nor the intent of the OECD Principles of Good Laboratory Practice. A study is defined as the experiment or set of experiments in which the test item is examined to obtain data intended for submission to regulatory authorities. This will, and does, include all phases of the experiment (including laboratory phases) and, ultimately, the data reported (to the receiving authorities) does not distinguish between phases.

Similarly, the Study Plan is defined as the document defining the objectives and design for the conduct of the study – thus suggesting for a single study in its entirety there is one Study Plan.

The alternative option described above will result in more than one Study Plan for a particular study, and has the potential to result in confusion and a loss of planned and systematic management.