swiss
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Appendix 1

GLOSSARY

Version

2.0

This glossary includes abbreviations and definitions of terms being important and/or frequently used in the Guidelines for Good Operational Practice as well as in its corresponding documents.

Wherever applicable, the terms and definitions are based on ICH GCP, legal and regulatory authorities (i.e. Swissmedic, swissethics, etc.) or other internationally acknowledged organisations (European Medicines Agency, International Organization for Standardization, etc.). Not referenced definitions are included in italics. Respective comments were agreed upon and approved by the CTU network.

Revision History and Update

This glossary has been revised to reflect the changes implemented by ICH E6 (R2) and ISO 9001:2015.

Term	Abb.	Definition	Reference
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).	ICH E6(R2), 1.2
Annual Safety Report	ASR	*The Annual Safety Report is a summary of the current status of knowledge and describes the identified and potential risks of active substances / medicinal products during clinical trials.*	
		Once a year, the investigator shall present to the responsible ethics committee a list of events or adverse reactions as specified in Articles 40 to 42 (ClinO) and, on this basis, shall submit a report on their severity and causal relationship to the intervention, and on the safety of participants.	ClinO Art. 43
		The sponsor is also obliged to submit to Swissmedic, once a year, a list of all undesirable side effects, SUSARs and a report on the safety of trial subjects, together with a re-evaluation of the risk-benefit ratio.	Swissmedic
Audit		A systematic and independent examination of study related activities and documents to determine whether the evaluated study related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).	ICH E6(R2), 1.6
		An audit is a systematic, independent and documented process to establish, whether relevant activities and the results derived from these are suitable to achieve the objective, were actually done (evidence), and complied with the planned requirements.	DIN EN ISO 19011
Audit Certificate		A declaration of confirmation by the auditor that an audit has taken place.	ICH E6, 1.7
Auditee		The organisation being audited.	SN EN ISO 19011:2002, 3.7
Auditor		A person with the competence to conduct an audit.	SN EN ISO 19011:2002, 3.7
Audit Report		A written evaluation by the sponsor's auditor of the results of the audit.	ICH E6(R2), 1.8
Audit Trail		Documentation that allows reconstruction of the course of events.	ICH E6(R2), 1.9

Term	Abb.	Definition	Reference
Backup		The entire system that supports the process of backing up copies of data, so that these copies may be used to restore the original after data loss. Organizing the storage space and media required and managing the backup process can be complex, and corporate backup systems normally include a central module that supports this management, identifying the data to be backed up and the method to be used, logging activities and their outcome, managing media etc. This central system interacts with 'backup clients' installed on each machine that is backed up, which respond to the instructions of the central system and which generate the file copies, produce local logs etc.	ECRIN
Blinding / Unblinding		A procedure in which one or more parties to the trial are 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). For Unblinding Procedures refer to ICH E6, 4.7 and 5.13.4	ICH E6(R2), 1.10
Bologna system		The Bologna educational system is the currently accepted higher education system designed to ensure comparability in the standards and quality of higher education qualifications in Europe.	European Higher Education Area
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 study subject.	ICH E6(R2), 1.11
Electronic Case Report Form	eCRF	An auditable electronic record designed to record information required by the clinical trial protocol to be reported to the sponsor on each trial subject.	GCDMP
Clinical Data Management Application	CDMA	Refers to the specific system established to hold the data for a single trial. As well as the data itself, the CDMA contains the schedule and check logic for that trial, and the specific data collection instruments, i.e. the eCRFs, that have been set up for the trial. A CDMA is therefore a specific application of the underlying CDMS.	ECRIN
Clinical Research		See Clinical Study / Clinical Trial.	
Clinical Study / Clinical Trial		Any investigation in human subjects 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) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. *Comment: The new Federal Act on Human Research (HRA) clearly differentiates between "Clinical Trials" under ClinO and non-clinical "Research Projects" under HRO. Depending on the research approach in Switzerland either one of these ordinances apply. Regarding ease of reading and ordinance applicability the following definitions do apply:* – ***Clinical Research:*** *encompasses both Clinical Trials (ClinO) & Research Projects (HRO)* – ***Clinical Trials:*** *refer only to studies conducted according to ClinO* – ***Research Projects:*** *refer only to studies conducted according to HRO*	ICH E6(R2), 1.12
Clinical Study Report / Clinical Trial Report	CSR / CTR	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).	ICH E6(R2), 1.13

Term	Abb.	Definition	Reference
Clinical Trials Ordinance	ClinO	Ordinance on Clinical Trials in Human Research of 20 September 2013 (www.admin.ch/opc/en/classified-compilation/20121176/index.html) *Comment: English is not an official language of the Swiss Confederation. A translation has no legal force.* *German version: Verordnung über klinische Versuche in der Humanforschung (Verordnung über klinische Versuche; KlinV) vom 20. September 2013* *French version: Loi fédérale relative à la recherche sur l'être humain (Loi relative à la recherche sur l'être humain, LRH) du 30 septembre 2013*	The Federal Authorities of the Swiss Confederation
Clinical Trial Unit	CTU	*Clinical Trial Units (CTUs) are organisations established for the conduct of clinical studies with staff specialised in clinical research.* *Comment: In Switzerland, they are public organisations, initiated through a unique partnership between the Swiss National Science Foundation (SNSF), the universities and the (university) hospitals to develop and improve academic clinical research.*	
Coding		In clinical trials, the process of assigning data to categories for analysis NOTE: Adverse events, for example, may be coded using MedDRA.	CDISC
Competent Authority	CA	A competent authority is the organisation with the authority to act on behalf of the government to ensure that all medicinal products and medical devices meet the essential requirements laid down in the Federal Law prior to marketing authorisation.	EU Clinical Trials Register
Confidentiality		Prevention of disclosure, to other than authorised individuals, of a sponsor's proprietary information or of a subject's identity.	ICH E6(R2), 1.16
Confidential Disclosure Agreement	CDA	*A CDA is a legal document that ensures confidentiality of proprietary information that a sponsor gives to the principle investigator. A signed, study specific CDA may be required before a sponsor will provide its proprietary information, such as the study protocol, to an Investigator.*	
Conflict of Interest	CI	One potential source of bias in clinical studies is a financial interest of the clinical investigator in the outcome of the study because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered study. It requires applicants looking to conduct a clinical trial to submit a list of all investigators who will be working on the trial paired with a certification that either no financial arrangements exist that would cause a problem, or explaining the nature and extent of those holdings and why they do not pose a problem to the conduct of the trial.	FDA
Continuing Education		*Formal lectures, courses, seminars, webinars, or any other similar type of educational program designed to educate an individual and give him or her further skills or knowledge to be applied in his or her line of work. These programs are intended to educate persons on new advancements, or to build upon a person's expertise in a given field; they may be optional for some professions, but can be required to maintain status, certification, or licensure in other professions. (Citation from www.businessdictionary.com)*	

Term	Abb.	Definition	Reference
Contract		A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.	ICH E6(R2), 1.17
		The contract is the legally binding agreement. *Comment: The concept of contract is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents.*	ISO 9000:2015, 3.4.7.
Contract Research Organisation	CRO	A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.	ICH E6(R2), 1.20
Coordinating Investigator		An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicentre trial.	ICH E6(R2), 1.19
Council for International Organizations of Medical Sciences	CIOMS	The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organisation established jointly by WHO and UNESCO in 1949. "The main objectives of CIOMS are: to facilitate and promote international activities in the field of biomedical sciences and to serve the scientific interests of the international biomedical community in general." *Note: The CIOMS Form I has been a widely accepted standard for expedited adverse event reporting.*	CIOMS
Customer		Person or organisation that could or does receive a product or a service that is intended for a required by this person or organisation. *Comment: A customer can be internal or external to the organisation.*	ISO 9000:2015, 3.2.4.
Data Management	DM	Tasks associated with the entry, transfer, and/or preparation of source data and derived items for entry into a clinical trial database. NOTE: Data management could include database creation, data entry, review, coding, data editing, data QC, locking, or archiving; it typically does not include source data capture.	CDISC
Data Management Plan	DMP	The DMP should document the processes and procedures employed to promote consistent, efficient and effective data management practices. It should document the relevant convention of a particular study, before data collection begins. Comment: For details regarding content and structure refer to the relevant chapter Data Management Plan in GCDMP	GCDMP
Database Lock		A database is locked when an organisation's pre-specified database closure procedures have been completed or otherwise approved. At the time of lock, to the best of the sponsor's knowledge, the data is complete, meets pre-specified acceptance criterion, and is acceptable for analysis. Access granted to database users has been restricted to "read-only."	GCDMP
Declaration of Helsinki	DoH	World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects	WMA

Term	Abb.	Definition	Reference
Development Safety Update Report	DSUR	The DSUR should provide safety information from all on-going clinical studies that the sponsor is conducting or has completed during the review period including: – clinical studies conducted using an investigational drug whether with or without a marketing approval, i.e., human pharmacology, therapeutic exploratory and therapeutic confirmatory studies (Phase I – III) – clinical studies conducted using marketed drugs in approved indications, i.e., therapeutic use studies (Phase IV) – other therapeutic use of an investigational drug – comparability studies conducted to support changes in the manufacturing process of medicinal products.	ICH E2F
Development Team		*The development team is a project team established by the responsible person of the CTU for the development and review of Standard Operating Procedures.*	
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.	ICH E6(R2), 1.21
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, and/or results of a trial, the factors affecting a trial, and the actions taken.	ICH E6(R2), 1.22
Documented Information		Information required to be controlled and maintained by an organisation and the medium on which it is contained. Documented information can be in any format and media and from any source. Documented information can refer to: – the management system, including related processes; – information created in order for the organisation to operate (documentation); – evidence of results achieved (records).	ISO 9001:2015, 3.8.6.
Electronic Remote Data Capture	eRDC	The data entry direct from sites. In most eRDC systems access for data entry will be via a web browser.	ECRIN
Encrypted Transmission		Transmission over the internet can be encrypted at various levels. In this context encryption needs to apply to the whole of the data interchange, and not (as is sometimes the case) just to the initial certificate. The generally recommended encryption level is the 128 bit Advanced Encryption Standard (AES-128), earlier standards having now been shown to be insecure. File transfer should therefore have to use data encrypted to at least this standard, as should remote access systems, e.g. VPN and Citrix.	ECRIN
Essential Documents		Essential Documents are those documents, which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. Essential documents for the trial should be supplemented of may be reduced where justified (in advance of trial initiation) based on the importance an relevance of the specific documents to the trial.	ICH E6(R2), 8.1

Term	Abb.	Definition	Reference
Ethics Committee	EC	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable 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.	ICH E6(R2) 1.27
European Medicines Agency	EMA	The European Medicines Agency (EMA) is a decentralised body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.	EMA
Failover to manual		Any computer mediated randomisation / dynamic balancing system needs to have a manual system available for those situations when the system is unavailable, e.g. because of power loss (i.e. a failover to manual). A critical component of such a system will be well-trained staff who can revert to manual systems as necessary. In addition, good record systems are necessary, so that previous allocations (in dynamic balancing) or randomisation lists can be accessed, and so that the manual allocation decision can later be processed into the computer system.	ECRIN
Financial Disclosure	FD	Financial Disclosure by Clinical Investigators requires the sponsor of a marketing application for any drug product, including any biological product, or any device to submit certain information concerning the compensation to, and financial interests of, clinical investigators conducting certain clinical studies. Requires the sponsor to certify to the absence of certain financial interests of clinical investigators and/or disclose those financial interests.	FDA
Functional Specifications		*A functional specification in software development is the documentation that describes the requested behaviour of an engineering system. The documentation typically describes what is needed by the system user as well as requested properties of inputs and outputs (e.g. of the software system).*	
Good Clinical Data Management Practices	GCDMP	Society for Clinical Data Management guidance on accepted practices for the clinical data management.	GCDMP
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.	ICH E6(R2), 1.24
Good Manufacturing Practice	GMP	EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use. *Comment: For Manufacture of Investigational Medicinal Products Annex 13 is relevant.*	Eudralex
Human Research Act	HRA	Federal Act on Research involving Human Beings of 30 September 2011 (www.admin.ch/opc/en/classified-compilation/20061313/index.html) *Comment: English is not an official language of the Swiss Confederation. A translation has no legal force.* *German version: Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG) vom 30. September 2011* *French version: Loi fédérale relative à la recherche sur l'être humain (Loi relative à la recherche sur l'être humain, LRH) du 30 septembre 2011*	The Federal Authorities of the Swiss Confederation

Term	Abb.	Definition	Reference
Human Research Ordinance	HRO	Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013 (www.admin.ch/opc/en/classified-compilation/20121177/index.html) *Comment: English is not an official language of the Swiss Confederation. A translation has no legal force.* *German version: Verordnung über die Humanforschung mit Ausnahme der klinischen Versuche (Humanforschungsverordnung, HFV) vom 20. September 2013* *French version: Ordonnance relative à la recherche sur l'être humain à l'exception des essais cliniques (Ordonnance relative à la recherche sur l'être humain, ORH) du 20 septembre 2013*	The Federal Authorities of the Swiss Confederation
Impartial Witness		A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, 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.	ICH E6(R2), 1.26
Informed Consent	IC	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.	ICH E6(R2), 1.28
Informed Consent Form	ICF	Informed consent is documented by means of a written, signed and dated Informed Consent Form. See also Informed Consent.	
Inspection		The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical study and that may be located at the site of the study, at the sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).	ICH E6(R2), 1.29
Institution (medical)		Any public or private entity or agency or medical or dental facility where clinical trials are conducted.	ICH E6(R2), 1.30
Intellectual Property		*Intellectual property rights are the legally recognised exclusive rights to creations of the mind. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as discoveries, inventions, designs etc. Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions trade secrets.*	
Interim Analysis		Any analysis intended to compare treatment arms with respect to efficacy or safety at any time prior to the formal completion of a trial.	ICH E9, Glossary
Interim Clinical Trial / Study Report		A report of intermediate results and their evaluation based on analyses performed during the course of a trial.	ICH E6(R2), 1.32

Term	Abb.	Definition	Reference
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The work carried out by ICH under the Efficacy Guidelines is concerned with the design, conduct, safety and reporting of clinical trials. *NOTE: Following guidelines are of most importance for the GGOP.* – ICH E2A: Clinical safety data management. Definitions and Standards for Expedited Reporting I – ICH E2C (R2): Periodic Safety Update Reports for Marketed Drugs (PSUR) – ICH E2F: Development Safety Update Report (DSUR) – ICH E6: Guideline for Good Clinical Practice E6 (R2) – ICH E8: General Considerations for Clinical Trials	ICH
International Organization for Standardization	ISO	ISO is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 160 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.	ISO
Investigational (Medicinal) Product	I(M)P	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. *Comment: There is no difference between IP and IMP. GCP uses IP and the Directive 2001/20/EC, Article 2 (d) IMP as abbreviations. Both are included as both are common.*	ICH E6(R2), 1.33 Directive 2001/20/EC
Investigational Medicinal Product Dossier	IMPD	The Investigational Medicinal Product Dossier is required for approval of clinical trials by the competent authorities in the EU. It should provide information on quality data, non-clinical pharmacology and toxicology data, clinical trial and previous human experience data, and overall risk and benefit assessments for the test product, reference product and placebo.	IMPD
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 Principal Investigator, Sub Investigator.	ICH E6(R2), 1.34
Investigator-Initiated Trial	IIT	A clinical trial conducted by researchers without the participation of the pharmaceutical industry that fulfils the following criteria: 1. The sponsor / sponsor-investigator is a university, a hospital, a public scientific organisation, a non profit institution, a patient organisation or a researcher 2. The ownership of the data should belong to the sponsor / sponsor-investigator 3. No agreement in place allowing to use the data for regulatory or marketing purposes The design, conduct, recording and reporting of the clinical trial should be under the control of the sponsor / sponsor-investigator	European Science Foundation
Investigator Site File	ISF	See Trial Master File.	

Term	Abb.	Definition	Reference
Investigator's Brochure	IB	A compilation of the clinical and nonclinical data on the investigational product(s), which is relevant to the study of the investigational product(s) in human subjects (see 7. Investigator's Brochure).	ICH E6(R2), 1.36
Legally Acceptable Representative		An individual or juridical or other body authorised under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical study.	ICH E6(R2), 1.37
License		See Marketing Authorisation.	
Management		Coordinated activities to direct and control an organisation Management can include establishing policies and objectives, and processes to achieve these objectives.	ISO 9000:2015, 3.3.3.
Management System	MS	Set of interrelated or interacting elements of an organisation to establish policies and objectives, and processes to achieve those objectives.	ISO 9000:2015, 3.5.3.
Marketing Authorisation		An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorisation is based (e.g. "The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence"). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorisation, and the period of validity of the authorisation. Once a product has been given marketing authorisation, it is included on a list of authorised products - the register - and is often said to be "registered" or to "have registration". *Comment: Marketing authorisation may occasionally also be referred to as a license or product license.*	European Commission
Marketing Authorisation Holder	MAH	The person or company in whose name the marketing authorisation has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorisation. The authorisation holder must be subject to legislation in the country that issued the marketing authorisation, which normally means being physically located in the country.	European Commission
Matrix	MAT	A Matrix is a template for SOPs provided by the Swiss Clinical Trial Organisation (SCTO) for procedures, which are considered essential to ensure that clinical trials are planned and conducted according to the protocol, Good Clinical Practice (GCP) Guidelines and regulatory requirements. Matrices are developed, approved and released by the QA Working Group of the SCTO.	

Term	Abb.	Definition	Reference
Medical Device		Medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: – Diagnosis, prevention, monitoring, treatment or alleviation of disease, – Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, – Investigation, replacement or modification of the anatomy or of a physiological process, – Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.	Directive 2007/47/EC
Medical Dictionary for Regulatory Activities	MedDRA	In the late 1990s, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed MedDRA, a rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. *Comment: MedDRA is used by regulatory authorities and the regulated biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing activities, and for data entry, retrieval, evaluation, and presentation. In addition, it is the AE classification dictionary endorsed by the ICH for safety reporting.*	MEDDRA
Medicinal Product		(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. See also Substance.	Directive 2001/83/EC
Monitor		The Monitor is appointed by the sponsor and verifies that the rights and well-being of human subjects are protected, the reported trial data are accurate, complete, and verifiable from source documents, and the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable legal and regulatory requirement(s).	ICH E6(R2), 5.18
Monitoring		The act of overseeing the process of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s).	ICH E6(R2), 1.38
Monitoring Report		A written report from the monitor to the sponsor after each site visit and/or other study-related communication according to the sponsor's SOPs.	ICH E6(R2), 1.39
Multicentre Trial		A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.	ICH E6(R2), 1.40

Term	Abb.	Definition	Reference
Non-interventional Study		A study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data. *Comment: To classify a study as non-interventional, it must meet all of the following criteria:* – *are studies involving products with a marketing authorisation that are prescribed in the usual manner and used in accordance with the authorisation;* – *when the patient is assigned to a therapeutic strategy within current practice and not according to a protocol;* – *the diagnostic or monitoring procedures are only those ordinarily applied to the therapeutic strategy;* – *and epidemiological methods are used to analyse the data.*	Directive 2001/20/EC
Non-Investigational Medicinal Product	NIMP	Products which are not the object of investigation (i.e. other than the tested product, placebo or active comparator) may be supplied to subjects participating in a trial and used in accordance with the protocol. For instance, some clinical trial protocols require the use of medicinal products such as support or rescue/escape medication for preventive, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject. They may also be used in accordance with the protocol to induce a physiological response. See also Investigational Medicinal Product (IMP).	European Commission
Organisation		Person or group of people who have their own functions with responsibilities, authorities and relationships to achieve their objectives. *Comment: In the Guidelines for Good Operational Practice the term organisation refers to the CTU. If any other organisation is referred to, it is specified.*	ISO 9000:2015, 3.2.1.
Participant		See Subject.	
Participant Information		See Subject Information.	
Periodic Safety Update Report	PSUR	Periodic Safety Update Reports for Marketed Drugs. A report, which contains a concise critical summary of the safety profile of the drug under study, as well as the safety issues that have arisen during the reporting period.	ICH E2C (R1)
Pharmaceutical Medicine		*Pharmaceutical medicine is the discipline concerned with the medical aspects of research, development, evaluation, registration, monitoring, and marketing of medicines in the interests of patients.*	
Postgraduate Education		*Postgraduate education is a higher qualification after a first degree university level (bachelor), such as masters and PhDs.*	
Principal Investigator	PI	See Investigator.	
Procedure		Specified way to carry out an activity or a process. Procedures can be documented or not.	ISO 9000:2015, 3.4.5
Process		Set of interrelated or interacting activities that use inputs to deliver an intended result.	ISO 9000:2015, 3.4.1

Term	Abb.	Definition	Reference
Product		Output of an organisation with at least one activity necessarily performed between the organisation and the customer.	ISO 9000:2015, 3.7.6
Project		Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.	ISO 9000:2015, 3.4.2
Protocol		A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.	ICH E6(R2), 1.44
Protocol Amendment		A written description of a change(s) to or formal clarification of a protocol. *Comment: An amendment becomes an integral part of the protocol.*	ICH E6(R2), 1.45
Provider		Supplier. Organisation that provides a product or a service (3.7.7.)	ISO 9000:2015, 3.2.5
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 the applicable regulatory requirement(s).	ICH E6(R2), 1.46
Quality Assurance Manager		*The Quality Assurance Manager is a person either designated by the CTU Management for the respective CTU, or by the SCTO Management for the SCTO. He/she should be qualified by education and/or experience for this role.*	
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.	ICH E6(R2), 1.47
Quality Management	QM	Management with regard to quality. *Comment: QM can include establishing quality policy policies and quality objectives, and proceses to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement.*	ISO 9000:2015, 3.3.4
Quality Management System	QMS	Part of a management system with regard to quality.	ISO 9000:2015, 3.5.4
Query		A request for clarification on a data item collected for a clinical trial; specifically a request from a sponsor or sponsor's representative to an investigator to resolve an error or inconsistency discovered during data review.	CDISC
Record		Document stating results achieved or providing evidence of activities performed. Records can be used, for example, to formalise traceability and to provide evidence of verification, preventive action and corrective action. Generally, records need not be under revision control.	ISO 9000:2015, 3.8.10.
Regulatory Authorities	RA	Bodies having the power to regulate. In the ICH GCP guideline the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections (see ICH E6, 1.29). These bodies are sometimes referred to as competent authorities.	ICH E6(R2), 1.49
Research Project		See Clinical Study / Clinical Trial.	

Term	Abb.	Definition	Reference
Safety Signals		Information that arises from one or multiple sources (including observations or experiments), which suggests a new, potentially causal association, or a new aspect of a known association between an intervention [e.g., administration of a medicine]and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.	CIOMS
Self-Evident Corrections		A self-evident correction is a change to data or resolution of a query that can easily and obviously be made on the basis of other existing information on the CRF without sending a query to the investigative site.	GCDMP
Serious Adverse Event / Serious Adverse Drug Reaction	SAE / SADR	Any untoward medical occurrence that at any dose: – results in death, – is life-threatening, – requires inpatient hospitalisation or prolongation of existing hospitalisation, – results in persistent or significant disability/incapacity, or – is a congenital anomaly/birth defect. In addition, important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation, or development of drug dependency or drug abuse. *Comment: See also ICH E2A.*	ICH E6(R2), 1.50 FDA
Service		Output or an organisation with at least one activity necessarily performed between the organisation and the customer.	ISO 9000:2015, 3.7.7.
Service Level Agreement	SLA	*In contrast to a contract, an SLA would focus only on the performance metrics and service quality agreed to by both parties, and may be used as a measurement tool as part of the contract.* *Comment: The rationale for having a *separate* SLA document is that the SLA can be revised without having to revise the contract. The contract can just refer to the agreed SLA. The contract might then last for 2 years but the SLA may be reviewed quarterly, for example. This reduces the administrative burden of reviewing the contract too frequently.*	
Source Data		All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).	ICH E6(R2), 1.51
Source Data Verification	SDV	The process of ensuring that data that have been derived from source data accurately represent the source data.	CDISC
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).	ICH E6(R2), 1.52

Term	Abb.	Definition	Reference
Specification		Document stating requirements. A specification can be related to activities (e.g. procedure document, process, specification and test specification), or products (e.g. product specifications, performance specification and drawing). It can be that, by stating requirements, a specification additionally is stating results achieved by design and development and thus in some cases can be used a record.	ISO 9000:2015, 3.8.7.
Sponsor		An individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.	ICH E6(R2), 1.53
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). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.	ICH E6(R2), 1.54
Standard Operating Procedure	SOP	Detailed, written instructions to achieve uniformity of the performance of a specific function.	ICH E6(R2), 1.55
Statistical Analysis Plan	SAP	A statistical analysis plan is a document that contains a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and includes detailed procedures for executing the statistical analysis of the primary and secondary variables and other data.	ICH E8
Study Drug		See Investigational Medicinal Product.	
Study Manager		*An appropriately qualified individual, who supervises on behalf of the sponsor the overall conduct of the study, handles the data, verifies the data, conducts the statistical analyses, and prepares the study report.*	
Study Master File		See Trial Master File.	
Study Nurse		*Study nurse or research nurse is a nurse who co-supervises clinical studies at hospitals, doctor's offices or the pharmaceutical industry. The study nurse is responsible for the protocol defined conduct of the study.*	
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.	ICH E6(R2), 1.56
Subject		An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.	ICH E6(R2), 1.57
Subject information		*Study information text(s) or any written information on the proposed research, which is handed out to the potential study subject, explaining all relevant information concerning the study in an easily understandable layman's language.* *Comment: See also ICH E6, 4.8.5 and 4.8.6*	

Term	Abb.	Definition	Reference
Substance		Any matter irrespective of origin which may be: – human, e.g. human blood and human blood products; – animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; – vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; – chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.	Directive 65/65/EEC
Summary of Product Characteristics	SmPC	SmPCs are a key part of the marketing authorisation of all medicines authorised in the European Union and the basis of information for healthcare professionals on how to use a medicine safely and effectively. They are kept updated throughout the lifecycle of a medicine as new efficacy or safety data emerge. SmPCs are also the basis for the preparation of package leaflets, so are important documents in enabling information on medicines to reach patients.	EMA
Suspected Unexpected Serious Adverse Reaction	SUSAR	*SUSARs are Adverse Drug Reactions that are suspected to be both serious and unexpected.* *See also SAE and Unexpected Adverse Drug Reaction.*	
Swiss Clinical Trial Organisation	SCTO	The Swiss Clinical Trial Organisation (SCTO) is the central cooperative platform for patient-oriented, clinical research in Switzerland.	SCTO
Swiss Group for Clinical Cancer Research	SAKK	The Swiss Group for Clinical Cancer Research (Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung, SAKK) is organised as a membership association. Based on a service agreement with the Swiss Confederation, SAKK is a decentralised, academic research institute conducting trials at all major Swiss hospitals and abroad. The SAKK is a non-profit organisation that investigates the efficacy and tolerability of new cancer therapies and further develops existing tumour treatments.	SAKK
Swiss National Science Foundation	SNSF	The Swiss National Science Foundation (SNSF) is the most important Swiss agency promoting scientific research. It supports, as mandated by the Swiss Federal government, all disciplines, from philosophy and biology to the nanosciences and medicine.	SNF
Test Documentation Set		*Set of documents for use in defined stages of software testing, each stage potentially producing its own separate type of document.*	
Test Plan		*A test plan is a document detailing a systematic approach to testing a system such as a machine or software. The plan typically contains a detailed understanding of what the eventual workflow will be.*	
Therapeutic Products Act	TPA	Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (www.admin.ch/opc/en/classified-compilation/20002716/index.html) *Comment: English is not an official language of the Swiss Confederation. A translation has no legal force.* *German version: Bundesgesetz über Arzneimittel und Medizinprodukte (Heilmittelgesetz, HMG) vom 15. Dezember 2000* *French version: Loi fédérale sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPTh) du 15 décembre 2000*	The Federal Authorities of the Swiss Confederation

Term	Abb.	Definition	Reference
Top Management		Person or group of people, who direct and control an organisation at the highest level. *Comment: Depending on the CTUs, there are different terms for top management, e.g. executive board, executive manager, etc. Steering bodies may also have different names, e.g. technical committee, steering committee, management board or other terms.*	ISO 9000:2015, 3.1.1.
Training		The acquisition of knowledge, abilities, competencies and/or practical skills as a result of teaching by persons qualified by education and/or experience in the specific required competencies. Training can be provided in the form of courses, tutorials, online courses or written instructions.	
Trial Manager		See Study Manager.	
Trial Master File / Study Master File	TMF / SMF	A Trial Master File contains the minimal set of Essential Documents as defined in GCP Art. 8.2 - 8.4. It should be established at the beginning of the trial, both at the investigator/institution's site (Investigator Site File) and at the sponsor's office (Trial Master File/Study Master File).	ICH E6(R2), 8
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).	ICH E6(R2), 1.60
Validation		Validation in the clinical data management context refers to the process of ensuring that an IT system is 'fit for purpose', i.e. meets the requirements of the system's users. The IT system may be defined as hardware, software or (most often) some combination of both. 'Absolute' validation, i.e. of all possible inputs and situations, is impossible in all but the simplest situations. Validation must therefore be focused on major functionality and areas where an error might have relatively serious consequences, and / or be difficult to detect in normal usage. In other words validation should always be planned and based on a risk assessment.	ECRIN
Vulnerable Participant / Vulnerable Subject		Individuals whose willingness to volunteer in a clinical study 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.	ICH E6(R2), 1.61
Well-being (of the trial subject)		The physical and mental integrity of the subjects participating in a clinical trial.	ICH E6(R2), 1.62
World Health Organisation	WHO	WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.	WHO