Glossary

October 2013

The *Good Clinical Data Management Practices* adopt the ICH definitions for terms defined within the ICH guidelines. Unless otherwise noted, these definitions were taken from *ICH E6*.[1]

(ASQ) in a definition indicates the American Society for Quality as a source.

A

access control

Policy and procedure that defines accessibility to a physical space or electronic source of information. The policy usually includes the concept of audit trails, either paper (e.g., signature log) or electronic.

adverse drug reaction (ADR)

In the pre-approval clinical experience with a new medicinal product or with its new usage (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, and ADR is 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 *ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*[2]).

adverse event (AE)

In a subject or clinical-investigation subject administered a pharmaceutical product, any untoward medical occurrence which does not necessarily have a causal relationship with the treatment. An adverse event (AE) can therefore be any unfavorable 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*[2]).

amendment (to the protocol)

See **protocol amendment**.

analysis dataset

The final data set, including derived items and excluding redundant data points, which is used to perform the analyses required for safety assessment, efficacy assessment, submission to regulatory authorities, or other review. Can be comprised of one or more data files.

analysis file

Same as analysis dataset in the context of the GCDMP.

annotated crf

A document that maps the names of the collected items to their corresponding database tables, variable item names, forms, visits and any other objects needed for a person to correctly analyze data collected in a clinical trial. Annotated collection documents are required so that any person can understand where variables for analysis originate.

applicable regulatory requirement(s)

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

Application Service provider (ASP)

An application service provider is a vendor who provides, manages and distributes software-based services to customers over a network.

approval (in relation to institutional review boards)

The affirmative decision of the institutional review board (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.

audit

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

audit certificate

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

audit report

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

audit trail

Documentation that allows reconstruction of the course of events.

B

batch job

A series of processes run in an electronic system that perform specific tasks, such as data validation, query generation, external data upload, or lab reference range normalization.

biologics

A biological product (as a vaccine or blood serum) used in medicine

blinding/masking

A procedure in which one or more parties to the trial is kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

C

case report form (CRF)

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

CDISC

Acronym for the **Clinical Data Interchange Standards Consortium**.

central lab

A vendor contracted for a clinical trial that processes samples collected from subjects and provides the results of laboratory tests or other medical analyses

(e.g., ECG results, pathology results) to the sponsor. Refer to the Laboratory Data Handling chapter.

change control

A procedure that defines how planned changes to any part of a computer system are handled in a manner as to maintain compliance with required functionality of that system. The procedure ensures that changes applied to the system do not unexpectedly impact the functionality of the system in question, or any other computer systems. The procedure should also define how unexpected changes to a system are prevented and managed.

checklist

(ASQ) A tool used to ensure that all important steps or actions in an operation have been taken. Checklists contain items that are important or relevant to an issue or situation. Checklists are often confused with check sheets and data sheets.

CLIA

See Clinical Laboratory Improvement Amendments.

Clinical Laboratory Improvement Amendments (CLIA)

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. See www.fda.gov/medicaldevices/deviceregulationandguidance/ for more information.

clinical trial/study

Any investigation using human subjects that is intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution,

metabolism, and excretion of an investigational product(s) for the purpose of ascertaining its safety and/or efficacy. The terms “clinical trial” and “clinical study” are synonymous.

clinical trial/study report

A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report (see the *ICH Guideline for Structure and Content of Clinical Study Reports*[3]).

code libraries

A repository of validated programming logic that can be used during the programming of edit checks or other programs used in the collection, review, or analysis of clinical trial data.

common causes

(ASQ) Causes of variation that are inherent in a process over time. They affect every outcome of the process and everyone working in the process. See also **special causes**.

comparator (product)

An investigational or marketed product (i.e., active control) or placebo used as a reference in a clinical trial.

compliance (in relation to trials)

Adherence to all the trial-related requirements, GCP requirements, and the applicable regulatory requirements.

composite endpoint

Overall outcome that the protocol is designed to evaluate based on more than one common endpoint such as myocardial infarction plus repeat intervention.

compound

A chemical molecule with potential pharmacological activity.

confidentiality

Prevention of disclosure of a sponsor's proprietary information or of a subject's identity to unauthorized individuals.

conformance

(ASQ) An affirmative indication or judgment that a product or service has met the requirements of a relevant specification, contract, or regulation.

contract

A written, dated, and signed agreement that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters between two or more involved parties. The protocol may serve as the basis of a contract.

coordinating committee

A committee that a sponsor may organize to coordinate the conduct of a multi-center trial.

coordinating investigator

An investigator assigned responsibility for the coordination of investigators at different centers that are participating in a multi-center trial.

contract research organization (CRO)

A person or an organization (e.g., commercial, academic, or otherwise) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

control chart

(ASQ) A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either control limit.

corrective action (CA)

(ASQ) The implementation of solutions that lead to the reduction or elimination of an identified problem.

CS

Clinically Significant.

D

data cleaning

The process of collecting, reviewing, and confirming modifications to clinical data in such a way that data provided for statistical analysis is complete, accurate, and consistent with other data points.

data module

A category of a type of data, such as CRF.

database backup

A duplicate copy of all electronic data and metadata that can be retrieved in the event of system failure or data corruption.

database lock

The closing of a database after all clinical trial data has been reviewed, queries resolved and issues addressed, such that the database cannot be altered in any way.

development/test environment

Computer system instances that are used for study build and test, prior to release to the production instance. Defined quality procedures and documentation allow transition of programming code from one instance to another.

device

I. A means of data collection such as a paper CRF, Personal Digital Assistant, or medical instrumentation. II. An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

direct access

Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsor’s monitors and auditors) with

direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

disaster recovery plan

A disaster recovery plan is a comprehensive statement of consistent actions to be taken before, during and after a disaster. The plan should be documented and tested to ensure the continuity of operations and availability of critical resources in the event of a disaster. (www.drj.com)

discrepancy

Inconsistency in two or more data points collected in a clinical trial that must be addressed prior to database lock.

documentation

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, or results of a trial; the factors affecting a trial; and the actions taken.

double data entry

The process of purposely entering clinical trial data twice for studies with paper collection media. The two entries are done independently. The goal is to ensure entry into the electronic system is completed without transcription errors.

E

e-CRF

Acronym for **electronic case report form**. An auditable electronic record designed to record information to be reported to the sponsor on each trial

subject, as required by the clinical trial protocol. See also **case report form**.

edits - hard and soft edit

Programmed or manual verifications performed on a clinical database for the purpose of ensuring a quality final analysis set for analysis. Hard edits refer to verifications that require a data change or entry in order to resolve it while Soft edits also accept a confirmation of the existing data.

EHR

Electronic Health Record.

electronic record

Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

electronic signature

Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

electronic submission

The set of required documents for a submission, rendered in an acceptable electronic format that is transmitted to a regulatory agency in lieu of paper documents for review and approval.

EMR

Electronic Medical Record.

endpoint

Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

essential documents

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see *ICH E6,* Section 8. “Essential Documents for the Conduct of a Clinical Trial”[1]).

EU

European Union.

exposure

The condition of being subject to some effect or influence; in context of a clinical trial this generally refers to exposure to the test article/drug.

external data

Data that are collected externally and merged in the CDMS or analyzed together with data collected on the e/CRF.

F

false negative

A test result that is erroneously classified in a negative category (as of diagnosis) because of imperfect testing methods or procedures. In statistics a Type II error.

false positive

A test result that shows evidence of a result or condition although it is not actually present. In statistics, a Type I error.

field

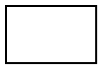
A particular area (as of a record in a database) in which the same type of information is regularly recorded.

flag

A tag placed on a data point that defines a status (e.g., discrepant, closed, or other status) that indicates an action is required.

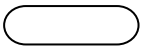
flow diagram, flow chart

A graphic means for depicting the steps or activities that constitute a process. The flow diagram (flow chart) is constructed from standard symbols (the delay and database symbols have been added to Juran's list[4]).



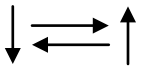
The *activity symbol* is a rectangle that designates an activity. Within the rectangle is a brief description of that activity.

The *decision symbol* is a diamond that designates a decision point from which the process branches into two or more paths. The path taken depends on the answer to the question that appears within the diamond. Each path is labeled to correspond to an answer to the question.



The *terminal symbol* is a rounded rectangle that unambiguously identifies the beginning or end of a process. "Start" or "begin" is used to designate the starting point of a process flow. "Stop" or "end" is used to designate the end of process flow.

The document symbol is a document pertinent to the process.



The flow line represents a process path that connects process elements. The arrowhead indicates the direction of the flow.

The *connector* is a circle that is used to indicate a continuation of the flow diagram.

The *delay symbol* is a rectangle rounded on one side that identifies a waiting point or delay in the process flow.

The *database symbol* is a cylinder that represents a database application and the contained data.

frozen

A temporary locked state for data that allows the generation of queries but does not allow a change to data points.

G

global library

In a Clinical Data Management System, the superset of all standard objects (e.g., CRF modules, edit checks, fields, etc.).

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

H

hard coding

Computer programs utilize logic and hardware to allow dynamic responses based on user input. For example, Web site can be programmed to tabulate the total bill when books are selected for purchase on-line or the average weight of the patients in the active treatment arm each time a program is run on a dataset. “Hard coding” is the limiting of the dynamic response by actually typing the data *in* the computer program itself rather than letting the data come from a dataset or the user. This approach can be dangerous because it is not visible in the analysis tables and listings or to the regulatory authorities and because it is easily forgotten once typed into the computer program.

hard lock

The final state of the database where no changes are permitted and all user access is removed.

I

impartial witness

A person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject’s legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

in-control process

(ASQ) A process in which the statistical measure being evaluated is in a state of statistical control (i.e., the variations among the observed sampling results can be attributed to a constant system of chance causes). See also **out-of-control process**.

independent data-monitoring committee (IDMC) (data and safety monitoring board, monitoring committee, data monitoring committee)

An independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints. Such a committee may also recommend to the sponsor whether to continue, modify, or stop a trial.

independent ethics committee (IEC)

An independent body—i.e., a review board or a committee, whether institutional, regional, national, or supranational, constituted of medical professionals and non-medical members—that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection. These responsibilities are accomplished by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The legal status, composition, function, operations, and regulatory requirements pertaining to IECs may differ among countries but should allow the IEC to act in agreement with GCP, as described in this guideline.

informed consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed-consent form.

inspection

1. (ICH) The act by a regulatory authority (or authorities) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research

organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority. 2. (ASQ) Measuring, examining, testing, and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic.

institution (medical)

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

institutional review board (IRB)

An independent body—constituted of medical, scientific, and non-scientific members—that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

instrument

A device for capturing or measuring the present value of a quantity under observation.

interim clinical trial/study report

A report of intermediate results and their evaluation based on analyses performed during the course of a trial.

intervention

A method of interfering with the outcome or course, especially of a condition or process.

Investigational New Drug application (IND)

An IND application is submitted to the FDA when a sponsor or investigator wishes to initiate trials with human subjects. The IND regulations can be found at the following link: https:// www.fda.gov/cber/ind/ind.htm. “ND” is synonymous with “Notice of Claimed Investigational Exemption for a New Drug.”

investigational product

A pharmaceutical form of an active ingredient or placebo that is being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also **subinvestigator**.

investigator/institution

An expression meaning “the investigator and/or institution, where required by the applicable regulatory requirements.”

investigator meeting

The kickoff meeting for an upcoming trial where the participating investigators review and provide feedback on the protocol or procedures in a protocol. Training of the principal investigator or other site staff on protocol procedures and/or EDC system entry is conducted at the investigator meeting as well.

investigator's brochure

A compilation of the clinical and non-clinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects (see *ICH E6*, Section 7. "Investigator's Brochure"[1]).

IOM

Institute of Medicine.

ISE

Integrated Summary of Efficacy.

ISO

(ASQ) English acronym for **International Organization for Standardization**.

ISO 9000 series standards

(ASQ) A set of five individual, but related, international standards on quality management and quality assurance developed to help companies effectively document the elements that should be implemented to maintain an efficient quality system. Initially published in 1987, the standards are not specific to any particular industry, product, or service. The standards were developed by the International Organization for Standardization (ISO), a specialized international agency for standardization that is composed of the national standards bodies of 91 countries.

ISS

Integrated Summary of Safety.

L

legacy system

An electronic system previously in production, but no longer actively used, that may contain data needed for current analysis or other use and therefore must be maintained by the sponsor organization.

legally acceptable representative

An individual, juridical, or other type of body that is authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

local lab

Local labs are labs in close proximity to individual clinical study sites or patients and are most often used when timely results are needed.

M

MedDRA

Medical Dictionary for Regulatory Activities is a medical terminology used to classify adverse event information associated with the use of biopharmaceuticals and other medical products. See www.meddra.org for additional information.

medical monitor

An individual, other than the principle investigator, who evaluates clinical trial data from a safety perspective.

medical monitoring

The act of evaluating the clinical trial data from a safety perspective.

monitoring

The act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

monitoring report

A written report to the sponsor that is produced by the monitor after each site visit and/or other trial-related communication, as specified by the sponsor's SOPs.

multi-center trial

A clinical trial that is conducted according to a single protocol but at more than one site and therefore is carried out by more than one investigator.

N

NCS

Non Clinically Significant.

new drug application (NDA)

The documentation submitted to the U.S. Food and Drug Administration. As described by the FDA:

> The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions: Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks. Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain. Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. . .

> . . . The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.[5]

The NDA regulations are 21 CFR 314.

non-clinical study

Biomedical studies that are not performed on human subjects.

O

OCR

Optical Character Recognition.

open access

See National Cancer Institute's cancer Biomedical Informatics Grid (caBIG®) for additional details.

open development

See National Cancer Institute's cancer Biomedical Informatics Grid (caBIG®) for additional details.

open source

See National Cancer Institute's cancer Biomedical Informatics Grid (caBIG®) for additional details.

opinion (in relation to an independent ethics committee)

The judgment and/or the advice provided by an independent ethics committee (IEC). See also **independent ethics committee**.

out-of-control process

(ASQ) A process in which the statistical measure being evaluated is not in a state of statistical control (i.e., the variations among the observed sampling results can be attributed to a constant system of chance causes). See also **in-control process**.

original medical record

See **source documents**.

P

Pareto Principle / 80-20 rule

An observation that 20% of the input creates 80% of the result

phase I - IV

Refer to the FDA glossary (clinicaltrials.gov).

predicate rule

The overreaching regulations that the industry must follow for GxP (Good "*Anything*" Practice or any collection of quality guidelines).

production environment

The location (e.g., website, server, EDC) where real clinical data is entered and stored.

protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these details could be provided in

other protocol-referenced documents. Throughout the *ICH GCP Guideline*, the term “protocol” refers to protocol and protocol amendments.

protocol amendment

A written description of a change (or changes) to, or formal clarification of, a protocol.

protocol deviation

Any alteration/modification to the IRB-approved protocol. The protocol includes the detailed protocol, protocol summary, consent form, recruitment materials, questionnaires, and any other information relating to the research study. (Partners Human Research Committee; http://healthcare.partners.org)

protocol violation

Any protocol deviation that is not approved by the IRB prior to its initiation or implementation. (Partners Human Research Committee; http://healthcare.partners.org)

Q

quality assurance (QA)

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and with the applicable regulatory requirement(s).

quality control (QC)

The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

quality assurance/quality control

(ASQ) Two terms with many interpretations because of the multiple definitions for the words “assurance” and “control.” For example, “assurance” can mean the act of giving confidence, the state of being certain, or the act of making certain. “Control” can mean an evaluation to indicate needed corrective responses, the act of guiding, or the state of a process in which the variability is attributable to a constant system of chance causes (for a detailed discussion on the multiple definitions, see *ANSI/ISO/aSQC a3534-2, Statistics—Vocabulary and Symbols—Statistical Quality Control*[6]). One definition of quality assurance includes the following: all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality. One definition for quality control includes the following: the operational techniques and activities used to fulfill requirements for quality. Often, however, “quality assurance” and “quality control” are used interchangeably to discuss the actions that ensure the quality of a product, service, or process.

quality audit

(ASQ) A systematic, independent examination and review to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the objectives.

query rule

See edit check.

R

random sampling

(ASQ) A commonly used sampling technique in which sample units are selected in such a manner that all combinations of *n* units under consideration have an equal chance of being selected as the sample.

randomization

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments. Used to reduce bias.

regulatory authorities

Bodies having the power to regulate. In the *ICH GCP Guideline*, the expression "regulatory authorities" includes the authorities that review submitted clinical data and the authorities that conduct inspections (see Section 1.29[1]). These bodies are sometimes referred to as "competent authorities."

research misconduct

Falsification of data in proposing, designing, performing, recording, supervising, or reviewing research or in reporting research results. Falsification includes acts of omission and commission. Deliberate noncompliance with the regulations can be considered misconduct but is secondary to falsification of data. Research misconduct does not include honest error or differences of opinion.[7]

S

safety database

A database typically used by Drug Safety or Pharmacovigilence departments to collect adverse event data.

SAS transport file

A machine-independent file that allows you to move a SAS data set from one operation system to another. (http://kb.iu.edu/data/aevb.html)

serious adverse event (SAE); serious adverse drug reaction (serious ADR)

Any untoward medical occurrence that at any dose:[2]

- Results in death;
- Is life-threatening;
- Requires hospitalization or prolongs hospitalization of a subject;
- Results in persistent or significant disability/incapacity; or
- Is a congenital anomaly/birth defect.

Service Level Agreement (SLA) - from the Vendor chapter

An SLA is part of a service contract where the level of service is formally defined.

SLA

Service Level Agreement.

s**ource data**

All information that is necessary for the reconstruction and evaluation of the trial, including information about clinical findings, observations, or other activities in a clinical trial. Source data are contained in source documents such as original records or certified copies of original records.

source documents

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

special causes

(ASQ) Causes of variation that arise because of special circumstances. These causes are not an inherent part of a process. Special causes are also referred to as assignable causes. See also **common causes**.

specification

(ASQ) A document that states the requirements to which a given product or service must conform.

sponsor

An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

sponsor-investigator

An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). A sponsor-investigator must fulfill the obligations of both a sponsor and an investigator.

standard operating procedures (SOPs)

Detailed instructions written to achieve uniformity of the performance of a specific function.

statistical process control (SPC)

(ASQ) The application of statistical techniques to control a process. Often the term “statistical quality control” is used interchangeably with “statistical process control.”

statistical quality control (SQC)

(ASQ) The application of statistical techniques to control quality. Often the term “statistical process control” is used interchangeably with “statistical quality control,” although statistical quality control includes acceptance sampling as well as statistical process control.

sub-investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also **investigator**.

subject/trial subject

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

subject identification code

A unique identifier assigned by the investigator to each trial subject to protect the subject’s identity and to be used in lieu of the subject’s name when the investigator reports adverse events and/or other trial related data.

T

trial site

The location(s) where trial-related activities are actually conducted.

trigger

An event that precipitates other events.

Type I error

(ASQ) An incorrect decision to reject something that is acceptable, such as a statistical hypothesis or a lot of products.

Type II error

(ASQ) An incorrect decision to accept something that is unacceptable.

U

UAT

User Acceptance Testing.

unexpected adverse drug reaction

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., investigator's brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). See the *ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*.[2]

V

variable

See also field.

VCL

Virtual Central Lab

vulnerable subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include subjects with incurable diseases, persons in nursing homes, unemployed or impoverished persons, subjects in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

W

well-being (of the trial subjects)

The physical and mental integrity of the subjects participating in a clinical trial.

WHOdrug

WHO Drug is a dictionary of medicinal product information. It is used to identify drug names and provides information about a drug's active ingredients and its therapeutic use(s).

X

XML

Extensible Markup Language is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.

References

1. International Conference on Harmonisation. *Guideline for Good Clinical Practice, E6.* Geneva, Switzerland: Author; 1996.

2. International Conference on Harmonisation. *Guideline for Good Clinical Practice, E2.* Geneva, Switzerland: Author; 1996.

3. International Conference on Harmonisation. *Guideline for Good Clinical Practice, E3.* Geneva, Switzerland: Author; 1996.

4. Juran JM. *Juran's Quality Control Handbook*, 4th ed. New York, NY: McGraw-Hill; 1988.

5. US Food and Drug Administration. New Drug Application (NDA) Process Web site. Available at: http://www.fda.gov/cder/regulatory/applications/nda.htm. Accessed on February 27, 2007.

6. American Society for Quality. *ANSI/ISO/ASQC A3534-2-1993: Statistics—Vocabulary and Symbols—Statistical Quality Control.* Milwaukee, WI: American National Standards Institute; 1993.

7. Woolen S. Office for Good Clinical Practice Web site. October 2001. Available at: http://www.fda.gov/oc/gcp/. Accessed on February 27, 2007.

Chapter Revision History

Publication Date	Comments
September 2000	Initial publication.
May 2007	Revised for style, grammar, and clarity. Substance of chapter content unchanged.
October 2013	Revised with the addition of approximately seventy-five (75) terms.