

❖ AIM

This document defines the minimum information and documents necessary for the organisation of multi-site studies. These requirements are based on the OECD monograph N°13 on multi-site studies (ref: ENV/JM/MONO(2002)9, or : [http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono\(2002\)9](http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)9)).

❖ ALL STUDIES (GLP COMPLIANT OR NOT)

Information to be defined in study plan:

Address of each Test Site (TS)
Name of each Principal Investigator (PI) or Responsible Scientist (non GLP studies) with telephone number, fax number and e-mail
Details concerning the archiving of materials generated by the TS (location, GLP status...)
Details concerning the type of report supplied to the Study Director, e.g. results only or full phase report for inclusion in the final study report (with dates). Both paper and electronic versions of the phase report should be supplied.

Documents to be supplied to the Study Director:

Where a phase plan exists a copy will be sent together with any amendment to the Study Director. If not, a copy of the Test Site SOP/method or at least a reference will be provided

❖ ADDITIONAL REQUIREMENTS FOR GLP-COMPLIANT STUDIES

Information to be defined in study plan:

GLP status of TS and, if compliant, a copy of the latest GLP accreditation certificate
If not compliant, the rationale for using a non GLP test site
References to the GLP (or other) regulations to be followed
Name of the responsible person for Quality Assurance (QA) at the TS, with telephone number, fax number and e-mail.

Documents to be supplied to the Study Director:

Completed "Principal Investigator Agreement" (provided by Iris Pharma).
Completed GLP compliance and QA statements for the phase report signed by the PI and QA.
Documents to be supplied to the Lead QA
Quality Assurance programme for the delegated phase

Please note that we will communicate with the Test Site via e-mail by preference unless you have other requirements.