

Key Word	Subsection	Relevant guidelines
SOPs	audit and definition deviations, non compliance electronic data handling monitoring and QA, QC	1.6, 5.19.1 1.55 5.18.4q, 5.20.1 5.5.3 1.38, 1.39, 5.18.2c, 5.18.4q, 5.18.5 5.1.1
Source data/documents	agreement for direct access data, definition directly recorded in CRF documents, consistent with CRF documents, definition documents, explain discrepancies essential documents monitoring of verification, statistical sampling	5.1.2, 5.15.1, 6.10 1.51 6.4.9 4.9.2, 5.18.4m 1.22, C2411.52 4.9.2 8.3.13 5.18.1b, 5.18.4k, 5.18.4m 5.18.3
Statistics	analysis description of in protocol input into trial	1.13, 1.44, 5.5.1 6.9 5.4.1, 5.5.1, 5.18.3
Subinvestigator	definition	1.56
Subject	identification code responsibilities in consent form to sign and date consent form	1.58, 5.5.5, 8.3.21, 8.4.3 4.8.10e 4.8.8
Telephone	records of calls	8.3.11
Termination of study	actions required in event of by IEC/IRB by investigator by sponsor criteria for in protocol essential documents after	4.12, 5.21 3.1.2, 4.12.3 4.12.1 4.12.2 6.9.4 8.4
Training	auditors investigator of individuals in trial	5.19.2 4.1.1, 5.6.1, 5.18.3 2.8
Transcription	verification of copies	1.52
Transformation of data	requirement original versus processed	5.5.4
Unexpected	ADR report to IEC/IRB adverse drug reaction expedited reporting of ADRs	3.3.8, 4.11.1 1.60 5.17.1, 8.3.17
Updates	consent form IB laboratory documents safety	3.1.2, 4.4.1, 4.8.11 4.4.2, 5.12.2, 8.3.1 8.3.6, 8.3.7 5.17.3

Key Word	Subsection	Relevant guidelines
Up-to-date	investigator brochure investigator CV trial records	5.6.2, 7.1 4.1.1 5.18.4k
Verify	compliance with GCP, protocol etc data are reliable, CRFs enrolment of eligible subjects investigational product investigator qualifications reports, notifications etc source documents are accurate sponsor to verify data sponsor to verify subject consent subject rights are protected	5.18.1, 5.18.4d, 5.18.4h 5.18.1, 5.18.4m 5.18.4i 5.18.4c 5.18.4b 5.18.4l 5.18.4k 5.5.1 5.15.2, 5.18.4e 5.18.1
Vulnerable subjects	definition IEC/IRB to safeguard	1.61 3.1.1
Withdrawn subjects	data requirements in protocol need to withdraw if distressed	6.5.3 4.8.14
Witness	actions required by and consent information impartial, definition need for	4.8.9 4.8.6 1.26 4.8.9

INTRODUCTION

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).

This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

1. GLOSSARY

1.1 Adverse Drug Reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.

Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function (see the ICH Guideline for *Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*).

1.2 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for *Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*).

1.3 Amendment (to the protocol)

See Protocol Amendment.

1.4 Applicable Regulatory Requirement(s)

Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

1.5 Approval (in relation to Institutional Review Boards)

The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

1.6 Audit

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

1.7 Audit Certificate

A declaration of confirmation by the auditor that an audit has taken place.

1.8 Audit Report

A written evaluation by the sponsor's auditor of the results of the audit.