

# GCP Fact or Fiction

All clinical laboratories supporting the conduct of an FDA regulated clinical trial must be certified under the Clinical Laboratory Improvement Act (CLIA).

# GCP Fact

FDA has no explicit regulatory requirements regarding the certification of clinical laboratories used in regulated clinical trials

# GCP Fact or Fiction

Any analytical chemistry laboratory supporting the conduct of a clinical trial (e.g., performing plasma concentration analysis or characterization of the test drug) must adhere to FDA's Good Laboratory Practices (GLP) regulations.

# GCP Fact

FDA's GLP regulations apply only to *nonclinical laboratory studies (as defined in 21 CFR 58.3(d))* that support or are intended to support applications for research or marketing permits. Studies using human subjects or clinical studies are specifically excluded.

# GCP Fact or Fiction

FDA regulations require that the completed final Case Report Form (CRF) must be signed by the investigator of record. (i.e.. an investigator identified on the Form FDA 1572)

# GCP Fact

Although it is a good practice for the clinical investigator to sign the CRF, to document review, there is no regulatory requirement that the CRF be signed.

# GCP Fact or Fiction

Clinical trials conducted outside of the U.S. NOT under an IND must be reviewed by an Institutional Review Board (IRB) or Ethics Committee that conforms to Section 3 of the ICH Good Clinical Practice: Consolidated Guideline published by FDA in the Federal Register on May 9, 1997.

# GCP Fact

312.120 - Foreign clinical trials not under an IND must be conducted in accordance with

- Declaration of Helsinki

*OR*

- The laws and regulations of the country

*WHICHEVER* represents greatest protection

Where ICH GCP is local law, FDA requirements are satisfied by following local law

# GCP Fact or Fiction

FDA GCP regulations require that any changes made to entries in the Case Report Form must not obscure the original entry, shall be initialed and dated by the individual making the changes, and shall indicate the reason for the change.

# GCP Fact

FDA *regulations* (312.62) do not explicitly address how changes to case history records are to be completed.

However:

- ICH GCP 4.9.3 recommends changes be documented by date, initials, and explanation
- Changes to electronic case history records must meet audit trailing requirements of 21 CFR 11

# GCP Fact or Fiction

If a study record required to be maintained under 21 CFR 312 is created or maintained electronically, the computer system used must conform to FDA's Electronic Records; Electronic Signatures rule 21 CFR 11.

# GCP Fact

21 CFR 11 applies to records that are required under any and all of FDA's regulations when those records are in electronic form

Case histories and Drug disposition records are required records under 312.62

# GCP Fact or Fiction

An original signed radiology report provided to a clinical investigator by an outside consultant, is considered to be the source document for the diagnostic result reported in the Case Report Form (CRF).

# GCP Fact

The terms "source document" and "source data" are not defined in 21 CFR 312 but are found in the ICH GCP sections 1.51 and 1.52 respectively

For a diagnostic x-ray result reported in the CRF, *both* the original radiology report and the x-ray film are source documents

# GCP Fact or Fiction

All data reported in the CRF must be supportable by a separate source document.

# GCP Fact

An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation. Case histories include the CRF and supporting data. If source data is recorded directly in the CRF form, separate supporting documentation is not required. See also ICH 6.4.9

# GCP Fact or Fiction

The clinical investigator must maintain the original signed consent form for each subject in the subject's medical chart.

# GCP Fact

Regulations (312.62(b)) require that the investigator maintain the signed consent form as part of a subject's case history. Regulations do not require that it be in the medical chart.

# GCP Fact or Fiction

FDA requires that sponsors regularly perform audits of their study monitoring as part of their quality assurance program.

# GCP Fact

Although regulations do not require implementation of a quality assurance program for the conduct of clinical trials, it is an effective measure to maintain and improve study quality.

- Such programs should be implemented according to written procedures and should be independent of study conduct

# GCP Fact or Fiction

It is current FDA policy under Compliance Policy Guide 7151.02 not to review or copy reports and records resulting from routine study monitoring.

# GCP Fact

FDA investigators may routinely request, review, and copy reports of *routine study monitoring*. CPG 7151.02 applies only to audit reports resulting from the sponsor's written QA program. Although FDA investigators are authorized to review and copy these records, they will not routinely request to do so. (see also ICH 5.19.3 (d))

# GCP Fact or Fiction

Since FDA published "ICH Good Clinical Practice: Consolidated Guideline" in the Federal Register on May 9, 1997, any deviations from ICH GCPs may be cited by FDA investigators on Form FDA 483.

# GCP Fact

Deviations from regulations covering IRBs, informed consent, clinical investigators and sponsors are reportable on the FDA 438. ICH GCP are not legally binding as regulation and should not be listed on the FDA 483 unless the deviation also represents a departure from FDA regulations.

# GCP Fact or Fiction

Under FDA regulations a Site Management Organization (SMO) is considered to be a Contract Research Organization (CRO).

# GCP Fact

A CRO means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the FDA. To the extent that an SMO meets this definition it would be considered a CRO.

# GCP Fact of Fiction

Under FDA's new Financial Disclosure Rule (21 CFR 54) published in the Federal Register on February 2, 1998, any clinical investigator who has a significant equity interest in a Sponsor, may not serve as a principal investigator in a study by that sponsor.

# GCP Fact

The rule requires applicants to certify to the absence of certain financial interests of the clinical investigators and/or disclose those financial interests, as required, when covered clinical studies are submitted to FDA. It does not prohibit any investigators from participating as investigators due to their financial interests.

# GCP Fact or Fiction

Items listed on the FDA-483 are considered by the FDA to be violations of law or regulations and the recipient is obligated to correct each item listed.

# GCP Fact

The observations listed on a 483 represent the observations of the inspector. The determination of whether any condition is violative is an agency decision after considering all circumstances. If the observations are determined by the Agency, after review, to be deviations from regulatory requirements, then the firm is obligated to take appropriate corrective action.