CDISC CDISC Glossary, 2018-12-21

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NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C67497	CDISC Glossary	CDISC Glossary	The terminology of the Clinical Data Interchange Standards Consortium (CDISC) glossary.	NA

CDISC Glossary (CDISC Glossary)

NCI Code: C67497, Codelist extensible: NA

C67497	CDISC Glossary			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C80442	510(k)		510(k). Premarket Notification (PMN) required for certain medical devices. See http://www.fda.gov/cdrh/510khome.html.	Premarket Device Notification
C42610	abbreviation		A set of letters that are drawn from a word or from a sequence of words and that are used for brevity in place of the full word or phrase. NOTE: An abbreviation is NOT pronounced as a word, but each letter is read in sequence (e.g., NIH). Compare to acronym.	Abbreviation
C71733	absorption		The process by which medications reach the blood stream when administered other than intravenously, for example, through nasal membranes. See also ADME (pharmacokinetics).	Biological Absorption
C156638	accelerated approval	fast track designation	Regulatory mechanism by which new drugs meant to treat serious life-threatening diseases and that provide meaningful therapeutic benefit to patients over existing treatments can be approved rapidly. [after FDA, Guidance for Industry Expedited Programs for Serious Conditions - Drugs and Biologics; after NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Accelerated Approval
C93495	acronym		A word formed from the beginning letters (e.g., ANSI) or a combination of syllables and letters (e.g., MedDRA) of a name or phrase. NOTE: An acronym is usually pronounced as a word, not by speaking each letter individually. Compare to abbreviation	Acronym
C142550	action letter		An official communication from FDA to an NDA sponsor announcing an agency decision. See also approval letter, approvable letter, not-approvable letter.	FDA Action Letter
C142528	activation (EDC)		Enabling an eClinical trial system to capture data; usually used for EDC systems.	Electronic Data Capture Activation
C82533	active ingredient		Any component of a drug product intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. [Segen's Medical Dictionary]	Active Ingredient
C98704	adaptive design		A study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study. [FDA, Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics]	Adaptive Design
C142382	adequate and well-controlled studies		Studies used to support drug marketing authorization and intended to provide substantial evidence of effectiveness required by law to support a conclusion that a drug is effective. NOTE: For additional information see COA glossary of terms. [After 1. FDA Clinical Outcome Assessment (COA) Glossary; 2. 21 CFR 314.126]	Adequate and Well-controlled Study
C142383	administrable dosage form		Pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured items and their corresponding manufactured dose forms has been carried out. [After ISO 11615 Identification of medicinal products-Data elements and structures for the unique identification and exchange of regulated medicinal product information, Second edition 2017-10]	Administrable Dosage Form
C142384	admission criteria		Basis for selecting target population for a clinical trial. Subjects must be screened to ensure that their characteristics match a list of admission criteria and that none of their characteristics match any single one of the exclusion criteria set up for the study. See also inclusion criteria, exclusion criteria.	Admission Criteria
C142385	adverse drug reaction (ADR)	adverse drug experience	Any noxious and unintended response associated with the use of a drug in humans. NOTE: 1. Post-approval: an adverse event that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. 2. Pre-approval: an adverse event that occurs at any dose and where a causal relationship is at least a reasonable possibility. 3. FDA 21 CFR 310.305 defines an adverse drug experience to include any adverse event, "whether or not considered to be drug-related." CDISC recognizes that current usage incorporates the concept of causality. [WHO Technical Report 498(1972); ICH E2A]	Adverse Drug Reaction

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C41331	adverse event (AE)	adverse experience;side effects	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 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. NOTE: For further information, see the ICH Guideline for Clinical safety Data Management: Definitions and standards for expedited Reporting. [After ICH E2A] See also serious adverse event, serious adverse experience.	Adverse Event
C41332	adverse reaction		A response to a medicinal product, devices, or procedures, which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility. In the context of drug development, the term is used as a synonym of adverse drug reaction. (After ICH E2A)	Adverse Reaction
C156645	AEGIS (ADROIT Electronically Generated Information Service)		A subscription service that provides subscribing organizations with access to adverse drug reaction data from the Medicines Control Agency ADROIT (Adverse Drug Reaction On-line Information Tracking) database.	ADROIT Electronically Generated Information Service
C156646	AHIC (American Health Information Community)		A US government-charted commission providing input and recommendations to HHS on how to make health records digital and interoperable, and assure the privacy and security of those records (HITSP).	American Health Information Community
C156621	ALCOA		Acronym for a number of attributes or dimensions that are considered of universal importance for data integrity of source data and the records that hold those data. These include that the data and records be: A-Attributable (to both subject and to any actor on a record); L-Legible (available for human review, possible to read electronically if an encoded eRecord); C-Contemporaneous (timing of data collection with respect to the time the observation is made: the more promptly an observation is recorded, the better the quality.); O-Original (the first suitably accurate and reliable recording of data for the intended purpose); A-Accurate (free from error especially as the result of care; an accurate diagnosis conforming exactly to truth or to a standard). NOTE: ALCOA stemmed from FDA's Dr. Stan Woollen's talks in the early 90's on earmarks for the quality of records and has become a widespread acronym reflecting best practices for clarity and usability of data. [From EMA Reflection Paper on eSOURCE in effect since 2010] See also: Data Quality and the Origin of ALCOA. See also: Six Primary Dimensions for Data Quality Assessment. See also ALCOA+, data integrity.	Attributable, Legible, Contemporaneous, Original, Accurate
C156622	ALCOA +	ALCOA Plus	Acronym for a number of attributes or dimensions included in ALCOA, plus the following: Complete, Consistent, Enduring, and Available when needed. NOTE: ALCOA + is a recent way to summarily refer to the attributes or dimensions of data integrity.) After EMA Reflection Paper on eSOURCE in effect since 2010. See also WHO Annex V, Guidance on Good Data and Record Management Practices. See also ALCOA, data integrity.	Attributable, Legible, Contemporaneous, Original, Accurate Plus
C142753	alert		To cause a high-priority signal (or warning) to be transmitted to the relevant stakeholder by way of the local system or another system (usually according to an established set of rules). For example, the system may transmit an alert to a patient's cardiologist that the patient has experienced another heart attack. another example is that the pharmacy system may transmit an alert to the prescribing physician that a potentially dangerous drug-drug interaction may occur based on the current list of medications. another example is that the system may notify a patient's physician that laboratory results (that are not within normal limits) are available. [HL7 EHR-SFM Glossary of Terms, 2010]	System Alert
C16275	algorithm		Step-by-step procedures for making a series of choices among alternative decisions to reach a calculated result or decision. NOTE: An algorithm may be used clinically to guide treatment decisions for an individual patient on the basis of the patient's clinical outcome or result. [after AMA Style Guide, 9th Edition]	Algorithm
C142387	alpha error		The likelihood that a relationship observed between two variables is due to chance. The probability of a Type 1 error. [Modified from AMA Manual of Style]	Alpha Error
C41200	amendment		A written description of a change(s) to, or formal clarification of, a protocol.	Amendment
C142388	American National Standards Institute (ANSI)		Founded in 1918, ANSI itself does not develop standards. ANSI's roles include serving as the coordinator for US voluntary standards efforts, acting as the approval body to recognize documents developed by other national organizations as American National Standards, acting as the US representative in international and regional standards efforts, and serving as a clearinghouse for national and international standards development information. [HL7]	American National Standards Institute

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C142389	analysis dataset		An organized collection of data or information with a common theme arranged in rows and columns and represented as a single file; comparable to a database table. NOTE: standardizing analysis datasets is intended to make review and assessment of analysis more consistent [ADaM].	Analysis Dataset
C142390	analysis set		A set of subjects whose data are to be included in the main analyses. This should be defined in the statistical section of the protocol. NOTE: There are a number of potential analysis sets, including, for example, the set based upon the intent-to-treat principle. [ICH E9]	Analysis Set of Subjects
C142391	analysis variables		Variables used to test the statistical hypotheses identified in the protocol and analysis plan; variables to be analyzed. [PR Project] See also variable.	Analysis Variable
C142436	anchor		Designation for a planned activity, often marking the transition between epochs or elements of a clinical study plan (e.g., "FPFV-first patient first visit").	Clinical Study Anchor
C142392	anonymization		The process of protecting privacy that removes the association between the identifying data and the data subject. In anonymized data, the patient cannot be identified by the recipient of the information. [ISO TS 25237:2008; TransCelerate Protection of Personal Data in Clinical Documents - A Model Approach]	Anonymization
C156629	anticipated adverse event		Other adverse events that are not study endpoints and are not "expected" (i.e., because they are not in the investigator's brochure) that that can be anticipated to occur with some frequency during the course of the trial, regardless of drug exposure, depending on the patient population and disease under study. NOTE: Examples of such "anticipated" events include known consequences of the underlying disease or condition under investigation, events anticipated from any background regimen, or re-emergence or worsening of a condition relative to pretreatment baseline. [after FDA, Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies]	Anticipated Adverse Event
C142393	applet		A small application, typically downloaded from a server.	Applet
C142394	applicable regulatory requirement(s)		Any law(s) or regulation(s) addressing the conduct of clinical trials of investigational products. [ICH E6(R2) Glossary, 1.4]	Applicable Regulatory Requirement
C142551	approvable letter		An official communication from FDA to an NDA/ BLA sponsor that lists issues to be resolved before an approval can be issued. [Modified from 21 CFR 314.3; Guidance to industry and FDA staff (10/08/2003)]	FDA Approvable Letter
C70800	approval (in relation to Institutional Review Boards)		The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements. [ICH E6]	Institutional Review Board Approval
C70799	approval letter		An official communication from FDA to inform an applicant of a decision to allow commercial marketing consistent with conditions of approval. [Modified from 21 CFR 314.3; Guidance to industry and FDA staff (10/08/2003)]	Approval Document
C142684	arm		A planned sequence of elements, typically equivalent to a treatment group. [SDTM] See element.	Sequence Arm
C25217	assessment		A measurement, evaluation, or judgment for a study variable pertaining to the status of a subject. NOTE: Assessments are usually measured at a certain time, and usually are not compounded significantly by combining several simultaneous measurements to form a derived assessment (e.g., BMI) or a result of statistical analysis. The term assessment is intended to invoke some degree of evaluation or judgment concerning subject status. Refer to COA glossary of terms. See also variable, outcome, endpoint. [After Clinical Outcome Assessment (COA) Glossary of Terms FDA FDA eCOA Glossary]	Assessment
C25358	attributable		A quality by which records and data can be traced back to the subject to whom they pertain, as well as to those persons who have acted on the records.	Attribution
C62618	attribute (n)		In data modeling, refers to specific items of data that can be collected for a class.	Object Attribute
C45269	audit		A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). [ICH E6 Glossary]	Audit

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C115469	audit certificate		Document that certifies that an audit has taken place (at an investigative site, CRO, or clinical research department of a pharmaceutical company). [ICH E6 Glossary]	Audit Certificate
C142395	audit report		A written evaluation by the auditor of the results of the audit. [Modified from ICH E6 Glossary]	Audit Report
C142396	audit trail		A process that captures details such as additions, deletions, or alterations of information in an electronic record without obliterating the original record. An audit trail facilitates the reconstruction of the history of such actions relating to the electronic record. [after ICH E6, CSUICI]	Audit Trail
C156618	authorised auxiliary medicinal product		A medicinal product that is currently authorised for marketing in a country or region, that is related to the specific needs of the clinical trial as described in the protocol, but not as an investigational medicinal product, regardless of labelling of the auxiliary medicinal product. [after EU CTR]	Authorized Auxiliary Medicinal Product
C156617	authorised investigational medicinal product		A medicinal product that is currently authorised for marketing in a country or region and used as an investigational medicinal product, irrespective of changes to the labelling of the medicinal product. [after EU CTR]	Authorized Investigational Medicinal Product
C41192	authorization		The process of giving someone permission to do or have something. In multi-user computer systems, a system administrator defines for the system which users are allowed access to the system and what privileges of use are permitted. [HL7 EHR-S FM Glossary of Terms, 2010].	Authorization
C156473	auxiliary medicinal product		A medicinal product that is related to the specific needs of the clinical trial as described in the protocol, but not as an investigational medicinal product. NOTE: Auxiliary medicinal products may be authorised for marketing in a country or region or non-authorised. [after EU-CTR]	Auxiliary Medicinal Product
C142397	back translation (natural language)		The process of translating a document that was translated from one language to another back to the original language. Used to ensure that consent forms, surveys, and other clinical trial documents will be clear and accurate in the translated form.	Back Translation
C142649	background material		Information pertinent to the understanding of a protocol. NOTE: Examples include investigator brochure, literature review, history, rationale, or other documentation that places a study in context or presents critical features. [PR Project]	Protocol Background Material
C142398	balanced study		Trial in which a particular type of subject is equally represented in each study group.	Balanced Study
C142399	bandwidth		An indicator of the throughput (speed) of data flow on a transmission path; the width of the range of frequencies on which a transmission medium carries electronic signals. All digital and analog signal channels have a bandwidth.	Bandwidth
C142400	baseline assessment		Assessment of subjects as they enter a trial and before they receive any treatment.	Baseline Assessment
C142401	baseline characteristics		Demographic, clinical, and other data collected for each participant at the beginning of the trial before the intervention is administered. NOTE: Randomized, controlled trials aim to compare groups of participants that differ only with respect to the intervention (treatment). although proper random assignment prevents selection bias, it does not guarantee that the groups are equivalent at baseline. any differences in baseline characteristics are, however, the result of chance rather than bias. The study groups should be compared at baseline for important demographic and clinical characteristics. Baseline data may be especially valuable when the outcome measure can also be measured at the start of the trial. [CONSORT statement]	Baseline Characteristics
C142402	baseline imbalance		A systematic error in creating intervention groups, such that they differ with respect to prognosis. That is, the groups differ in measured or unmeasured baseline characteristics because of the way participants were selected or assigned. NOTE: also used to mean that the participants are not representative of the population of all possible participants. [ICH E9]	Baseline Imbalance
C142403	Bayesian approaches		Approaches to data analysis that provide a posterior probability distribution for some parameter (e.g., treatment effect), derived from the observed data and a prior probability distribution for the parameter. The posterior distribution is then used as the basis for statistical inference. [ICH E9 Glossary]	Bayesian Approach
C142404	Bayesian statistics		Statistical approach named for Thomas Bayes (1701-1761) that has among its features giving a subjective interpretation to probability, accepting the idea that it is possible to talk about the probability of hypotheses being true and of parameters having particular values.	Bayesian Statistics

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C142405	beta error		Probability of showing no significant difference when a true difference exists; a false acceptance of the null hypothesis. See also Type 2 error. [AMA Manual of style]	Beta Error
C28232	bias		Bias refers to defects in study design, measurement, analysis or interpretation such that they cause a result to depart from the true value in a consistent direction. [after AMA Manual of style, ICH E9, CONSORT Statement]	Bias
C16341	bioanalytical assays		Methods for quantitative measurement of a drug, drug metabolites, or chemicals in biological fluids.	Bioassay
C70913	bioavailability		Rate and extent to which a drug is absorbed or is otherwise available to the treatment site in the body.	Bioavailability
C71763	bioequivalence		Scientific basis on which drugs with the same active ingredient(s) are compared. NOTE: To be considered bioequivalent, the bioavailability of two products must not differ significantly when the two products are given in studies at the same dosage under similar conditions.	Bioequivalence
C71778	Biologics licensing application (BLA)		Biologics licensing application (BLA). an application to FDA for a license to market a new biologic product in the United states.	Biologics License Application
C16342	biomarker	biological marker	A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how an individual feels, functions, or survives. Categories of biomarkers include: susceptibility/risk biomarker; diagnostic biomarker; monitoring biomarker; prognostic biomarker; predictive biomarker; safety biomarker; pharmacodynamic/response biomarker. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Biomarker
C142406	biometric signature		A signature based on the verification of an individual's identity, based on measurement of the individual's physical feature(s) or repeatable action(s), where those features and/or actions are both unique to that individual, and measureable [21 CFR 11]	Biometric Signature
C156644	biosimilar		A biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components. This requires that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product (see section 351(i)(2) of the PHS Act). [after FDA, Guidance for Industry: Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product]	Biosimilar
C16347	biostatistics		Branch of statistics applied to the analysis of biological phenomena.	Biostatistics
C142407	blind review		Checking and assessing data prior to breaking the blind, for the purpose of finalizing the planned analysis. [Modified ICH E9]	Blind Review
C142408	blinded (masked) medications		Products that appear identical in size, shape, color, flavor, and other attributes to make it very difficult for subjects and investigators (or anyone assessing the outcome) to determine which medication is being administered.	Blinded Medication
C70840	blinded study		A study in which the subject, the investigator, or anyone assessing the outcome is unaware of the treatment assignment(s). NOTE: Blinding is used to reduce the potential for bias. [Modified ICH E6 Glossary] See also blinding/masking, double-blind study, single-blind study, triple-blind study; contrast with open-label or unblinded study.	Blinded Clinical Study
C49068	blinding	masking	A procedure to limit bias by preventing subjects and/ or study personnel from identifying which treatments or procedures are administered, or from learning the results of tests and measures undertaken as part of a clinical investigation. NOTE: Masking, while often used synonymously with blinding, usually denotes concealing the specific study intervention used. [After ICH E6 (R2) Glossary, 1.10]. The term masking is often preferred to blinding in the field of ophthalmology. [from AMA Manual of Style]. See also double-blind study, single-blind study, triple-blind study. Contrast with open-label and/or unblinded study.	Blinded
C142701	branch		Point within a study design where there is an allocation of subject subsets to particular procedures or treatment groups.	Study Branch
C80012	browser		Computer program that runs on the user's desktop computer and is used to navigate the World Wide Web. See also web browser.	HTML Browser
C63626	cache		Storage area on a computer's hard drive where the browser stores (for a limited time) web pages and/or graphic elements.	Memory Cache

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C142409	carry-over effect		Effects of treatment that persist after treatment has been stopped, sometimes beyond the time of a medication's known biological activity.	Carry-over Effect
C142588	case history		An adequate and accurate record prepared and maintained by an investigator that records all observations and other data pertinent to the investigation of each individual administered the investigational drug (device or other therapy) or employed as a control in the investigation. NOTE: Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study. [21 CFR 312.62(b)]	Investigational Subject Case History
C40988	case report form (CRF)	case record form	A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor for each trial subject. NOTE: In common usage, CRF can refer to either a CRF page, which denotes a group of one or more data items, linked together for collection and display, or a casebook, which includes the entire group of CRF pages on which a set of clinical study observations can be or have been collected by completion of such CRF pages for a subject in a clinical study. See also CRF (paper), eCRF. [ICH E6 Glossary, FDA Final Guidance on eSource].	Case Report Form
C142411	case report tabulations (CRT)		In a paper submission, listings of data that may be organized by domain (type of data) or by subject. See also eCRT.	Case Report Tabulation
C142412	categorical data		Data evaluated by sorting values (for example, severe, moderate, and mild) into various categories.	Categorical Data
C142413	causality assessment		An evaluation performed by a medical professional concerning the likelihood that a therapy or product under study caused or contributed to an adverse event.	Causality Assessment
C142415	CDISC SHARE		A global, accessible, electronic library, which, through advanced technology, enables precise and standardized data element definitions that can be used within applications and across studies to improve biomedical research and its link with healthcare. In the first iteration, CDISC SHARE will contain the existing CDISC standards, such as CDASH and SDTM, providing machine-readable elements (variables) within those standards. This will allow a range of applications used within organizations to automatically access those definitions. [CDISC]	CDISC Shared Health And Research Electronic Library
C142416	CDISC Standard (The)		CDISC term for a proposed uniform CDISC standard intended to address the full life-cycle of a clinical trial including protocol representation, capture of source data, submission, and archiving using a set of fully integrated and consistent models, terms, and controlled vocabularies derived from the current set of CDISC standards.	CDISC Standard
C142417	certified copy		A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original. [ICH E6 (R2)]	Certified Copy
C142418	certified IRB professional (CIP)		Persons certified to participate on an institutional review board, who satisfy the educational and employment requirements and pass an examination conducted by the applied Research ethics national association (aRena), the membership division of Public Responsibility in Medicine and Research (PRiM&R).	Certified IRB Professional
C156647	CHI (consolidated health informatics)		CHI began as an eGov initiative to establish a portfolio of existing health information interoperability standards (health vocabulary and messaging) enabling all agencies in the federal health enterprise to "speak the same language" based on common enterprise-wide business and information technology architectures. CHI is currently managed under the Office of the National Coordinator for Health Informational Technology's (ONC) Federal Health Architecture (FHA) Program Management Office. Ref: The United States Health Information Knowledgebase [USHIK]. [HITSP]	Consolidated Health Informatics
C41106	class		A definition of objects with properties (attributes, methods, relationships) that all objects in the class have in common. [HL7, 2001] in data modeling, a class defines a set of objects that share the same attributes, relationships, and semantics. A class is usually an entity that represents a person, place, or thing.	Object Class
C142419	clean database		A set of reviewed data in which errors have been resolved to meet QA requirements for error rate and in which measurements and other values are provided in acceptable units; database that is ready to be locked. See also database lock, clean file.	Clean Database
C142420	clean file		When all data cleaning is completed and database is ready for quality review and unblinding.	Clean File

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C142421	client		A program that makes a service request of another program, usually running on a server, that fulfills the request. Web browsers (such as Firefox and Microsoft explorer) are clients that request HTML files from web servers.	Client Computer
C142422	clinical benefit		A therapeutic intervention may be said to confer clinical benefit if it prolongs life, improves function, and/or improves the way a subject feels.	Clinical Benefit
C142423	clinical clarification		A query resolution received from the sponsor staff (medical monitors, DSMB monitoring board, etc.). See also self-evident change.	Clinical Clarification
C15783	clinical data		Data pertaining to the medical well-being or status of a patient. Category also includes clinical reports and individual patient data (IPD) as defined in the EMA Policy 0070 Implementation Guide. [http://www.ema.eoropa.eu/docs/en_GB/document_library/REPORT/2014/10/WC500174378.PDF]	Clinical Data
C142424	clinical development plan		A document that describes the collection of clinical studies that are to be performed in sequence, or in parallel, with a particular active substance, device, procedure, or treatment strategy, typically with the intention of submitting them as part of an application for a marketing authorization. NOTE: The plan should have appropriate decision points and allow modification as knowledge accumulates. [from ICH E9] See also development plan.	Clinical Development Plan
C142425	clinical document		A documentation of clinical observations and services. NOTE: an electronic document should incorporate the following characteristics: persistence, stewardship, potential for authentication, wholeness, and human readability. [SPL]	Clinical Document
C142426	clinical document architecture		Specification for the structure and semantics of "clinical documents" for the purpose of exchange. [HL7; SPL]	Clinical Document Architecture
C39547	clinical efficacy		Power or capacity to produce a desired effect (i.e., appropriate pharmacological activity in a specified indication) in humans. [SQA]	Treatment Efficacy
C142427	clinical encounter		Contact between subject/patient and healthcare practitioner/researcher, during which an assessment or activity is performed. Contact may be physical or virtual. [CDISC]	Clinical Encounter
C70755	clinical hold (of a clinical trial)		An order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. NOTE: The clinical hold order may apply to one or more of the investigations covered by an IND. [21 CFR 312.42]	Study on Hold
C142430	clinical investigation		Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. Considered synonymous with clinical research by FDA. See clinical study, clinical trial. [FDA Science & Research]	Clinical Investigation
C142378	clinical outcome assessment (COA)		Any assessment that may be influenced by human choices, judgment, or motivation and may support or refute treatment benefit. NOTE: Unlike biomarkers that rely completely on an automated process or algorithm, COAs reflect interpretation of reporting from a patient, a clinician, or an observer. There are four types of COAs. See also patient-reported outcome (PRO), clinician-reported outcome (ClinRO), observer-reported outcome (ObsRO), and performance outcome (PerfO). [FDA Clinical Outcome Assessment (COA) Glossary]	Clinical Outcome Assessment
C142552	clinical outcome assessment (COA) qualification		A formal conclusion by FDA that, within the stated context of use, the results of the COA measurement can be relied upon to have a specific interpretation and application. NOTE: For qualified COAs, FDA permits drug developers to use the COA in the qualified context in IND and NDA/BLA submissions without requesting that the relevant CDER review group reconsider and reconfirm the suitability of the COA. [FDA Clinical Outcome Assessment (COA) Glossary]	FDA Clinical Outcome Assessment Qualification
C16975	clinical pharmacology		Science that deals with the characteristics, effects, properties, reactions, and uses of drugs, particularly their therapeutic value in humans, including their toxicology, safety, pharmacodynamics, and pharmacokinetics (ADME).	Clinical Pharmacology
C25320	clinical protocol		See protocol.	Clinical Study Protocol
C142435	clinical research and development		The testing of a drug compound in humans primarily done to determine its safety and pharmacological effectiveness. Clinical development is done in phases, which progress from very tightly controlled dosing of a small number of subjects to less tightly controlled studies involving large numbers of patients. [SQA]	Clinical Research and Development

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C25465	clinical research associate (CRA)		Person employed by a sponsor or by a contract research organization acting on a sponsor's behalf, who monitors the progress of investigator sites participating in a clinical study. At some sites (primarily in academic settings), clinical research coordinators are called CRAs.	Clinical Research Associate
C51811	clinical research coordinator (CRC)	clinical coordinator;research coordinator;study coordinator;trial coordinator	Person who handles most of the administrative responsibilities of a clinical trial on behalf of a site investigator, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor's visit. Synonyms: trial coordinator, study coordinator, research coordinator, clinical coordinator	Clinical Coordinator
C70668	clinical research subject		A person who is enrolled into a clinical study or trial. See also study and trial.	Clinical Trial Subject
C82562	clinical significance		Change in a subject's clinical condition regarded as important whether or not due to the test intervention. NOTE: some statistically significant changes (in blood tests, for example) have no clinical significance. The criterion or criteria for clinical significance should be stated in the protocol. The term "clinical significance" is not advisable unless operationally defined.	Clinical Significance
C15206	clinical study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [ClinicalTrials.gov] See also clinical trial.	Clinical Study
C142439	clinical study (trial) report		A written description of a study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analysis are fully integrated into a single report. NOTE: For further information, see the ICH Guideline for Structure and Content of Clinical Study Reports. [ICH E6 Glossary]	Clinical Study Report
C142437	clinical study data element		A single observation associated with a subject in a clinical study. A data element in an eCRF represents the smallest unit of observation captured for a subject in a clinical investigation. NOTE: Examples include birth date, white blood cell count, pain severity measure, and other clinical observations made and documented during a study. Data element identifiers should be attached to each data element as it is entered or transmitted by the originator into the eCRF. See also eCRF, data element identifier, data originator, item. [After FDA Guidance for Industry Electronic Source Data in Clinical Investigations , Body text and Glossary]	Clinical Study Data Element
C71104	clinical trial		A research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device). NOTE: NIH Office of Science Policy further specifies that a clinical trial is a type of research study that prospectively assigns subjects to interventions, and the EU clinical trial regulations set forth 3 specific conditions, any one of which qualifies a study as a clinical trial. These conditions include applying diagnostic or monitoring procedures not used in normal clinical practice to subjects. [after ICH E6 [R2], EU CTR 2014] See also clinical study, clinical investigation.	Clinical Trial
C142440	clinical trial authorization		Authorization granted by a Medicines Regulatory Agency to conduct a clinical trial in a jurisdiction. NOTE: If an ethical committee allows a trial to proceed it is called an approval to proceed. [After ISO 11615:2017, 3.1.12]	Clinical Trial Authorization
C142441	clinical trial data		Data collected in the course of a clinical trial. See also clinical trial information.	Clinical Trial Data
C142446	clinical trial exemption (CTX)		A scheme that allows sponsors to apply for approval for each clinical study in turn, submitting supporting data to the Medicines Control Agency (MCA), which approves or rejects the application (generally within 35 working days). NOTE: Approval means that the company is exempt from the requirement to hold a clinical trial certificate (CTC). [UK]	Clinical Trial Exemption
C142447	clinical trial information		Data collected in the course of a clinical trial or documentation related to the integrity or administration of that data. A superset of clinical trial data.	Clinical Trial Information
C142449	clinical trial materials		Complete set of supplies provided to an investigator by the trial sponsor.	Clinical Trial Material

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C142452	clinical trial registry		A web-based publicly accessible platform for providing structured information about clinical trials. NOTE: Such registries help patients, family members, health care professionals, researchers, and the public identify studies in which they might participate. Some registries include clinical trial results. Examples include: EU Clinical Trials Register (EU CTR), for studies in the EU or the EEA after 1 May 2001; ClinicalTrials.gov, a web-based resource from the National Library of Medicine (NLM) in the US. [After International Committee of Medical Journal Editors]	Clinical Trial Registry
C156620	clinical trial results registry		A web-based publicly accessible platform for providing structured summary results information about clinical trials. See also clinical trial registry.	Clinical Trial Results Registry
C142453	clinician-reported outcome (ClinRO)		A type of clinical outcome assessment. A measurement based on a report that comes from a trained health-care professional after observation of a patient's health condition. [After BEST Resource]	Clinician-reported Outcome
C70918	Cmax		Used in pharmacokinetics and bioequivalence to indicate maximum plasma concentration for a drug.	Cmax
C142454	codelist		Finite list of codes and their meanings that represent the only allowed values for a data item. See also controlled vocabulary. A codelist is one type of controlled vocabulary.	Codelist
C80216	coding		In clinical trials, the process of assigning data to categories for analysis NOTE: Adverse events, for example, may be coded using MedDRA.	Encode
C142455	cognitive debriefing		A qualitative research tool used to determine whether concepts and items are understood by patients in the same way that PRO instrument developers intend. NOTE: Cognitive debriefing interviews involve incorporating follow-up questions in a field test interview to gain better understanding of how patients interpret questions asked of them and to collect and consider all concepts elicited by an item. [from PRO Draft Guidance Glossary]	Cognitive Debriefing
C61512	cohort		A group of individuals who share a common exposure, experience or characteristic or a group of individuals followed-up or traced over time in a cohort study. [AMA Manual of Style] See also cohort study.	Cohort
C15208	cohort study		Study of a group of individuals, some of whom are exposed to a variable of interest, in which subjects are followed over time. Cohort studies can be prospective or retrospective. [AMA Manual of Style] See also prospective study.	Cohort Study
C54696	combination product		1. A product comprising two or more individual products. 2. Two or more separate products packaged together in a single package or as a unit. 3. A product that is packaged separately but is used only with another product. [Modified from SPL Glossary]	Combination Product
C142456	commercially confidential information (CCI)		Any information contained in clinical reports or other documents that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the company (the Marketing Application Holder) and cause harm (if disclosed). [After EMA Policy 0070 implementation Guide]	Commercially Confidential Information
C19984	common data element (CDE)		A structured item characterized by a stem and response options together with a history of usage that can be standardized for research purposes across studies conducted by and for NIH. NOTE: The mark up or tagging facilitates document indexing, search and retrieval, and provides standard conventions for insertion of codes. [NCI, CaBIG]. See also item, item (PRO), stem, data element, data element identifier.	Common Data Element
C142575	Common Technical Document		A format agreed upon by ICH to organize applications to regulatory authorities for registration of pharmaceuticals for human use. [ICH] See also eCTD.	ICH Common Technical Document
C142457	comparative study		One in which the investigative drug is compared against another product, either active drug or placebo.	Comparative Study
C142458	comparator (product)		An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial. [ICH E6 Glossary] See also control.	Comparator
C142544	Competent Authority (CA)		The regulatory body charged with monitoring compliance with the national statutes and regulations of European Member States.	European Union Competent Authority
C142734	compliance (in relation to trials)		Adherence to trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory requirements. [Modified ICH E6 Glossary]	Trial Compliance
C42608	computer application	application software	Software designed to fill specific needs of a user; for example, software for navigation, project management, or process control.	Computer Application

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C45728	concept		Discrete notion having a single meaning. In a controlled vocabulary a concept is mapped to one or more of the words that convey its meaning.	Concept
C142433	concept of interest		In the context of clinical outcomes, the thing measured by a COA assessment (e.g., pain intensity). [After Clinical Outcome Assessment (COA) Glossary of Terms FDA FDA eCOA Glossary]	Clinical Outcomes Assessment Concept of Interest
C156640	concerned member state (CMS)		A classification of a Member States in the Mutual Recognition Procedure (MRP) in the European authorization route resulting in a mutually recognized product. In the Mutual Recognition Procedure, one or more Member States that is a CMS is asked to mutually recognize the Market Authorization of the Reference Member State (RMS). [After Heads of Medicines Agencies (HMA) website http://www.hma.eu/medicinesapprovalsystem.html] See also Mutual Recognition Procedure (MRP) and Reference Member State (RMS).	Concerned Member State
C53324	confidence interval (CI)		A measure of the precision of an estimated value. The interval represents the range of values, consistent with the data, that is believed to encompass the "true" value with high probability (usually 95%). The confidence interval is expressed in the same units as the estimate. Wider intervals indicate lower precision; narrow intervals, greater precision. [CONSORT Statement]	Confidence Interval
C16466	confidentiality		Prevention of disclosure to other than authorized individuals of a sponsor's proprietary information or of a subject's identity. [ICH E6 Glossary]	Confidentiality
C142460	confirmatory trial		Phase 3 trial during which the previously revealed actions of a therapeutic intervention are confirmed. NOTE: Procedures in confirmatory trials should be set firmly in advance. Compare to exploratory trial.	Confirmatory Trial
C142461	conformity assessment		The process by which compliance with the EMA's essential requirements is assessed. See also Notified Body.	Conformity Assessment
C16468	consent form	informed consent form	Document used during the informed consent process that is the basis for explaining to potential subjects the risks and potential benefits of a study and the rights and responsibilities of the parties involved. NOTE: The informed consent document provides a summary of a clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation, etc.) and explains an individual's rights as a subject. it is designed to begin the informed consent process, which consists of conversations between the subject and the research team. if the individual then decides to enter the trial, s/he gives her/his official consent by signing the document. See also informed consent.	Consent Form
C156633	construct validation (COA)		Establishing, using quantitative methods, the extent to which the relationships among items, domains, and concepts of a clinical outcome assessment conform to a priori hypotheses concerning logical relationships that should exist with other measures or characteristics of patients and patient groups. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Clinical Outcome Assessment Construct Validation
C142462	consumer safety officer (CSO)		FDA official who coordinates the review process of various applications.	Consumer Safety Officer
C156632	content validation (COA)		Establishing from qualitative research the extent to which the clinical outcome assessment instrument measures the concept of interest including evidence that the items and domains of an instrument are appropriate and comprehensive relative to its intended measurement concept, population, and use. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Clinical Outcome Assessment Content Validation
C78690	content validity		The extent to which a variable (for example, a rating scale) measures what it is supposed to measure. [ICH E9 Glossary] evidence from qualitative research demonstrating that the instrument measures the concept of interest, including evidence that the items and domains of an instrument are appropriate and comprehensive, relative to its intended measurement concept, population, and use. NOTE: Testing other measurement properties will not replace or rectify problems with content validity. [FDA Final PRO Guidance]	Content Validity
C142434	context of use		In the context of clinical outcomes, a comprehensive statement that fully and clearly describes and justifies the way a COA is to be used and the drug development-related purpose of the use. NOTE: The context of use defines the boundaries within which the available data adequately justify use of the COA and describes important criteria regarding the circumstances under which the COA is qualified. [FDA Clinical Outcome Assessment (COA) Glossary]	Clinical Outcomes Assessment Context of Use
C142463	contingent subject trial contact		Planned response to an anticipated but conditional event in a clinical trial. [CDISC Trial Design Project]	Contingent Subject Trial Contact

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C115464	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 Glossary]	Contractual Agreement
C54148	contract research organization (CRO)		A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH E6 Glossary]	Contract Research Organization
C142703	control	comparator	Comparator against which the study treatment is evaluated [e.g., concurrent (placebo, no treatment, dose-response, active), and external (historical, published literature)]. [After ICH E10]	Study Control
C142464	control (of electronic records)		To prepare and maintain case histories and other records for regulated clinical investigations. NOTE: Control is often used as a casual synonym for the terms in 21 CFR 312.62 requiring investigative sites to prepare, maintain, and retain adequate and accurate case histories. [After 1. 21 CFR 11; 2. CSUCT]	Control of Electronic Records
C28143	control group		The group of subjects in a controlled study that receives no treatment, a standard treatment, or a placebo. [21 CFR 314.126] See also controls.	Control Group
C142532	control of electronic records		Processes or operations intended to ensure authenticity, integrity, and confidentiality of electronic records. NOTE: The protocol incorporates scientific rationale for selection of comparator and describes how the comparator serves as a reference point for the evaluation. SDTM provides a codelist for type of control. [After 21 CFR 11; CSUCT]	Electronic Records Control
C28279	controlled study		A study in which a test article is compared with a treatment that has known effects. The control group may receive no treatment, active treatment, placebo, or dose comparison concurrent control. NOTE: For further information on "adequate and well-controlled study" see 21 CFR 314.126.	Controlled Study
C48697	controlled vocabulary	controlled terminology	A finite set of values that represent the only allowed values for a data item. These values may be codes, text, or numeric. See also codelist.	Controlled Vocabulary
C142465	coordinating committee		A committee that a sponsor may organize to coordinate the conduct of a multicenter trial. [ICH E6]	Coordinating Committee
C51818	coordinating investigator		An investigator assigned the responsibility for the coordination of investigators at different centers participating in a multicenter trial. [ICH E6]	Coordinating Investigator
C48834	correlation		The degree to which two or more variables are related. Typically the linear relationship is measured with either Pearson's correlation or spearman's Rho. NOTE: Correlation does not necessarily mean causation. [after hyperstat online Glossary; ADaM]	Correlation
C142645	covariate (prognostic)		Factor or condition that influences outcome of a trial. [ADaM]	Prognostic Covariate
C142625	CRF (paper)		Case report form in which the data items are linked by the physical properties of paper to particular pages. NOTE: Data are captured manually and any comments, notes, and signatures are also linked to those data items by writing or typescript on the paper pages. See also eCRF, case report form.	Paper Case Report Form
C142410	CRF data		Subset of clinical trial data that are entered into fields on a CRF.	Case Report Form Data
C156634	criterion validation (COA)		Establishing the extent to which the scores of a clinical outcome assessment instrument are related to a known gold standard measure of the same concept. For most COAs, criterion validity cannot be measured because there is no gold standard. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Clinical Outcome Assessment Criterion Validation
C82637	crossover trial		A trial design for which subjects function as their own control and are assigned to receive investigational product and controls in an order determined by randomizations, typically with a washout period between the two products. [Center for the advancement of Clinical Research; ADaM]	Crossover Study
C49704	CTCAE (Common Terminology Criterion for Adverse Events)		Standard terminology developed to report adverse events occurring in cancer clinical trials. CTCAE are used in study adverse event summaries and Investigational New Drug (IND) reports to the Food and Drug Administration. The CTCAE contain a grading scale for each adverse event term representing the severity of the event. (NCI)	Common Terminology Criteria for Adverse Events
C70818	CUI (common unique identifier)		A code used in the Enterprise Vocabulary System (EVS) to link a particular concept across one or more terms.	Concept Unique Identifier
C54631	curriculum vitae (CV)		Document that outlines a person's educational and professional history.	Curriculum Vitae

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C25474	data		Representations of facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by humans or by automated means. [FDA]	Data
C142469	data acquisition		Capture of data into a structured, computerized format without a human-to-computer interface (i.e., from another measuring instrument or computerized source). Contrast with data entry, electronic data capture.	Data Acquisition
C94204	data and safety monitoring board (DSMB)		See data monitoring committee.	Data and Safety Monitoring Board
C142470	data capture		See data entry.	Data Capture
C142471	data clarification		Answer supplied by the investigator in response to a query. NOTE: The investigator may supply a new data point value to replace the initial value or a confirmation of the queried data point.	Data Clarification
C115521	data clarification form		A form used to query an investigator and collect feedback to resolve questions regarding data.	Data Clarification Form
C103159	data collection		In the context of clinical research, accessing and recording information that provides source data for analysis and interpretation See data entry and data capture. [CDISC]	Data Collection
C142472	data collection instrument		A substrate or tool (either electronic or paper) used to record, transcribe, or collect clinical data. [PR Project]	Data Collection Instrument
C41002	data element		Smallest unit of information in a transaction. [From body and glossary of FDA Final Guidance on eSource] See also eXtensible markup language (XML) data element, common data element, clinical study data element.	Data Element
C142474	data element identifier		Information associated with a data element that includes the origin of the data element, the date and time of entry, and the identification number of the study subject to whom the data element applies. NOTE: Data element identifiers should be attached to each data element as it is entered or transmitted by the originator into the eCRF. [From body and glossary of FDA Final Guidance eSource]	Data Element Identifier
C142475	data encryption standard (DES)		A FIPS approved cryptographic algorithm for encrypting (enciphering) and decrypting (deciphering) binary coded information. Encrypting data converts it to an unintelligible form called cipher. Decrypting cipher converts the data back to its original form called plaintext. The standard specifies both enciphering and deciphering operations, which are based on a 64 bit binary number called a key. Unauthorized recipients of the cipher who know the algorithm but do not have the correct key cannot derive the original data algorithmically. NOTE: Data that are considered sensitive by the responsible authority or data that represent a high value should be cryptographically protected if vulnerable to unauthorized disclosure or undetected modification during transmission or while in storage. [from Federal Information Processing Standards (FIPS) Publication 46-2]	Data Encryption Standard
C142379	data entry		Human input of data into a structured, computerized format using an interface such as a keyboard, pen-based tablet, or voice recognition. NOTE: Although data capture is often used synonymously, capture implies direct entry of original source data into an electronic record rather than transcription (entry) from paper source. Contrast with data acquisition, electronic data capture; direct entry. See data collection.	Data Entry
C142476	data integrity		A condition of data reflecting the degree to which the data are complete, consistent, accurate, trustworthy, and reliable at any given time as well as consistently so maintained throughout the data life cycle. NOTE: The data should be collected and maintained in a secure manner, so that they are Attributable, Legible, Contemporaneously recorded, Original (or a true copy) and Accurate (ALCOA). Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices. (After MHRA Guidance on "GxP data integrity") See also ALCOA, ALCOA+. Compare to data quality.	Data Integrity
C142477	data integrity verification		Process of manually supervised verification of data for internal consistency.	Data Integrity Verification
C142478	data interchange		Transfer of information between two or more parties, which maintains the integrity of the contents of the data for the purpose intended. See also interoperability.	Data Interchange
C142479	data item		A named component of a data element. Usually the smallest component [ANSI]. See also data model, data element.	Data Item
C142483	data listing		Set of observations organized by domain.	Data Listing

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C18086	data management		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.	Data Management
C142484	data management conventions		Procedures and policies for data management (e.g., documented procedure(s) for resolving self-evident changes). [ICH E6] See self-evident change.	Data Management Convention
C142487	data model		Unambiguous, formally stated, expression of items, the relationship among items, and the structure of the data in a certain problem area or context of use. A data model uses symbolic conventions agreed to represent content so that content does not lose its intended meaning when communicated.	Data Model
C142488	data monitoring		Process by which clinical data are examined for completeness, consistency, and accuracy.	Data Monitoring
C142489	data monitoring committee (DMC)		Group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an ongoing clinical trial. The DMC advises the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial. NOTE: A DMC can recommend stopping a trial if it finds toxicities or if treatment is proved beneficial. [After FDA guidance on establishment and operation of clinical trial data monitoring committees]	Data Monitoring Committee
C16493	data origin		Source of information collected in the course of a clinical trial, specifically used to differentiate between data as collected versus data that are derived or calculated. NOTE: In CDISC, a metadata attribute defined for each dataset variable in the Define.xml document of an SDTM submission that refers to the source of a variable (e.g., CRF, derived, sponsor defined, PRO, etc.). See also data element originator.	Data Source
C142490	data originator		Metadata characterizing the entity creating a data element in an eCRF for a clinical investigation. NOTE: Per FDA Final Guidance on eSource, "Each data element is associated with an origination type that identifies the source of its capture in the eCRF. This could be a person, a computer system, a device, or an instrument that is authorized to enter, change, or transmit data elements into the eCRF (also sometimes known as an author)." See also data element, data element originator, origin. [CDISC, Note is from FDA Final Guidance on eSource]	Data Originator
C142491	data quality		A dimension of data contributing its trustworthiness and pertaining to accuracy, sensitivity, validity, and suitability to purpose. Key elements of data quality include attribution, legibility (decipherable, unambiguous), contemporaneousness, originality (i.e., not duplicated), accuracy, precision, completeness, consistency (logical, not out of range), and those who have modified the data. NOTE: Scientists may reasonably trust data that are accurate (high quality) that have also been reviewed by investigators and protected from unauthorized alteration (high integrity). See also ALCOA, data integrity.	Data Quality
C142492	data security		Degree to which data are protected from the risk of accidental or malicious alteration or destruction and from unauthorized access or disclosure. [FDA]	Data Security
C142493	data selection criteria		The rules by which particular data are selected and/ or transferred between the point of care and the patient record; subsequently, from the patient record to the database; and from database to inclusion in sub-population analyses.	Data Selection Criteria
C142494	data storage		To maintain data by placing the data, or a copy of the data, onto an electronically accessible device for preservation (either in plain-text or encrypted format). [HL7 eHR-s FM Glossary of Terms, 2010].	Data Storage
C142495	data subject		An individual who is the subject of personal data, persons to whom data refers. [ISO/TS 25237:2008]	Data Subject
C43582	data transformations		Algorithmic operations on data or data sets to achieve a meaningful set of derived data for analysis. [ADaM] See also derived variable.	Data Transformation
C42645	data type		Data types define the structural format of the data carried in the attribute and influence the set of allowable values an attribute may assume. [HL7]	Data Type
C142500	data validation		1. Checking data for correctness and/or compliance with applicable standards, rules, and conventions. 2. Process used to determine if data are inaccurate, incomplete, or unreasonable. The process may include format checks, completeness checks, check key tests, reasonableness checks, and limit checks. [1. FDA. 2. ISO]	Data Validation
C15426	database		A collection of data or information, typically organized for ease and speed of search and retrieval.	Database

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C142503	database lock		Action taken to prevent further changes to a clinical trial database or any equivalent clinical data storage system. NOTE: Locking of a database is done after review, query resolution, and a determination has been made that the database is ready for analysis.	Database Lock
C47824	dataset		A collection of structured data in a single file. [CDISC, ODM, and SDS] Compare to analysis dataset, tabulation dataset.	Data Set
C45970	de-identification		1. The process of rendering data into a form that does not identify individuals and where identification is not likely to take place. A general term for a process of removing the association between a set of identifying data and the data subject. 2. Removal of elements connected with data which might aid in associating those data with an individual. Examples include name, birth date, social security number, home address, telephone number, e-mail address, medical record numbers, health plan beneficiary numbers, full-face photographic images). [1. ISO/TS 25237: 2008 - Health Informatics - Pseudonymization; 2. HIPAA: 45 CFR, 164.514]	Deidentification
C142507	de-identified information		Records that have had enough personally identifiable information removed or obscured such that the remaining information does not identify an individual, and there is no reasonable basis to believe that the information can be used to identify an individual. [Guide to Protecting Personally Identifiable Information (PII): Special Publication NIST pubs/800-122]	De-identified Information
C142504	decision rule		Succinct statement of how a decision will be reached based upon the expected foreseen clinical benefits in terms of outcomes of the primary endpoint. [FDA documentation]	Decision Rule
C142505	Declaration of Helsinki		A set of recommendations or basic principles that guide medical doctors in the conduct of biomedical research involving human subjects. it was originally adopted by the 18th World Medical assembly (Helsinki, Finland, 1964) and recently revised (64th WMA General Assembly, Fortaleza, Brazil, October 2013).	Declaration of Helsinki
C142506	Define-XML		Table used by XML review tools to configure a review engine to deal with CDISC standard data for a trial.	Define.xml
C142508	demographic data		Characteristics of subjects or study populations, which include such information as age, sex, family history of the disease or condition for which they are being treated, and other characteristics relevant to the study in which they are participating.	Demographic Data
C142509	dependent variable		Outcomes that are measured in an experiment and that are expected to change as a result of an experimental manipulation of the independent variable(s). [Center for advancement of Clinical Research]	Dependent Variable
C142538	deployment		Readying an electronic clinical trial system for field use by providing or disseminating capture devices, tokens, or passwords for users of an activated system. See activation.	Electronic System Deployment
C142510	derived variable		New variable created as a function of existing variables and/or application of mathematical functions. See also variable, raw data.	Derived Variable
C142442	design configuration		Clinical trial design developed to compare treatment groups in a clinical trial. NOTE: The configuration usually requires randomization to one or more treatment arms, each arm being allocated a different (or no) treatment. examples include: Parallel Group Design, Crossover Design, Factorial Designs. [from ICH E9]	Clinical Trial Design Configuration
C142443	development plan		An ordered program of clinical trials, each with specific objectives. [adapted from ICH E9, see ICH E8]. See also clinical development plan.	Clinical Trial Development Plan
C156648	DIBD (development international birth date)		Analogous to the International Birth Date (IBD) for a PSUR, defined as the date of first marketing approval worldwide. [After ICH E2F - Development Safety Update Report]	Development International Birth Date
C80447	digital signature		An electronic signature, based on cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters, such that the identity of the signer and the integrity of the data can be verified. [21 CFR 11]	Digital Signature
C142511	direct access		Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. NOTE: The 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 Glossary]	Direct Access

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C142512	direct entry		Recording of data by human or automated action where an electronic record is the original means of capturing the data into an electronic records system without a paper source document. Examples are an individual keying original observations into a system or the automatic recording into the system of the output from measuring devices such as a balance that measures subject's body weight or an ECG machine. Compare to data entry, data acquisition.	Direct Data Entry
C142513	direct identifier		A piece of data that can be used to uniquely identify an individual (e.g., name, patient ID, social security number, exact address, telephone number, e-mail address, government issued identifiers, passport/VISA numbers) either without additional information or with cross-linking through other information that is in the public domain. [After PhUSE De-identification Standard for SDTM 3.2, version 1.0.1.]	Direct Identifier
C142444	discontinuation		The act of concluding participation, prior to completion of all protocol-required elements, in a trial by an enrolled subject. NOTE: Four categories of discontinuation are distinguished: a) dropout: Active discontinuation by a subject (also a noun referring to such a discontinued subject); b) investigator initiated discontinuation (e.g., for cause); c) loss to follow-up: cessation of participation without notice or action by the subject; d) sponsor initiated discontinuation. Note that subject discontinuation does not necessarily imply exclusion of subject data from analysis. "Termination" has a history of synonymous use, but is now considered nonstandard. See also withdrawal and ICH E3, section 10.1 and FDA Guidance for Industry: Submission of Abbreviated Reports & Synopses in Support of Marketing Applications, IV A.	Clinical Trial Discontinuation
C142473	discrepancy		The failure of a data point to pass a validation check. NOTE: Discrepancies may be detected by computerized edit checks or observed/ identified by the data reviewer as a result of manual data review. See also query.	Data Discrepancy
C2991	disease		Any deviation from or interruption of the normal structure or function of a part, organ, or system of the body as manifested by characteristic symptoms and signs. [Dorland's Medical Dictionary]	Disease or Disorder
C142571	document (HL7)		An ordered presentation of XML elements, possibly including text and tabular analyses, description, and figures. Descriptors for HL7 documents include type, class, and element. NOTE: In HL7, a document can be either physical (referring to the paper) or logical (referring to the content) with the following characteristics: 1) Stewardship; 2) Potential for authentication; 3) Wholeness; 4) Human readability; 5) Persistence; 6) Global vs. local context.	HL7 Document
C142751	document root		The element in an XML document that contains all other elements; the first element in the document. [SPL Glossary]	XML Document Root
C142515	document type definition (DTD)		XML specification for content and presentation of data and text in a document including definitions for the elements considered to be legal in the document. NOTE: Agreeing on a common DTD facilitates interoperability among systems incorporating the agreed standards. [from XML files.com]	Document Type Definition
C19498	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 Glossary]	Document
C62289	domain		A collection of observations with a topic-specific commonality about each subject in a clinical investigation. NOTE: CDISC classifies domains. For example, the Interventions class is a domain that captures investigational treatments, therapeutic treatments, and surgical procedures that are intentionally administered to the subject (usually for therapeutic purposes) either as specified by the study protocol (e.g., exposure), coincident with the study assessment period (e.g., concomitant medications), or other substances self-administered by the subject (such as alcohol, tobacco, or caffeine). The Events class captures occurrences or incidents independent of planned study evaluations occurring during the trial (e.g., "adverse events" or "disposition") or prior to the trial (e.g., "medical history"). The Findings class captures the observations resulting from planned evaluations such as observations made during a physical examination, laboratory tests, ECG testing, and sets of individual questions listed on questionnaires.	Domain
C54076	domain name		The way a particular web server is identified on the internet. For example, www.fda.gov names the World Wide Web (www) server for the Food and Drug administration, which is a government (.gov) entity. [Center for advancement of Clinical Research]	Domain Name
C94394	dosage		The amount of drug administered to a patient or test subject over a period of time; a regulated time bound administration of individual doses. NOTE: For example, a daily dosage specified in a prescription or a clinical trial, such as one 100mg tablet taken 4 times per day. [After AMA Manual of style]	Cumulative Dose

C67497	CDISC Glossary			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C42636	dosage form		Physical characteristics of a drug product, (e.g., tablet, capsule, or solution) that contains a drug substance, generally-but not necessarily-in association with one or more other ingredients. [21 CFR 314.3 and after IDMP]. See also drug product.	Pharmaceutical Dosage Form
C142516	dosage regimen		The number of doses per given time period; the elapsed time between doses (for example, every six hours) or the time that the doses are to be given (for example, at 8 a.m. and 4 p.m. daily); and/or the amount of a medicine (the number of capsules, for example) to be given at each specific dosing time. [from Center for advancement of Clinical Research]	Dosage Regimen
C142517	dosage strength		1. Proportion of active substance to excipient, measured in units of volume or concentration. NOTE: The strength of a drug product tells how much of the active ingredient is present in each dosage. [NOTE: FDA Glossary of Terms]	Dosage Strength
C25488	dose		Specified quantity of a medicine, to be taken at one time or at stated intervals. [ISO 11615:2012 Health Informatics]	Dose
C15228	double-blind study		A study in which neither the subject nor the investigator nor the research team interacting with the subject or data during the trial knows what treatment a subject is receiving.	Double Blind Study
C142518	double-dummy		A technique for retaining the blind when administering supplies in a clinical trial, when the two treatments cannot be made identical. supplies are prepared for Treatment a (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). subjects then take two sets of treatment; either a (active) and B (placebo), or a (placebo) and B (active). [ICH E9]	Double-Dummy
C142445	dropout		A subject in a clinical trial who for any reason fails to continue in the trial until the last visit or observation required of him/her by the study protocol. [from ICH E9]	Clinical Trial Dropout
C1909	drug		Article other than food intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or any function of the body. not a device or a component, part, or accessory of a device. [from FDA Glossary of Terms, CDER] See also medicinal product, active substance.	Pharmacologic Substance
C142519	drug development process		The program for advancing an investigational product from preclinical studies through approval for marketing following review by regulatory agencies.	Drug Development Process
C79370	drug distribution		In pharmacokinetics, the processes that control transfer of a drug from the site of measurement to its target and other tissues. See also ADME.	Pharmacokinetics: Distribution
C459	drug product		A finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo. [21CFR210.3]	Medication
C142520	dynamic HTML		Collective term for a combination of tags and options, style sheets, and programming that allows users to create web pages in hypertext Mark-up language (HTML) that are more responsive to user interaction than previous versions of HTML.	Dynamic Hypertext Markup Language
C142525	eCertified copy		A copy of an electronic record that is created through the application of a process validated to preserve the data and metadata of the original and where the validation of the process is certified by the dated signature of an authorized person. [CDISC, after EMA/INS/GCP/454280/2010 GCP Inspectors Working Group (GCP IWG) June 2010]	Electronic Certified Copy
C142526	eClinical trial		Clinical trial in which primarily electronic processes are used to plan, collect (acquire), access, exchange, and archive data required for conduct, management, analysis, and reporting of the trial. NOTE: FDA has recently drawn a distinction between studies and trials. Both words refer to systematic efforts to obtain evidence relevant to regulatory authorities, but, depending on regulatory context and particularly in the case of postmarketing commitments, a study might not be the appropriate word for a clinical trial (prospective, controlled, randomized), but should be reserved instead for surveillance, structured gathering of information, epidemiological studies, or even animal studies [DRAFT Guidance for industry Postmarketing studies and Clinical Trials-implementation of section 505(o) of the Federal Food, Drug, and Cosmetic act]. Synonyms: eClinical study, eClinical investigation.	Electronic Clinical Trial

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C142523	eCRF (electronic case report form)		An auditable electronic record of information that is reported to the sponsor (or sponsor's agent such as an EDC provider) on each trial subject to enable data pertaining to a clinical investigation protocol to be systematically captured, reviewed, managed, stored, analyzed, and reported. The eCRF is a CRF in which related data items and their associated comments, notes, and signatures are linked programmatically. See also case report form, CRF, eSRF.[CSUICI; Revised from FDA Final Guidance on eSource]	Electronic Case Report Form
C142524	eCRT (electronic case report tabulation)		CRTs provided in electronic format for esubmissions (electronic regulatory submissions). NOTE: according to FDA guidance, eCRTs are datasets provided as SAS Transport files with accompanying documentation in electronic submissions. They enable reviewers to analyze each dataset for each study. Each CRF domain should be provided as a single dataset; however, additional datasets suitable for reproducing and confirming analyses may also be needed. Becoming obsolete, being replaced by SDTM.	Electronic Case Report Tabulation
C142527	EDC (electronic data capture)		The process of collecting clinical trial data into a permanent electronic form. NOTE: Permanent in the context of these definitions implies that any changes made to the electronic data are recorded with an audit trail. EDC usually denotes manual entry of CRF data by transcription from source documents. The transcription is typically done by personnel at investigative sites. See also data entry, direct data entry, data acquisition.	Electronic Data Capture
C142521	edit check		An auditable process, usually automated, of assessing the content of a data field against its expected logical, format, range, or other properties that is intended to reduce error. NOTE: Time-of-entry edit checks are a type of edit check that is run (executed) at the time data are first captured or transcribed to an electronic device at the time entry is completed of each field or group of fields on a form. Back-end edit checks are a type that is run against data that has been entered or captured electronically and has also been received by a centralized data store.	Edit Check
C156649	EDR (electronic document room)		The electronic document room is an extension of the e-Submissions central document room. A check is performed on each submission sent to the EDR for file formats used and the integrity of bookmarks and hypertext links.	Electronic Document Room
C18919	effect	treatment effect	An effect attributed to a treatment in a clinical trial. In most clinical trials, the treatment effect of interest is a comparison (or contrast) of two or more treatments. [ICH E9] See also treatment effect.	Outcome of Therapy
C142522	effectiveness		The desired measure of a drug's influence on a disease or condition as demonstrated by substantial evidence from adequate and well-controlled investigations.	Effectiveness
C88183	efficacy		The capacity of a drug or treatment to produce beneficial effects on the course or duration of a disease at the dose tested and against the illness (and patient population) for which it is designed.	Efficacy
C142529	EHR (electronic health record)		An electronic record for healthcare providers to create, import, store, and use clinical information for patient care, according to nationally recognized interoperability standards. NOTE: The EHR has the following distinguishing features: able to be obtained from multiple sources; shareable; interoperable; accessible to authorized parties. [After National Office of Health Information Technology-HIT, USHHS]	Electronic Health Record
C142530	electronic personal health record (ePHR)		An electronic record for individuals to create, import, store, and use clinical information to support their own health.	Electronic Personal Health Record
C142531	electronic record		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. [21 CFR 11.3(b) (6)]	Electronic Record
C142533	electronic signature	eSignature	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. [CSUICI; 21 CFR 11.3(7)]	Electronic Signature
C45259	EMR (electronic medical record)		An electronic record for healthcare providers within one healthcare organization to create, store, and use clinical information for patient care. An electronic record derived from a computerized system used primarily for delivering patient care in a clinical setting. NOTE: EMRs may serve as source documents, and such data could serve also as source data for clinical trials provided that the controls on the EMR system and the transfer of such data to the eClinical trial system were to fulfill regulatory requirements (e.g., 21 CFR 11).	Electronic Medical Record

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C25212	endpoint		A defined variable intended to reflect an outcome of interest that is statistically analyzed to address a particular research question. NOTE: A precise definition of an endpoint typically specifies the type of assessments made, the timing of those assessments, the assessment tools used, and possibly other details, as applicable, such as how multiple assessments within an individual are to be combined. [After BEST Resource] See also outcome, variable.	End Point
C142715	enrolled		Status assigned to a subject who agrees to participate in a study, following completion of the informed consent process and meeting inclusion criteria. NOTE: Enrollment routinely requires verification of eligibility and inclusion in the analysis database. [after Clinicaltrials.gov]. NOTE: A less common definition assigns enrolled status is the point of enrollment, Can be defined from the signing of an informed consent form. Other ways of defining enrollment or subject status can be specified in some protocols, e.g. non-interventional studies. See also informed consent.	Study Subject Enrolled
C37948	enrollment		The action of enrolling one or more subjects. NOTE: The subject will have met the inclusion/exclusion criteria to participate in the trial and will have signed an informed consent form. See also enrolled.	Enrollment
C142466	enrollment (cumulative)		Current enrollment including any subjects who were once enrolled and have ended participation.	Cumulative Enrollment
C142467	enrollment (current)		Subjects actively continuing to participate in a clinical trial as of the current date.	Current Enrollment
C71738	epoch		Interval of time in the planned conduct of a study. An epoch is associated with a purpose (e.g., screening, randomization, treatment, follow-up), which applies across all arms of a study. NOTE: Epoch is intended as a standardized term to replace: period, cycle, phase, stage. See also arm, visit.	Clinical Trial Epoch
C137811	ePRO		Patient reported outcome data initially captured electronically. NOTE: Usually ePRO data is captured as eSource. [DIA ePRO Working Group]. See also patient reported outcome, PRO, eSource.	Electronic Patient-reported Outcome System
C142428	equipoise		A state in which an investigator is uncertain about which arm of a clinical trial would be therapeutically superior for a patient. NOTE: An investigator who has a treatment preference or finds out that one arm of a comparative trial offers a clinically therapeutic advantage should disclose this information to subjects participating in the trial.	Clinical Equipoise
C142539	equivalence trial		A trial with the primary objective of showing that the response to two or more treatments differs by an amount that is clinically unimportant. NOTE: This is usually demonstrated by showing that the true treatment difference is likely to lie between a lower and an upper equivalence margin of clinically acceptable differences.	Equivalence Trial
C142536	eSource		Source record that is electronic. See also source, electronic record.	Electronic Source Record
C142534	eSource data		Source data captured initially into a permanent electronic record (eSource document) used for the reconstruction and evaluation of a clinical study or a source data item included in an eCRF when direct entry is made. NOTE: permanent in the context of these definitions implies that any changes made to the electronic data are recorded via an audit trail. See also eSource document, source data, permanent data, data originator. [From body of FDA Final Guidance on eSource]	Electronic Source Data
C142535	eSource document		Electronic record containing source data for a clinical trial, used to aggregate a particular instance of eSource data items for capture, transmission, storage, and/ or display, and serving as a source document for a clinical investigation. NOTE: Electronic Source documents are recorded in electronic systems according to conventions (such as those for PDF documents) that ensure that all the fields of eSource data and associated contextual information (e.g. time of capture, time zone, authorship, origin, signatures, revisions, etc.) are linked to each other in a particular structure for presentation. The encoded specifications in the electronic record thus serve the same role as have the physical properties of paper (binding data items together). eSource documents are subject to regulations and guidance that apply to source documents. See also source documents. [relevant to FDA Final Guidance on eSource]	Electronic Source Document

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C142537	eSRF (electronic source report form)		The human-readable rendering of an electronic record serving as an eSource document that is part of a case history. The eSRF supports capture, transmission, storage, editing and/ or display of eSource documents (original records and certified copies of original records of clinical findings, observations, or other activities in a clinical investigation) used for reconstructing and evaluating the investigation. NOTE: Intended use distinguishes eCRF and eSRF. The eCRF is for capture, review and editing of protocol data belonging to the sponsor; the eSRF is for the human-readable representation of the eSource document for review or to maintain the eSource document that is part of the case history under 21CFR312.62. See also eCRF, eSource document. [CDISC, relevant to FDA Final Guidance on eSource]	Electronic Source Report Form
C142540	essential documents		Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. [ICH E6 Glossary]	Essential Trial Document
C97104	established name		The official name of a drug substance. [Food, Drug, and Cosmetic Act]	Established Drug Name
C142541	ethics committee		See institutional review board, independent ethics committee.	Ethics Committee
C16564	ethnicity		Denotes social groups with a shared history, sense of identity, geography, and cultural roots.	Ethnic Group
C142543	European Medicines Agency (EMA)		The regulatory agency for the EU.	European Medicines Agency
C142546	evaluable (for efficacy and safety)		Pertains to data or subjects that meet statistical analysis Plan criteria for inclusion in efficacy/safety datasets.	Evaluable for Safety and Efficacy
C25370	exclusion criteria		List of characteristics in a protocol, any one of which may exclude a potential subject from participation in a study.	Exclusion Criteria
C94618	excretion		The act or process of eliminating waste products from the body. See also ADME.	Excretion
C142547	exploratory IND study		A clinical study that is conducted early in Phase 1; involves very limited human exposure and has no therapeutic or diagnostic intent (e.g., screening studies, microdose studies) [FDA Guidance for industry, investigators, and Reviewers: exploratory IND studies, January 2006] See also Phase 0.	Exploratory Investigational New Drug Study
C39538	exploratory study		Phase 1 or 2 study during which the actions of a therapeutic intervention are assessed and measured. NOTE: Procedures in exploratory studies may appropriately be altered beyond the standard adequate and well controlled processes to expand the scope or method of investigation. [NOTE: After FDA eCOA Glossary] Compare to confirmatory study.	Therapeutic Exploratory Study
C17941	exposure		Contact between an agent and a target. A state of contact or close proximity to a medicinal product, chemical, pathogen, radioisotope or other substance. NOTE: Types of exposure may be described by many qualifiers (e.g., local, systemic, acute, chronic, cumulative, environmental, population, individual, gestational, or occupational.) See also exposure (individual), intervention, extent of exposure. [After International Programme on Chemical Safety (IPCS) 2004 WHO]	Exposure
C156623	exposure (individual)		The result of an intentional contact (e.g., intervention, dosage, drug/product use, misuse, or abuse) or an unintentional contact (circumstantial events leading to unknown, inadvertent, or accidental contact) resulting in inputs to the body of an individual which can occur directly through primary bodily contact routes or indirectly through secondary contact routes (such as via fluids as in fetal exposure during pregnancy or lactation/breast feeding or other biological transfers). [After FDA, Reviewer Guidance Evaluating the Risks of Drug Exposure in Human Pregnancies] See also exposure, intervention, extent of exposure.	Individual Exposure
C142548	eXtensible markup language (XML) data element		For XML, an item of data provided in a mark-up mode to allow machine processing. NOTE: The mark-up or tagging facilitates document indexing, search and retrieval, and provides standard conventions for insertion of codes. [FDA - GL/IEEE]	Extensible Markup Language Data Element
C156624	extent of exposure		A variable of exposure taking into consideration the strength, dose, duration, frequency, route, and/or timing or gestational stage in utero and other factors. NOTE: Measures of concentrations in biological fluids and tissues may be used to attempt to quantify the extent of exposures (e.g., Cmax, Cmin, Css, AUC in pharmacokinetics or other exposure measurement and assessment models). [After, FDA Guidance for Industry Exposure-Response Relationships] See also exposure, exposure (individual), intervention.	Extent of Exposure

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C142549	extraction transformation load (ETL)		A class of software applications for data extraction, transformation, and loading that are used to implement data interfaces between disparate database systems, often to populate data warehouses.	Extraction Transformation Load
C142557	feels		A patient's physical sensation (e.g., symptoms) or perceived mental state. A patient may feel pain, feel feverish, or perceive a severely low mood (as with depression). [FDA Clinical Outcome Assessment (COA) Glossary]	Feels
C25507	field		Locus on a data collection instrument (usually a CRF) for recording or displaying a data element. See data item.	Data Field
C100047	File Transfer Protocol (FTP)		A standard protocol for exchanging files between computers on the internet. See also TCP/IP.	File Transfer Protocol
C115575	final 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. [ICH E3]	Clinical Trial Final Report
C3367	finding		A meaningful interpretation of data or observations resulting from planned evaluations. Compare to conclusion, hypothesis.	Finding
C142558	first subject in - date, time (FSI - date, time)	FPI - date, time;first patient in - date, time	The date and/or date and time the first subject is enrolled into a study. See also enrollment.	First Subject In Date Time
C142559	first subject in - identity (FSI - identity)	FPI - identity;first patient in - identity	The first subject enrolled. See also enrollment.	First Subject In Identity
C142560	first subject screened - date, time	first patient screened - date, time	The date and/or date and time the first subject signs the informed consent form and is screened for potential enrollment or randomization into a study, but has not yet been determined to meet the inclusion/exclusion criteria for the trial.	First Subject Screened Date Time
C142561	first subject screened - identity	first patient screened - identity	The first subject who is so screened.	First Subject Screened Identity
C142562	first subject treated - date, time	first patient treated - date, time	The date and/or date and time when the first subject receives the test article or placebo in a clinical investigation.	First Subject Treated Date Time
C142563	first subject treated - identity	first patient treated - identity	The first subject who is so treated.	First Subject Treated Identity
C142564	first-in-humans study	first-in-man study	The first Phase 1 study in which the test product is administered to human beings.	First-in-Human Study
C17237	Food and Drug administration (FDA)		The United states regulatory authority charged with, among other responsibilities, granting IND and NDA approvals.	Food and Drug Administration
C19464	Form		A collection of items and item groups for capturing and displaying clinical trial data.	Form
C142565	frequentist methods		Statistical methods, such as significance tests and confidence intervals, which can be interpreted in terms of the frequency of certain outcomes occurring in hypothetical repeated realizations of the same experimental situation. [ICH E9]	Frequentist Method
C142502	frozen		Status of a database, file, or element that has been presumed to be in its final state pending "lock" and where further editing is prevented without "unfreezing." NOTE: Freezing and unfreezing are usually formalized in audit trails and differ from "locking" and "unlocking" only in the degree of approval required. See database lock.	Database Frozen
C142438	functional roles (in a study)		The function or responsibility assumed by a person in the context of a clinical study. Examples include data manager, investigator. [HL7]	Clinical Study Functional Role
C142468	functions	functioning	The manner in which a patient can perform successfully tasks and roles required for everyday living. A patient's ability to perform specified activities that are a meaningful (to the patient), part of typical (e.g., daily) life. [FDA Clinical Outcome Assessment (COA) Glossary]	Daily Living
C17357	gender		Subject self-identification re: masculine/feminine. [IOM] See also sex.	Gender
C142429	generalizability		The extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population and a broader range of clinical settings. [ICH E9]	Clinical Generalizability
C97054	generic name		The drug identifying name to which all branded (proprietary) names for that medicinal product are associated.	Generic Name

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C142566	global assessment variable		A single variable, usually a scale of ordered categorical ratings, which integrates objective variables and the investigator's overall impression about the state or change in state of a subject. [ICH E9]	Global Assessment Variable
C18232	glossary		A collection of specialized words or terms with their meanings.	Glossary
C94236	good clinical practice (GCP)	GCRP;good clinical research practice	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. NOTE: For Guidance on Good Clinical Practice see COMP/ICH/135/95; Declaration of Helsinki; 21 CFR 50, 21 CFR 54, 21 CFR 56, and 21 CFR 312. [ICH]	Good Clinical Practice
C142567	granularity		Refers to the size of an information unit in relation to a whole. NOTE: Structuring "privileges" in electronic systems is said to be highly granular when each of many roles can differ in their capacity to act on electronic records.	Granularity
C142568	group sequential design		A trial design that allows a look at the data at particular time points or after a defined number of patients have been entered and followed up based on formulating a stopping rule derived from repeated significance tests. [Center for Advancement of Clinical Research]	Group Sequential Design
C142569	handwritten signature		The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. NOTE: The act of signing with a writing or marking instrument such as a pen or stylus is preserved. [21CFR 11]	Handwritten Signature
C142542	harmonized standard		A European Norm (EN) that has been accepted by all Member States and has been published in the Official Journal of the European Communities (OJEC).	European Harmonized Standard
C80485	Health Level 7 (HL7)		An ANSI-accredited Standards Developing Organization (SDO) operating in the healthcare arena. NOTE: Level 7 refers to the highest level of the International Standards Organization's (ISO) communications model for Open Systems Interconnection (OSI), the application level. The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. Level 7 supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations, and, most importantly, data exchange structuring.	Health Level Seven
C142570	health-related quality of life (HRQoL)		A multi-domain concept that represents the patient's general perception of the effect of illness and treatment on physical, psychological, and social aspects of life. NOTE: Claiming a statistical and meaningful improvement in HRQoL implies: (1) that all HRQoL domains that are important to interpreting change in how the clinical trial's population feels or functions as a result of the targeted disease and its treatment were measured; (2) that a general improvement was demonstrated; and (3) that no decrement was demonstrated in any domain. [FDA Clinical Outcome Assessment (COA) Glossary] Compare to quality of life (QoL).	Health-related Quality of Life
C16666	healthcare provider		A person licensed, certified, or otherwise authorized or permitted by law to administer healthcare in the ordinary course of business or practice of a profession, including a healthcare facility. [HL7]	Health Care Provider
C49651	healthy volunteer		A healthy person volunteering to participate as a subject in a clinical trial, often a healthy person agreeing to participate in a Phase 1 trial. See also Phase 1.	Healthy Subject
C156650	HIE (Health Information Exchange)		The mobilization of healthcare information electronically across organizations within a region or community. HIE provides the capability to electronically move clinical information between disparate healthcare information systems, while maintaining the meaning of the information being exchanged. The goal of HIE is to facilitate access to, and retrieval of, clinical data to provide safer, more timely, efficient, effective, equitable, and patient-centered care. [HITSP]	Health Information Exchange
C70665	human subject	subject/trial subject	Individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3].	Human Study Subject
C142572	Huriet Law		France's regulations covering the initiation and conduct of clinical trials.	Huriet Law
C142573	hypertext		Links in a document that permit browsers to jump immediately to another document. NOTE: In most browsers links are displayed as colored, underlined text.	Hypertext
C142380	HyperText Markup Language (HTML)		A specification of the W3C that provides markup of documents for display in a web browser. [HL7] Contrast to XML.	Hypertext Markup Language

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C142574	hypothesis to test		In a trial, a statement relating to the possible different effect of the interventions on an outcome. The null hypothesis of no such effect is amenable to explicit statistical evaluation by a hypothesis test, which generates a P value. [CONSORT Statement]	Hypothesis To Test
C142577	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. [ICH]	Impartial Witness
C25532	inclusion criteria		The criteria in a protocol that prospective subjects must meet to be eligible for participation in a study. NOTE: Exclusion and inclusion criteria define the study population. See also exclusion criteria.	Inclusion Criteria
C142578	independent data monitoring committee (IDMC)		A committee established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy variables and recommend to the sponsor whether to continue, modify, or terminate the trial. [ICH E9] See also data monitoring committee.	Independent Data Monitoring Committee
C142579	independent ethics committee (IEC)		An independent body (a review board or a committee, institutional, regional, national, or supranational) constituted of medical/scientific professionals and non-scientific 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 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. NOTE: The legal status, composition, function, operations, and regulatory requirements pertaining to independent ethics committees may differ among countries but should allow the independent ethics committee to act in agreement with GCP as described in the ICH guideline. [ICH] See also institutional review board.	Independent Ethics Committee
C41184	indication		A health problem or disease that is identified as likely to be benefited by a therapy being studied in clinical trials. NOTE: Where such a benefit has been established and approved by regulatory authorities, the therapy is said to be approved for such an indication.	Indication
C142581	indirect identifier	quasi identifer	Data which in connection with other information can be used to identify an individual with high probability, e.g., age at baseline, race, gender, events, specific findings, etc. NOTE: two levels of indirect identifier are distinguished. Level 1 - not likely to change over time, is visible, and is available in other sources. Typically it is demographic data such as sex, age at a particular date, country, body mass index (BMI). Level 2 - longitudinal information that is likely to change such as measurements, events, age. See also quasi identifier. [PhUSE De-identification Standard for SDTM 3.2, version 1.0.1.]	Indirect Identifier
C16735	informed consent		An ongoing process that provides the subject with explanations that will help in making educated decisions about whether to begin or continue participating in a trial. informed consent is an ongoing, interactive process rather than a one-time information session. NOTE: Under 21 CFR 50.20, no informed consent form may include any "language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." In some cases, when the prospective subject is unable to provide legal consent, permission to participate may be obtained from a legally-authorized representative. See also consent form.	Informed Consent
C51981	ingredient		Active and/or inactive material used in pharmaceutical product. [After ISO 11615:2017, 3.1.28]	Ingredient
C142448	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 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(ies). [ICH] See also audit.	Clinical Trial Inspection
C21541	institution (medical)		Any public or private entity or agency or medical or dental facility where clinical trials are conducted. [ICH]	Healthcare Facility
C16741	institutional review board (IRB)	committee for the protection of human subjects;independent ethics committee;independent review board	An independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure 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 of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. [ICH E6 1.31]	Institutional Review Board

C67497	CDISC Glossary			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C142631	instrument		A means to capture data (e.g., questionnaire, diary) plus all the information and documentation that supports its use. NOTE: Generally, instruments include clearly defined methods and instructions for administration or responding, a standard format for data collection, and well-documented methods for scoring, analysis, and interpretation of results. [from PRO Draft Guidance] Compare to questionnaire, survey (see Comments on Draft PRO Guidance, April 4, 2006, by ISOQOL, p. 8).	Patient-Reported Survey Instrument
C54390	intended use		The specific clinical circumstance or purpose for which a medical product or test is being developed. NOTE: In the regulatory context, this term refers to the "Statement of Intended Use" prepared by the persons legally responsible for the labeling of medical products. [after NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Medical Product Intent of Use
C54398	intention-to-treat		The principle that asserts that the effect of a treatment policy can be best assessed by evaluating the basis of the intention to treat a subject (i.e., the planned treatment regimen) rather than the actual treatment given. NOTE: This has the consequence that subjects allocated to a treatment group should be followed up, assessed, and analyzed as members of that group irrespective of their compliance with the planned course of treatment. The principle is intended to prevent bias caused by loss of participants that may reflect non-adherence to the protocol and disrupt baseline equivalence established by random assignment. [ICH E9; after CONSORT statement]	Intent To Treat
C78688	inter-rater reliability		The property of scales yielding equivalent results when used by different raters on different occasions. [ICH E9]	Inter-rater Reliability
C142732	interaction (qualitative and quantitative)		The situation in which a treatment contrast (e.g., difference between investigational product and control) is dependent on another factor (e.g., center). A quantitative interaction refers to the case where the magnitude of the contrast differs at the different levels of the factor, whereas for a qualitative interaction, the direction of the contrast differs for at least one level of the factor. [ICH E9 Glossary]	Treatment Contrast Interaction
C142583	interim analysis schedule		The time/information points at which interim analyses are planned.	Interim Analysis Schedule
C142582	interim analysis(es)		Analysis comparing intervention groups at any time before the formal completion of the trial, usually before recruitment is complete. [CONSORT statement]	Interim Analysis
C115555	interim clinical trial/study report		A report of intermediate results and their evaluation based on planned analyses performed during the course of a trial. [ICH]	Interim Analysis Output
C78687	internal consistency		Pertaining to data that do not include contradictions.	Internal Consistency
C142584	international birth date (IBD)		The date of the first marketing authorization for a new product granted to any company in any country in the world. [ICH E2C(R2), Appendix A]	International Marketing Authorization Birth Date
C142585	international nonproprietary name (INN)		A unique name that is globally recognized and public property, which identifies pharmaceutical substances or active pharmaceutical ingredients. NOTE: The INN name is established by the World Health Organization (WHO). [After WHO]	International Nonproprietary Name
C20342	internet		A global system of computer networks that provides the common TCP IP infrastructure for e-mail, the World Wide Web, and other online activities.	Internet
C142586	internet service provider (ISP)		A company that provides access to the internet for individuals and organizations.	Internet Service Provider
C142381	interoperability		Ability of two or more systems or components to exchange information and to use the information that has been exchanged. [IEEE Standard Computer Dictionary]. See also syntactic, semantic.	Interoperability
C25218	intervention		The drug, device, therapy, or process under investigation in a clinical study that is believed to have an effect on outcomes of interest in a study (e.g., health-related quality of life, efficacy, safety, pharmacoeconomics). See also: test articles; devices; drug product; medicinal product; combination product.	Intervention or Procedure
C98388	interventional clinical trial		A trial which intervenes with the inviolability of the trial subject for the purpose of the investigation. For example, the administration of an investigational medical product to the trial subject or use of some extra means of intervention (i.e., samples, tests, or questionnaires) that would not otherwise be used. [Clinical Trial Directive EC/20/2001 definitions]	Interventional Study

C67497	CDISC Glossary			
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C142587	investigational product		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 authorization 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. NOTE: CDISC includes test articles in its definition of investigational products. Compare to Investigational Medicinal Product (IMP) from EU-CTR (EU) No 536/2014. [ICH]	Investigational Product
C25936	investigator		An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team). [21 CFR 50.3] See also sponsor-investigator, site investigator.	Investigator
C79303	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.	Investigational Brochure
C142591	investigator/institution		An expression meaning the investigator and/or institution, where required by the applicable regulatory requirements. [ICH E6 1.35]	Investigator/Institution
C142431	item		A representation of a clinical variable, fact, concept, or instruction in a manner suitable for communication, interpretation, or processing by humans or by automated means. NOTE: Items are collected together to form item groups. [CDISC] Compare to data item, item (PRO).	Clinical Item
C142629	item (PRO)		An individual question, statement, or task (and its standardized response options) that is evaluated by the patient to address a particular concept. [FDA Clinical Outcome Assessment (COA) Glossary] See also item generation, response option.	Patient-reported Outcome Item
C142592	item definition		Formal specification of the properties of an item or field of data in an eClinical trial. [CDISC ODM, CDISC CDASH]	Item Definition
C142630	item generation		Establishing the content to be covered by the items in a PRO instrument, including generating item wording, evaluating the completeness of item coverage of the concepts of interest, and performing initial assessment of clarity and readability. NOTE: PRO instrument item generation is potentially incomplete without patient involvement. [from ISOQOL comments on PRO Draft Guidance]	Patient-Reported Outcome Item Generation
C142593	item group definition		The specification in an eClinical trial of a collection of items often clinically related to each other and useful to consider as an ensemble. NOTE: Item groups are likely to have greater granularity in analysis datasets using SDTM which can, for example, distinguish between different therapy types: study therapy, prior therapy, concomitant therapy, protocol forbidden therapies, rescue therapies. [ODM]	Item Group Definition
C142594	Janus conceptual model		A logical design for a data warehouse intended to integrate submission data, protocol descriptions, and analysis plans from clinical and animal studies into an FDA review environment that uses a set of validated, standards-based tools to allow reproducible cross-study, data mining, and retrospective comparative analysis. [FDA Study Data Standards]	Janus Clinical Trials Repository Model
C142595	Janus study data repository		The Janus is a data repository for subject-level clinical and nonclinical study data submitted to FDA as part of a regulatory submission. NOTE: Sometimes written as JANUS, the term is not an acronym. [FDA Study Data Standards]	Janus Study Data Repository
C41203	label	package insert, patient package leaflet	Description of a drug product/ device that includes: the indication, who should use it, adverse events, instructions for use, and safety information. NOTE: Labels must be approved by regulatory authorities. [FDA; SPL]	Medical Product Label
C54694	labeling (content of)		All text, tables, and figures in labeling as described in regulations for a specific product (e.g., 21 CFR 201.56 and 201.57 for human prescription drugs; 201.66 for human over-the-counter drugs; 21 CFR 801 for medical devices; and 21 CFR 606.122 for blood products). See also structured product label.	Labeling
C142432	laboratory (clinical)		A laboratory providing analyses of samples collected in clinical care or research.	Clinical Laboratory
C142596	last subject in - date, time (LSI - date, time)	LPI - date, time;last patient in - date, time	The date and/or date and time when a last subject to participate in a clinical trial is enrolled.	Last Subject In Date Time
C142597	last subject in - identity (LSI - identity)	LPI - identity;last patient in - identity	The last subject enrolled in a clinical trial.	Last Subject In Identity

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C142598	last subject last visit - date, time (LSLV - date, time)	last subject out/complete (LSC/LPC or LSO/LPO) - date, time)	The date and/or date and time when a last subject has reached a planned or achieved milestone representing the completion of the trial.	Last Subject Last Visit Date Time
C142599	last subject last visit - identity (LSLV - identity)	LPC-dentity;LPO - identity;LSC - identity;LSO - identity;last subject complete - identity;last subject out - identity	The last subject to reach a planned or achieved milestone representing the completion of the trial.	Last Subject Last Visit Identity
C142514	legal authentication		A completion status in which a document has been signed manually or electronically by the individual who is legally responsible for that document. [HL7]	Document Legally Authenticated
C142600	legally acceptable representative		An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial. [ICH, E6 Glossary]	Legally Acceptable Representative
C84266	life-threatening adverse event/ experience		Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death). [FDA 21 CFR 312.32; ICH-E2A]	Life Threatening Adverse Event
C15273	longitudinal study		Investigation in which data are collected from a number of subjects over a long period of time (a well-known example is the Framingham study).	Longitudinal Study
C142601	low-interventional clinical trial		A clinical trial which fulfills all of the following conditions: (a) the investigational medicinal products, excluding placebos, are authorized; (b) according to the protocol of the clinical trial, (i) the investigational medicinal products are used in accordance with the terms of the marketing authorization; or (ii) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned. [REGULATION (EU) No 536/2014 Article 2.2.(3)]	Low-interventional Clinical Trial
C156625	manufacturer (device)		Any person or entity who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture; (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; (3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or (4) Is the U.S. agent of a foreign manufacturer. [after 21 CFR 803.3, FDA] See also manufacturer (drug).	Device Manufacture
C156626	manufacturer (drug)		Any person or entity involved in the processing, packing, or holding of a medicinal product, including packaging and labeling, testing, and quality control. [after 21 CFR 210.3] See also manufacturer (device).	Drug Manufacturer
C142485	mapping		In the context of representing or exchanging data, connecting an item or symbol to a code or concept. Compare to translation.	Data Mapping
C156642	marketing authorization	marketing approval	Authorisation issued from a medicines regulatory agency that allows a Medicinal Product to be placed on the market. [after ISO 11615 2017-10 on Regulated Medicinal Product information]	Marketing Authorization
C88074	marketing authorization holder		Organization or person that is permitted to market a medicinal product in a jurisdiction. [After ISO 11615:2017, 3.1.41]	Marketing Authorization Holder
C142602	marketing authorization procedure		Formal EU procedure applied by a medicines regulatory agency to grant a marketing authorization, to amend an existing one, to extend its duration or to revoke it. [After ISO 11615:2017, 3.1.43]	Marketing Authorization Procedure
C142603	marketing support trials		Clinical studies that are designed to clarify therapeutic benefits of a marketed product or to show potential decision-makers the rationale for preferring one therapy over another.	Marketing Support Trials
C63615	markup		Computer-processable annotations within a multimedia document. NOTE: in the context of the HL7 specification, markup syntax is according to the XML specification. [HL7]	Markup

C67497 CDISC Glossary

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C142604	matched-pair design		A type of parallel trial design in which investigators identify pairs of subjects who are 'identical' with respect to relevant factors, then randomize them so that one receives Treatment a and the other Treatment B. See also pairing.	Matched-Pair Design
C53319	mean		The sum of the values of all observations or data points divided by the number of observations; an arithmetical average.	Mean
C43820	MedDRA (Medical Dictionary for Regulatory Activities)		A global standard medical terminology designed to supersede other terminologies used in the medical product development process, including COSTART, ICD9, and others.	MedDRA
C28007	median		The middle value in a data set; that is, just as many values are greater than the median and lower than the median value. (With an even number of values, the conventional median is halfway between the two middle values.)	Median
C16830	medical device		Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more specific medical purpose(s). NOTE: Specific medical purposes include diagnosis; prevention; monitoring; treatment or alleviation of disease; diagnosis; monitoring; treatment; alleviation of or compensation for an injury; investigation; replacement; modification; or support of the anatomy or of a physiological process; supporting or sustaining life, control of conception; disinfection of medical devices providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. [After REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices]	Medical Device
C51836	medical monitor		A sponsor representative who has medical authority for the evaluation of the safety aspects of a clinical trial.	Medical Monitor
C53607	medical monitoring		Act of tracking the progress or severity of a disease, injury or handicap in patients in order to support a medical purpose in the context of medical care. NOTE: Medical monitoring refers to delivery of medical diagnosis and established treatment linked to a specific disease, and does not include monitoring of patient safety or well being in the context of tracking subject status during clinical trials. Such a medical purpose is a key in establishing that a given instrument, software program or measuring device is subject to regulations pertaining to a medical device. [After MHRA Guidance: Medical device stand-alone software including apps] See also medical device; DSMB, clinical trial, non-interventional trial.	Patient Monitoring
C156627	medication error		Any unintentional error in the prescribing, dispensing or administration of a medicinal product while in the control of the healthcare professional, patient or consumer. [HMA, Guideline on good pharmacovigilance practices (GVP)]	Medication Error
C142605	medicinal product		Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, or with the intent to make a medical diagnosis or to restore, correct or modify physiological functions. NOTE: 1. A Medicinal Product may contain one or more manufactured items and one or more pharmaceutical products. 2. In certain jurisdictions a Medicinal Product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis. [After IDMP]	Medicinal Product
C156643	medicinal product classification		Categorisation or grouping of Medicinal Products based on specific properties and according to various classification systems (e.g., UNII-SRS), which may be regional or international. NOTE: The classification system is specified using an appropriate identification system; the applicable controlled term and the controlled term identifier is specified. [after ISO 11615 2017-10 on Regulated Medicinal Product information]	Medicinal Product Classification
C142606	medicinal product identifier		Unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a jurisdiction. NOTE: proposed by IDMP as a new universal identifier. [After ISO 11615:2017, 3.1.53]	Medicinal Product Identifier
C142607	medicinal product name		Name as authorized by a Medicines Regulatory Agency. NOTE: As a general principle, a marketing authorization is granted to a single Marketing Authorization Holder or sponsor who is responsible for placing a single Medicinal Product on the market. The marketing authorization contains the name of the Medicinal Product, which can refer to, for example, a single invented name or a scientific name [when available, the INN of the active substance(s)] accompanied by a trademark or other characteristics. Other characteristics of the name can refer to strength, pharmaceutical form, intended usage or an administration device, etc. [After ISO 11615:2017, 3.1.54]	Medicinal Product Name

C67497	CDISC Glossary			
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C142608	Medicines and Healthcare products Regulatory agency (MHRA)		The UK government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. [MHRA]	Medicines And Healthcare Products Regulatory Agency
C142609	mega-trials	large sample trial	Massive trials that test the advantages of therapeutic interventions by enrolling 10,000 or more subjects.	Mega-Trial
C142553	memorandum of understanding (MOU)		A formal agreement between the Food and Drug administration (FDA) and federal, state, or local government agencies; academic institutions; and other entities. NOTE: The MOU constitutes an understanding between the parties but is a non-binding agreement. it is FDA's policy to enter into MOUs with other entities whenever there is a need to define lines of authority or responsibility, or to clarify cooperative procedures.	FDA Memorandum of Understanding
C142486	message (HL7)		The atomic unit of data transferred between systems. It comprises a group of segments in a defined sequence, each message has a message type that defines its purpose. NOTE: For example, the Admission, Discharge and Transfer (ADT) Message type is used to transmit portions of a patient's ADT data from one system to another. in HL7, a three-character code contained within each message identifies its type. [HL7]	Data Message
C17886	meta-analysis		The formal evaluation of the quantitative evidence from two or more trials bearing on the same question. NOTE: This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes also used to refer to the combination of the raw data. [from ICH E9 Glossary]	Meta-Analysis
C19536	metabolism		The biochemical alteration of substances introduced into the body.	Metabolic Process
C52095	metadata		Data that describe other data, particularly XML tags characterizing attributes of values in clinical data fields.	Metadata
C142726	migration		The act of moving a system or software product (including data) from an old to new operational environment in accordance with a software quality system. ISO/IEC/IEEE 12207:1995 5.5.5]	System Migration
C156663	minor		A subject who, according to the law of the applicable jurisdiction concerned, is under the age of legal competence to give informed consent. [after EU CTR]	Minor Person
C142610	missing data		Data not completed or corrupted in reports and case report forms, e.g., the data not captured when a subject withdraws from a trial. NOTE: Reviewers are concerned about missing data since patients who are not improved or who believe they have experienced side effects may be particularly prone to leave a trial, thus skewing the analysis of results if such analysis were to be done only on the subjects who had continued with the trial. Trial designs therefore specify plans for how such missing data will be treated in analysis. See also intention to treat. [FDA Guidance on Subject Withdrawal, 2008]	Missing Data
C53320	mode		The most frequently occurring value in a data set.	Mode
C16866	model		A formal structure for representing and analyzing a process such as a clinical trial or the information pertaining to a restricted context (e.g., clinical trial data). [CDISC]	Model
C50072	modem		From modulator/ demodulator; a device that converts digital data into analog data that can be transmitted via telephone or cable lines used for communications.	Modem Device
C103246	moiety		An entity that has a complete and continuous molecular structure and is part of a substance. The active moiety of the molecule is the basis for the physiological or pharmacological action of the drug substance. NOTE: The strength of a pharmaceutical product is often based on what is referred to as the active moiety. [after ISO 11238 2012-11 on Regulated information on Substances]	Chemical Moiety
C41201	monitor		Person employed by the sponsor or CRO who is responsible for determining that a trial is being conducted in accordance with the protocol and GCP guidance. NOTE: A monitor's duties may include, but are not limited to, helping to plan and initiate a trial, assessing the conduct of trials, and assisting in data analysis, interpretation, and extrapolation. Monitors work with the clinical research coordinator to check all data and documentation from the trial. [from ICH E6, 5.18] See also clinical research associate.	Study Monitor
C61256	monitoring		Act of overseeing, tracking, observing, or supervising something over a period of time in order to see how it develops, so that any necessary changes can be identified and made, whether performed by a person, device or system. See also subject monitoring, medical monitoring, study monitoring, trial monitoring.	Monitoring

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C115753	monitoring plan		A document that describes the strategy, methods, responsibilities, and requirements for monitoring the trial. NOTE: The term refers to the documented plan for site monitoring performed by the CRA(s). [After ICH E6(R2) Glossary, 1.64]	Clinical Trial Monitoring Plan
C142708	monitoring report		A written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs. [ICH]	Study Monitoring Report
C142709	monitoring visit		A visit to a study site to review the progress of a clinical study and to ensure protocol adherence, accuracy of data, safety of subjects, and compliance with regulatory requirements and good clinical practice guidelines. [from ICH E6, 5.18]	Study Monitoring Visit
C142611	multicenter study		See multicenter trial.	Multi-Institutional Clinical Study
C16104	multicenter trial		Clinical trial conducted according to a single protocol but at more than one site and, therefore, carried out by more than one investigator. [ICH E9 Glossary] See investigator/ institution.	Multi-Institutional Clinical Trial
C156635	mutual recognition procedure (MRP)		The EU procedure to be used when a product is already authorized in at least one Member State and the Marketing Authorization Holder wishes to obtain a Marketing Authorization (MA) for the same product in at least one other Member State. The Member State that has already authorized the product is known as the Reference Member State (RMS). The RMS submits their evaluation of the product to other Member State/s, these are known as Concerned Member State/s (CMS). If the applicant is successful, the CMS will then issue a MA for that product permitting the marketing of that product in their country. [After Heads of Medicines Agencies (HMA) website http://www.hma.eu/medicinesapprovalsystem.html] See also Reference Member State (RMS) and Concerned Member State (CMS).	Mutual Recognition Procedure
C142614	n-of-1 study		A trial in which an individual subject is administered a treatment repeatedly over a number of episodes to establish the treatment's effect in that person, often with the order of experimental and control treatments randomized.	N-of-1 Study
C142612	natural language		Language as used in ordinary communications among humans and distinguished from controlled terminologies and structured languages used exclusively for communication and interoperability among machines.	Natural Language
C43515	NCI Enterprise Vocabulary Services (EVS)		A US national resource to house and maintain a number of health-related glossaries and controlled vocabularies under strict versioning. Provides resources and services to meet the National Cancer Institute's needs for controlled terminology, and to facilitate the standardization of terminology and information systems across the NCI and the larger biomedical community.	NCI Enterprise Vocabulary Services
C72899	New Drug Application (NDA)		An application to FDA for a license to market a new drug in the United States.	New Drug Application
C142613	new safety information		With respect to a drug, information derived from a clinical trial, an adverse event report, a post-approval study, or peer-reviewed biomedical literature; data derived from the post-market risk identification and analysis system (REMS); or other scientific data regarding: (a) a serious risk or unexpected serious risk associated with use of the drug since the drug was approved, since the REMS was required or last assessed (b) the effectiveness of the approved REMS for the drug obtained since the last assessment of such strategy. [After 21 CFR, Part 505-1(b)]	New Safety Information
C156651	NOEL (no observable effect level)		The dose of an experimental drug given preclinically that does not produce an observable toxicity.	No Observable Effect Level
C48298	nomenclature		Application of naming conventions. Compare to vocabulary, terminology.	Nomenclature
C142615	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 authorization. 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. [Clinical Trial Directive EC/20/2001 definitions]	Non-Interventional Study
C48678	nonclinical study		Biomedical studies not performed on human subjects. [ICH E6 (R2)]	Nonclinical Study
C142554	not approvable letter		An official communication from FDA to inform a sponsor of a marketing application that the important deficiencies described in the letter preclude approval unless corrected.	FDA Not Approvable Letter

C67497	CDISC Glossary			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C142545	Notified Body (NB)		A private institution charged by the Competent Authority with verifying compliance of medical devices (not drugs) with the applicable Essential Requirements stated in the Medical Device Directive. This process, called Conformity Assessment, has EU-wide validity once completed by the NB.	European Union Notified Body
C142616	null hypothesis		The assertion that no true association or difference in the study outcome or comparison of interest between comparison groups exists in the larger population from which the study samples are obtained. NOTE: A null hypothesis (for example, "subjects will experience no change in blood pressure as a result of administration of the test product") is used to rule out every possibility except the one the researcher is trying to prove, and is used because most statistical methods are less able to prove something true than to provide strong evidence that it is false. The assertion that no true association or difference in the study outcome or comparison of interest between comparison groups exists in the larger population from which the study samples are obtained. See also research hypothesis. [from AMA Manual of Style]	Null Hypothesis
C142617	Nuremberg Code		Code of ethics, set forth in 1947, for conducting human medical research.	Nuremberg Code
C142450	objective		The reason for performing a trial in terms of the scientific questions to be answered by the analysis of data collected during the trial. NOTE: The primary objective is the main question to be answered and drives any statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing). Secondary objectives are goals of a trial that will provide further information on the use of the treatment.	Clinical Trial Objective
C142618	objective measurement		A measurement of a physiological or medical variable such as blood glucose level that is obtained by a measuring device rather than a human judgment or assessment. See also outcome, patient-reported outcome; objective measures are observations (SDTM) and could be endpoints. Patient-reported outcomes are subjective measurements.	Objective Measurement
C116555	observation		1. an assessment of patient condition or analysis of data collected on an individual patient or group of patients. 2. (SDTM) a discrete piece of information collected during a study. NOTE: observations (meaning 1) are required by protocol (e.g., require evaluation of patient or data by investigator/staff). such planned observations are typically distinguished from anecdotal comments noted during a clinical trial (which qualify as observations under meaning 2). See also variable. Referring to an ad hoc comment as an observation is colloquial. [1. CONSORT statement. 2. SDTM]	Clinical Observation
C142619	observer assessment		An assessment of patient condition made by an observer (investigator, nurse, clinician, family member, etc.). NOTE: Distinguished from self-assessment. The observer relies on his or her judgment to assess the subject. an interviewer simply capturing subject self assessments is not making an observer assessment. Compare to PRO, proxy assessment.	Observer Assessment
C142620	observer-reported outcome (ObsRO)		A type of clinical outcome assessment. A measurement based on a report of observable signs, events or behaviors related to a patient's health condition by someone other than the patient or a health professional. [After FDA-NIH BEST Resource]	Observer-reported Outcome
C132346	official protocol title	scientific protocol title	The formal descriptive name for the protocol sufficient to describe key elements of the study, aimed at a scientific audience. NOTE: The official protocol title should include the study acronym, if applicable [WHO ICTRP]. The official protocol title should be sufficiently different from other official protocol titles to create brevity with specificity [NIH Protocol Template].	Official Protocol Title
C21270	ontology		An explicit formal specification of how to represent relationships among objects, concepts, and other entities that belong to a particular domain of experience or knowledge. See also terminology.	Ontology
C142621	open to enrollment		The status of a study such that a subject can be enrolled into that study. NOTE: Registry terminology in common use is "open to recruitment"; however, recruitment can begin upon IRB approval of the site; whereas enrollment requires availability of study supplies, subject informed consent, etc., to allow participation of eligible subjects.	Open To Enrollment
C49659	open-label study		A trial in which subjects and investigators know which product each subject is receiving; opposite of a blinded or double-blind study. See blinding.	Open Label Study
C142622	operational model		The set of CDISC data standards (including ODM and LAB) used to capture and archive data from clinical trials.	Operational Model
C142580	opinion (in relation to independent ethics committee)		The judgment and/or the advice provided by an independent ethics committee. [ICH E6 Glossary]	Independent Ethics Committee Opinion

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C142623	original data		The first recorded study data values. NOTE: FDA is allowing original documents and the original data recorded on those documents to be replaced by copies provided that the copies have been verified as identical in content and meaning. (see FDA Compliance Policy Guide 7150.13). [Modified from CSUICI] See also certified copy, source.	Original Data
C82521	other serious (important medical events)		A category of important medical events that may not be immediately life-threatening, result in death, or hospitalization, but may jeopardize the patient or may require intervention to prevent one of the outcomes criteria events requiring assessment for potential regulatory reporting as a serious adverse event. Note: These "Other serious" events require medical and scientific judgement in the determination of in evaluating the need for reporting as a serious adverse event. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events. [after FDA 310.305, ICH E2A] See also serious adverse event.	Other Medically Important Serious Event
C20200	outcome		1. events or experiences that clinicians or investigators examining the impact of an intervention or exposure measure because they believe such events or experiences may be influenced by the intervention or exposure. 2. (SDTM) The result of carrying out a mathematical or statistical procedure. NOTE: 1. such events and experiences are called clinical outcomes independently of whether they are part of the original question/protocol of the investigation. [1. Guyatt, G., Schunemann H., Dept. epidemiology & statistics, McMaster University-personal communication] See also variable; outcome can be a result of analysis; outcome is more general than endpoint in that it does not necessarily relate to a planned objective of the study.outcome. The measureable characteristic (clinical outcome assessment, biomarker) that is influenced or affected by an individual's baseline state or an intervention as in a clinical trial or other exposure. [BEST Resource]	Outcome
C49489	outcome (of adverse event)		Refers to the resolution of an adverse event. NOTE: often denoted using a pick list from a controlled terminology such as: Recovered/resolved, recovering/ resolving, not recovered/not resolved, recovered/resolved with sequelae, fatal, or unknown. [SDTM events class of observation]	Adverse Event Outcome
C15365	outcomes research		Research concerned with benefits, financial costs, healthcare system usage, risks, and quality of life as well as their relation to therapeutic interventions. NOTE: Usually distinguished from research conducted solely to determine efficacy and safety. [Guyatt et al., 1993] See also pharmacoeconomics, quality of life.	Outcomes Research
C79083	outliers		Values outside of an expected range.	Outlier
C50873	overdose		Administration of a quantity of a medicinal product given per administration or cumulatively, which is above the maximum recommended dose according to the authorised product information. [After, EU Guideline on good pharmacovigilance practices (GVP)]	Overdose
C44185	p-value		Study findings can also be assessed in terms of their statistical significance. The p-value represents the probability that the observed data (or a more extreme result) could have arisen by chance when the interventions did not differ. [CONSORT statement]	P-Value
C84731	packaging		The material, both physical and informational, that contains or accompanies a marketed or investigational therapeutic agent once it is fully prepared for release to patients and/or subjects in clinical trials	Packing
C142624	pairing	matching	A method by which subjects are selected so that two subjects with similar characteristics (for example, weight, smoking habits) are assigned to a set, but one receives Treatment a and the other receives Treatment B. See also matched-pair design.	Pairing
C82639	parallel trial	parallel design trial;parallel group trial	Subjects are randomized to one of two or more differing treatment groups (usually investigational product and placebo) and usually receive the assigned treatment during the entire trial.	Parallel Study
C44175	parameter		A variable in a model, or a variable that wholly or partially characterizes a probability distribution (mathematics and statistics). NOTE: in clinical trials the term is often used synonymously with 'variable' for factual information (age, date of recovery), measurements, and clinical assessments. it is most appropriately linked to statistical conventions and as a numeric characteristic of a population. Parameters are rarely known and are usually estimated by statistical computation from samples. Thus the term is narrower than variable. [Parexel Barnett; ADaM; HyperStat Online] See also variable, outcome.	Parameter

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C156779	participant		A person or entity with a role in a clinical study. NOTE: Participant is used with growing frequency in some clinical and patient-facing documents like the informed consent form, Plain Language Summaries of study results, and publications. Subject or patient are terms used in regulatory guidelines, databases, other clinical research documents, or systems to refer to study participants. See also human subject, patient, study participant.	Entity With Role in Clinical Study
C142626	password aging		A practice applying to multi-user computer systems where the validity of a password expires after a certain pre-set period. NOTE: FDA requires that passwords that are part of electronic signatures be "periodically checked, recalled or revised," but does not mandate password aging. [After NIST, 21 CFR 11]	Password Aging
C16960	patient		Person under a physician's care for a particular disease or condition. NOTE: A subject in a clinical trial is not necessarily a patient, but a patient in a clinical trial is a subject. See also subject, trial subject, healthy volunteer. Although often used interchangeably as a synonym for subject, a healthy volunteer is not a patient.	Patient
C142627	patient file		One that contains demographic, medical, and treatment information about a patient or subject. It may be paper- or computer-based or a mixture of computer and paper records.	Patient File
C95401	patient-reported outcome (PRO)		A type of clinical outcome assessment. A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. NOTE: A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response. Symptoms or other unobservable concepts known only to the patient can only be measured by PRO measures. PROs can also assess the patient perspective on functioning or activities that may also be observable by others. [After BEST Resource]	Patient Reported Outcome
C142635	per-protocol analysis set		The set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model. [ICH E9]	Per-Protocol Analysis Set
C142632	performance outcome (PerfO)		A PerfO is a measurement based on a task(s) performed by a patient according to instructions that is administered by a health care professional. NOTE: Performance outcomes require patient cooperation and motivation. These include measures of gait speed (e.g., timed 25 foot walk test), memory recall, or other cognitive testing (e.g., digit symbol substitution test). [After 1. FDA Clinical Outcome Assessment (COA) Glossary; 2. FDA-NIH BEST Resource]	Performance Outcome
C70900	performed activity		Clinical trial events as they actually occurred (as compared with events planned in the protocol).	Performed Clinical Study Activity
C142633	period effect		An effect occurring during a period of a trial in which subjects are observed and no treatment is administered.	Period Effect
C142634	permanent data		Data that become or are intended to become part of an electronic record in relation to a regulatory submission. NOTE: Any changes made to such permanent data are recorded via an audit trail so that prior values are not obscured.	Permanent Data
C41109	permissible values		Limited universe of options for data items. (e.g., drop-down menus, codelists, pick lists).	Permissible Value
C90492	personally identifiable information (PII)		Any information about an individual maintained by an agency (or group) including but not limited to, education, financial transactions, medical history, and criminal or employment history, which can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, biometric records, etc., including any other personal information that is linked or linkable to an individual. Used in US [NIST Special publication 800-122]	Personal Information
C42639	pharmaceutical product		Qualitative and quantitative composition of a medicinal product in the dose form authorized by the regulatory authority for administration to patients, and as represented with any corresponding regulated product information. NOTE: A medicinal product may contain one or more pharmaceutical products. In many instances, the pharmaceutical product is the manufactured item. However, there are instances where the manufactured item undergoes further preparation before being administered to the patient (as the pharmaceutical product). [After ISO 11615:2017, 3.1.60]	Finished Pharmaceutical Product
C15720	pharmacodynamics		Branch of pharmacology that studies reactions between drugs and living structures, including the physiological responses to pharmacological, biochemical, physiological, and therapeutic agents.	Pharmacodynamics

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C142636	pharmacoeconomics		Branch of economics that applies cost-benefit, cost-utility, cost-minimization, and cost-effectiveness analyses to assess the utility of different pharmaceutical products or to compare drug therapy to other treatments.	Pharmacoeconomics
C68761	pharmacogenetic test		An assay intended to study interindividual variations in DNA sequence related to drug absorption and disposition or drug action. Compare to pharmacogenomic test.	Pharmacogenetic Test
C16973	pharmacogenetics		Study of the way drugs interact with genetic makeup or the study of genetic response to a drug.	Pharmacogenetics
C68762	pharmacogenomic test		An assay intended to study interindividual variations in whole genome or candidate gene maps, biomarkers, and alterations in gene expression or inactivation that may be correlated with pharmacological function and therapeutic response. Compare to pharmacogenetic test.	Pharmacogenomic Test
C20050	pharmacogenomics		Science that examines inherited variations in genes that dictate drug response and explores the ways such variations can be used to predict whether a person will respond favorably, adversely, or not at all to an investigational product.	Pharmacogenomics
C15299	pharmacokinetics		Study of the processes of bodily absorption, distribution, metabolism, and excretion (ADME) of medicinal products.	Pharmacokinetics
C16974	pharmacology		Science that deals with the characteristics, effects, and uses of drugs and their interactions with living organisms.	Pharmacology
C142637	pharmacovigilance		Term used for adverse event monitoring and reporting. pharmacovigilance. Process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. NOTE: Pharmacovigilance is a key public health function that comprises: collecting and managing data on the safety of medicines; looking at the data to detect 'signals' (any new or changing safety issue); evaluating the data and making decisions with regard to safety issues; acting to protect public health (including regulatory action);communicating with stakeholders; auditing of both the outcomes of action taken and the key processes involved. [After IDMP]	Pharmacovigilance
C48281	phase		One in a set of successive stages in a progression or sequence such as 1. a step in the progression of a therapy from initial experimental use in humans to postmarket evaluation. 2. a stage in the conduct of a clinical trial. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. For meaning 1, see Phase 0-5. For meaning 2, see epoch.	Trial Phase
C54721	phase 0		First-in-human trials, in a small number of subjects, that are conducted before Phase 1 trials and are intended to assess new candidate therapeutic and imaging agents. The study agent is administered at a low dose for a limited time, and there is no therapeutic or diagnostic intent. NOTE: FDA Guidance for Industry, Investigators, and Reviewers: Exploratory IND Studies, January 2006 classifies such studies as Phase 1. NOTE: A Phase 0 study might not include any drug delivery but may be an exploration of human material from a study (e.g., tissue samples or biomarker determinations). [Improving the Quality of Cancer Clinical Trials: Workshop summary-Proceedings of the National Cancer Policy Forum Workshop, improving the Quality of Cancer Clinical Trials (Washington, DC, Oct 2007)]	Phase 0 Trial
C15600	phase 1		The initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. NOTE: These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase 2 studies. The total number of subjects and patients included in Phase 1 studies varies with the drug, but is generally in the range of 20 to 80. Phase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. [after FDA CDER handbook, ICH E8]	Phase I Trial
C15601	phase 2		Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. NOTE: Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. [after FDA CDER handbook, ICH E8]	Phase II Trial

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C49686	phase 2a		Controlled clinical studies that occur after the completion of Phase 1 studies and the first set of exposure-response studies in patients, and before beginning Phase 2b (i.e., patient dose-ranging trial) and Phase 3 clinical efficacy-safety studies. [FDA draft Guidance for industry end of Phase 2a meetings, 9/08].	Phase IIa Trial
C15602	phase 3		Studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather the additional information about effectiveness and safety that is needed to confirm efficacy and evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. NOTE: Phase 3 studies usually include from several hundred to several thousand subjects. [after FDA CDER handbook, ICH E8]	Phase III Trial
C49689	phase 3b		A subcategory of Phase 3 trials done near the time of approval to elicit additional findings. NOTE: Dossier review may continue while associated Phase 3b trials are conducted. These trials may be required as a condition of regulatory authority approval.	Phase IIIb Trial
C15603	phase 4		Post approval studies to delineate additional information about the drug's risks, benefits, and optimal use that may be requested by regulatory authorities in conjunction with marketing approval. NOTE: These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time. [after FDA CDER handbook, ICH E8]	Phase IV Trial
C47865	phase 5		Postmarketing surveillance is sometimes referred to as Phase 5. See also outcomes research.	Phase V Trial
C753	placebo		A pharmaceutical preparation that does not contain the investigational agent. in blinded studies, it is generally prepared to be physically indistinguishable from the preparation containing the investigational product.	Placebo
C17005	population		Any finite or infinite collection of subjects from which a sample is drawn for a study to obtain estimates for values that would be obtained if the entire population were sampled. [AMA style Manual]	Population Group
C142639	postmarketing commitment (PMC)		Studies and clinical trials that applicants have agreed to conduct, but that will generally not be considered as meeting statutory purposes (see postmarketing requirement) and so will not be required.	Postmarketing Commitment
C97025	postmarketing requirement (pMR)		FDA-required postmarketing studies or clinical trials. [FDAAA; 21 CFR Part 314, subpart h; 21 CFR Part 601, subpart e]	Post Marketing Requirement
C142640	postmarketing surveillance		Ongoing safety monitoring of marketed drugs. See also Phase 4 studies, Phase 5 studies.	Postmarketing Surveillance
C142641	pragmatic trial		Term used to describe a clinical study designed to examine the benefits of a product under real world conditions.	Pragmatic Trial
C70880	pre-market approval application (PMA)		An application to FDA for a license to market a new device in the United States.	Pre-market Approval Application
C142555	preamble		A section preceding the text of a final FDA regulation published in the Federal Register. NOTE: "The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue" raised in comments submitted in response to the proposed regulation. [from 21CFR10.40]	FDA Regulation Preamble
C142642	preclinical studies		Animal studies that support Phase 1 safety and tolerance studies and must comply with good laboratory practice (GLP). NOTE: Data about a drug's activities and effects in animals help establish boundaries for safe use of the drug in subsequent human testing (clinical studies or trials).	Preclinical Study
C142643	primary completion date		The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome [measure], whether the clinical trial concluded according to the pre-specified protocol or was terminated. NOTE: The primary completion date may or may not be the same as the study completion date. [ClinicalTrials.gov]	Primary Completion Date
C85826	primary objective		The primary objective(s) is the main question to be answered and drives any statistical planning for the trial (e.g., calculation of the sample size to provide the appropriate power for statistical testing). [ICH E6 6.3] See also objective.	Trial Primary Objective

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C142644	primary outcome variable		An outcome variable specified in the protocol to be of greatest importance to the primary objective of the trial, usually the one used in the sample size calculation. NOTE: Differences between groups in the primary and secondary variable(s) are believed to be the result of the group-specific interventions. [CONSORT Statement] See also primary objective, outcome, endpoint.	Primary Outcome Variable
C156637	privacy breach		A privacy breach is the loss of, unauthorized access to, or disclosure of, personal information. [Office of the Privacy Commissioner of Canada] See also serious breach.	Privacy Breach
C102988	PROMIS		NIH-sponsored project for the development and evaluation of PRO item banks and computer adaptive testing for pain, fatigue, physical function, social function, and emotional well-being. [NIH]	Patient Reported Outcomes Measurement Information System
C71898	proprietary name	brand name	A commercial name granted by a naming authority for use in marketing a drug/device product. [SPL]	Proprietary Name
C142646	prospective study		Investigation in which a group of subjects is recruited and monitored in accordance with criteria described in a protocol.	Prospective Study
C142647	protected personal data (PPD)		Any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identified directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, psychological, mental, economic, cultural or social identity. Used in Europe [EU Directive 95/46/EC]	Protected Personal Data
C142451	protocol	study 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 could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments. NOTE: Present usage can refer to any of three distinct entities: 1) the plan (i.e., content) of a protocol, 2) the protocol document, and 3) a series of tests or treatments (as in oncology). [ICH E6 Glossary]	Clinical Trial Protocol
C132347	protocol amendment(s)		A written description of a change(s) to or formal clarification of a protocol. NOTE: If a protocol modification is substantial, it may require notification to the regulatory authority. For example, substantial impacts on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial. [ICH E3; ICH E6 (R2) Glossary 1.45]	Protocol Amendment
C142648	protocol approval (Sponsor)		Sponsor action at the completion of protocol development that is marked when the signature of the last reviewer on the protocol approval form has been obtained, signifying that all reviewer changes to the protocol have been incorporated. NOTE: Approval by the sponsor usually initiates secondary approvals by IRBs, regulatory authorities, and sites. Protocol amendments usually also require a cycle of approval by sponsor and study staff prior to taking effect.	Protocol Approval by Sponsor
C50996	protocol deviation		A variation from processes or procedures defined in a protocol. Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety, and are often acknowledged and accepted in advance by the sponsor. NOTE: Good clinical practice recommends that deviations be summarized by site and by category as part of the report of study results so that the possible importance of the deviations to the findings of the study can be assessed. Compare to protocol violation. [See ICH E3]	Protocol Deviation
C132299	Protocol Identifying Number		Any of one or more unique codes that refers to a specific protocol. NOTE: There may be multiple numbers (National number, coop group number). [PR Project; EudraCT]	Protocol Identifier
C142650	protocol referenced documents		Protocol referenced documents that optionally supplement the ICH GCP recommended sections of a protocol giving background information and rationale for the trial. [from ICH E6 1.44] See also protocol.	Protocol Referenced Documents
C142185	protocol violation		A significant departure from processes or procedures that were required by the protocol. Violations often result in data that are not deemed evaluable for a per-protocol analysis, and may require that the subject(s) who violate the protocol be discontinued from the study. Compare to protocol deviation.	Protocol Violation
C142651	proxy (as an origin of outcome measures)		A proposed standardized qualifier variable to describe the origin of observations of the Findings class resulting from outcomes measures. Proxy describes outcome data furnished by someone other than the patient and distinguishes the origin of the outcome from a self-report (PRO) directly from the patient. NOTE: The term proxy helps qualify outcomes measures that record feelings and symptoms reported by the patient but not recorded directly. [CDISC (extension of SDTM based on Table 2 Patrick, D.L., 2003)] See also observer assessment.	Proxy Data Origin

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C142652	proxy respondent		Someone other than the patient who is responding about the patient on behalf of the patient, not as an observer. [Patrick, D.L., 2003; DIA ePRO Workgroup] Compare to observer assessment.	Proxy Respondent
C142653	proxy-reported outcome		A measurement based on a report by someone other than the patient reporting as if he or she is the patient. NOTE: A proxy-reported outcome is not a patient-reported outcome (PRO). FDA does not consider a proxy-reported outcome as a valid endpoint. [After FDA Clinical Outcome Assessment (COA) Glossary]	Proxy-reported Outcome
C142654	pseudonymization		A privacy preservation technique that both replaces the direct association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. Typically, psuedonymization is implemented by replacing direct identifiers (like the subject's name) with a pseudonym such as a randomly generated value. [ISO/TS 25237:2008]	Pseudonymization
C142655	psychometric reliability	reliability, psychometric	The degree to which a psychometric 'instrument' is free from random error either by testing the homogeneity of content on multi-item tests with internal consistency evaluation or testing the degree to which the instrument yields stable scores over time. NOTE: Reliability pertains to questions concerning whether an instrument is accurate, repeatable, sensitive. Reliability is distinguished from validation, which answers whether the instrument (e.g., questionnaire) actually measure the selected "construct" (latent variable). For example a balance (scale) is easily understood as a possibly valid instrument to measure body weight. Its reliability would be assessed by measuring the sensitivity, repeatability and accuracy of the balance. The validity of using the balance for a particular purpose could then be established by comparing the measured reliability to the reliability required for that purpose. [After Patrick, D.L., 2003] Compare to psychometric validation; see also validation; instrument.	Psychometric Instrument Reliability
C142656	psychometric validation	validity, psychometric	The specialized process of validating questionnaires used in outcomes research to show that they measure what they purport to measure. NOTE: Several types of validity are distinguished. For example, [Guyatt et al., 1993; DIA ePRO Workgroup] See also validation; compare to psychometric reliability.	Psychometric Validation
C17034	psychometrics		The science of assessing the measurement characteristics of scales that assess human psychological characteristics.	Psychometrics
C94105	public protocol title	brief protocol title;short protocol title	A brief description intended for the lay public in easily understood language. NOTE: Public title may also be referred to as "brief title." [Segen's Medical Dictionary]	Study Protocol Document Version Public Title
C142657	qualitative variable		One that cannot be measured on a continuum and represented in quantitative relation to a scale (race or sex, for example). Data that fit into discrete categories according to their attributes.	Qualitative Variable
C15381	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]	Quality Assurance
C15311	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]	Quality Control
C17047	quality of life (QoL)		A broad ranging concept that incorporates an individual's physical health, psychological state, level of independence, social relationships, personal beliefs, and their relationships to salient features of the environment. NOTE: Quality of life is one way to measure the benefits or negative impacts of an "improvement" measured in terms of a physiological or psychological symptom. QoL research seeks to quantify what an intervention means to a patient's sense that their life has changed. NOTE: See also definition from FDA eCOA Glossary. [WHO Group, 1994]	Quality of Life
C142658	quantitative variable		One that can be measured and reported numerically to reflect a quantity or amount, ideally on a continuum.	Quantitative Variable
C142480	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.	Data Item Query
C142481	query management		Ongoing process of data review, discrepancy generation, and resolving errors and inconsistencies that arise in the entry and transcription of clinical trial data.	Data Item Query Management
C142482	query resolution		The closure of a query usually based on information contained in a data clarification.	Data Item Query Resolution

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C17048	questionnaire		A set of questions or items shown to a respondent in order to get answers for research purposes. [PRO Draft Guidance] See also instrument, survey.	Questionnaire
C17049	race		An arbitrary classification of a taxonomic group that is a division of a species. It usually arises as a consequence of geographical isolation within a species and is characterized by shared heredity, physical attributes and behavior, and in the case of humans, by common history, nationality, or geographic distribution. (NCI)	Race
C142659	radiopharmaceutical medicinal product		Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose. [DIRECTIVE 2001/83/EC Article 1.(11)]	Radiopharmaceutical Medicinal Product
C142660	random allocation		Assignment of subjects to treatment (or control) groups in an unpredictable way. NOTE: in a blinded study, assignment sequences are concealed, but available for disclosure in the event a subject has an adverse experience.	Random Allocation
C142661	random number table		Table of numbers with no apparent pattern used in the selection of random samples for clinical trials.	Random Number Table
C142662	random sample		Members of a population selected by a method designed to ensure that each person in the target group has an equal chance of selection.	Random Sample Population
C25196	randomization		The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. NOTE: Unequal randomization is used to allocate subjects into groups at a differential rate; for example, three subjects may be assigned to a treatment group for every one assigned to the control group. [ICH E6 1.48] See also balanced study.	Randomization
C142663	raw data		Data as originally collected. Distinct from derived. Raw data includes records of original observations, measurements, and activities (such as laboratory notes, evaluations, data recorded by automated instruments) without conclusions or interpretations. Researcher's records of subjects/patients, such as patient medical charts, hospital records, X-rays, and attending physician's notes. NOTE: These records may or may not accompany an application to a Regulatory authority, but must be kept in the researcher's file. See also eSource, source data, source documents.	Raw Data
C142666	RCRIM		Regulated Clinical Research and information Management, which is a Technical Committee within HL7 (an acronym pronounced "arcrim").	Regulated Clinical Research and Information Management
C142712	reconstruction (of a study)		For eClinical trials FDA expects archival trial records to support review of the data as well as the processes used for obtaining and managing the data so that the trustworthiness of results obtained can be evaluated. NOTE: Reconstruction from records should support evaluation of the operation and validity of computerized systems and the conformance of the systems to applicable regulations during design and execution of the trial as well as during the period of record retention. [from CSUCT VI D, 21 CFR Parts 11, 312]	Study Reconstruction
C142590	recruitment (investigators)		Process used by sponsors to identify, select, and arrange for investigators to serve in a clinical study.	Investigator Recruitment Process
C78343	recruitment (subjects)		Process used by investigators to find and enroll appropriate subjects (those selected on the basis of the protocol's inclusion and exclusion criteria) into a clinical study.	Recruitment
C142664	recruitment period		Time period during which subjects are or are planned to be enrolled in a clinical trial	Recruitment Period
C142665	recruitment target		Number of subjects that must be recruited as candidates for enrollment into a study to meet the requirements of the protocol. in multicenter studies, each investigator has a recruitment target.	Recruitment Target
C80496	Reference information Model (RIM)		An information model used as the ultimate defining reference for all HL7 standards. [HL7]	Reference Information Model
C156641	reference member state (RMS)		A classification of a Member States in the Mutual Recognition Procedure (MRP) in the European authorization route resulting in a mutually recognized product. The first Member State that has authorized the product in the RMS. [After Heads of Medicines Agencies (HMA) website http://www.hma.eu/medicinesapprovalsystem .html] See also Mutual Recognition Procedure (MRP) and Concerned Member State (CMS).	Reference Member State

C67497	CDISC Glossary			
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C93453	registry		A data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions. NOTE: The registry should contain basic information about each trial sufficient to inform interested subjects (and their healthcare practitioners) how to enroll in the trial. [FDAMA 113]	Study Registry
C70868	regulatory application		Application made to a health authority to investigate, market, or license a new product or indication.	Regulatory Application
C88081	regulatory authorities	health authority	Bodies having the power to regulate. NOTE: In the ICH GCP guideline the term includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities. [ICH]	Regulatory Authority
C142667	repeat rule		Guide for repeating activities specified in protocol, including such features as the number of cycles and the criteria for stopping.	Repeat Activity Until Rule
C142738	replacement		The act of enrolling a clinical trial subject to compensate for the withdrawal of another.	Trial Subject Replacement
C142668	research hypothesis		The proposition that a study sets out to support (or disprove); for example, "blood pressure will be lowered by [specific endpoint] in subjects who receive the test product." See also null hypothesis.	Research Hypothesis
C142669	residual risk		In assessing the risk of re-identifying a trial participant, the risk that remains after controls are taken into account (the net risk or after controls). [Institute of Medicine report, Appendix B]	Residual Risk
C142670	response option		One of several choices to be available for selection in response to a prompt, question or instruction (i.e., a stem) in a PRO item. See also common data element, stem.	Response Option
C115629	result synopsis		The brief report prepared by biostatisticians summarizing primary (and secondary) efficacy results and key demographic information.	Clinical Study Report Synopsis
C142671	results posting (results submission)		The process of submitting and updating summary information about the results of a clinical study to a structured, publicly accessible, Web-based results database, such as the ClinicalTrials.gov results database. [ClinicalTrials.gov]	Results Posting
C142672	results posting date (results submission date)		The date and time the summary information about the results of the clinical study are submitted to a structured, publicly accessible, Web-based results database, such as the ClinicalTrials.gov results database. [ClinicalTrials.gov]	Results Posting Date
C142673	retrospective data capture		Capture of clinical trial data is retrospective when it is recalled from memory rather than captured contemporaneously in real-time. NOTE: Retrospective capture is important in PROs because of "recall bias" and other errors documented in psychological research comparing contemporaneous self-reported assessments and those that rely on recall from memory.	Retrospective Data Capture
C156652	RHIO (Regional Health Information Organization)		A group of organizations with a business stake in improving the quality, safety and efficiency of healthcare delivery. RHIOs are the building blocks of the proposed National Health Information Network (NHIN) initiative.	Regional Health Information Organization
C142718	risk		In clinical trials, the probability of harm or discomfort for subjects. NOTE: Acceptable risk differs depending on the condition for which a product is being tested. A product for sore throat, for example, will be expected to have a low incidence of troubling side effects. However, the possibility of unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.	Subject Risk
C142674	risk based monitoring		A systematic, prioritized, risk-based approach to monitoring clinical trials. [After ICH E6(R2), 5.18.3]	Risk Based Monitoring
C142414	role (CDISC classifier)		Classifier for variables that describe "observations" in the SDTM. Role is a metadata attribute that determines the type of information conveyed by an observation-describing variable and standardizes rules for using the describing variable. [SDTM]	CDISC Classifier Role
C38114	route of administration (ROA)		Path by which the pharmaceutical product is taken into or makes contact with the body. [After ISO 11615:2017, 3.1.76]	Route of Administration
C142675	SAFE		BioPharma(TM) Digital Identity and Signature Standard.	SAFE-Biopharma Standard
C60828	safety		Relative freedom from harm. In clinical trials, this refers to an absence of harmful side effects resulting from use of the product and may be assessed by laboratory testing of biological samples, special tests and procedures, psychiatric evaluation, and/or physical examination of subjects.	Safety

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C142676	safety and tolerability		The safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diseases, signs, and symptoms), and other special safety tests (e.g., ECGs, ophthalmology). The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject. [ICH E9]	Safety and Tolerability
C53190	sample size		A subset of a larger population, selected for investigation to draw conclusions or make estimates about the larger population.	Sample Size
C142677	sample size adjustment		An interim check conducted on blinded data to validate the sample size calculations or reevaluate the sample size.	Sample Size Adjustment
C115467	sample size calculation		A statistical calculation to determine the number of subjects required for the primary analysis, which should be large enough to provide a reliable answer to the questions addressed and should be determined by the primary objective of the trial. [After ICH E9, 3.5]	Sample Size Calculation
C132349	schedule of activities	Schedule of Events;SoA	A standardized representation of planned clinical trial activities including interventions (e.g., administering drug, surgery) and study administrative activities (e.g., obtaining informed consent, distributing clinical trial material and diaries, randomization) as well as assessments. See also schedule of assessments. Compare to study design schematic.	Schedule of Activities
C142678	schedule of assessments		A tabular representation of planned protocol events and activities, in sequence. [after E3 Annexes IIIa and IIIb] Compare to study design schematic.	Schedule Of Assessments
C49628	screen failure		Potential subject who did not meet one or more criteria required for participation in a trial. See also screening of subjects.	Trial Screen Failure
C142721	screen/screening (of substances)		Screening is the process by which substances are evaluated in a battery of tests or assays (screens) designed to detect a specific biological property or activity. It can be conducted on a random basis in which substances are tested without any preselection criteria or on a targeted basis in which information on a substance with known activity and structure is used as a basis for selecting other similar substances on which to run the battery of tests. [SQA]	Substance Screening
C142689	screening (of sites)		Determining the suitability of an investigative site and personnel to participate in a clinical trial.	Site Screening
C48262	screening (of subjects)		A process of active consideration of potential subjects for enrollment in a trial. See also screen failure.	Trial Screening
C71485	screening trials		Trials conducted to detect persons with early, mild, and asymptomatic disease.	Screening Study
C96999	script		A program or a sequence of instructions that are interpreted or carried out by another program or by a person.	Script
C85827	secondary objective		See objective.	Trial Secondary Objective
C142680	secondary outcome variable		Data on secondary outcomes are used to evaluate additional effects of the intervention. The primary outcome is the outcome of greatest importance. [after CONSORT statement] See also outcome, endpoint.	Secondary Outcome Variable
C142679	secondary sponsor		Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. [WHO, CTR item 6]	Secondary Sponsor
C142681	self-evident change		A data discrepancy that can be easily and obviously resolved on the basis of existing information on the CRF (e.g., obvious spelling errors or the patient is known to be a male and a date of last pregnancy is provided). See also discrepancy.	Self-Evident Change
C54194	semantic		In the context of a technical specification, semantic refers to the meaning of an element as distinct from its syntax. syntax can change without affecting semantics. [HL7]	Semantics
C142682	semantic interoperability		The ability of data shared by systems to be understood at the level of fully defined domain concepts. [ISO 18308]	Semantic Interoperability
C156653	SEND (standard for the exchange of nonclinical data)		The CDISC standard for the exchange of nonclinical data whose focus is on data collected from animal toxicology studies. [CDISC]	Standard for the Exchange of Nonclinical Data
C142683	sensitive data		Any data that, in the event of re-identification, would harm a patient in terms of employability, reputation, insurability, or self-esteem or results in loss of income. NOTE: Examples include history of alcoholism, drug abuse, risky behavior, or venereal disease. [HIPAA]	Sensitive Data

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C142685	serious adverse drug reaction		Adverse drug reaction that at any dose of the drug: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/ birth defect. NOTE: FDA 21 CFR 310.305 defines an adverse drug experience to include any adverse event, "whether or not considered to be drug-related." CDISC recognizes that current usage incorporates the concept of causality. [1. WHO Technical Report 498(1972); 2. After ICH E2A, B] See ICH E6 definition and serious and severe definitions.	Serious Adverse Drug Reaction
C41335	serious adverse event (SAE)		Adverse event that: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/ birth defect. NOTE: For further information, see the ICH Guideline for Clinical safety Data Management: Definitions and standards for expedited Reporting. [After ICH E2A, B] Compare to serious adverse drug reaction.	Serious Adverse Event
C142686	serious adverse experience (SAE)		Any experience that suggests a significant hazard, contra-indication, side effect or precaution. See also serious adverse event.	Serious Adverse Experience
C156636	serious breach		A breach of Clinical Trial Regulation (EU) No 536/2014 or of the version of the protocol applicable at the time of the breach, which is likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial. [Article 52 of Regulation (EU) 536/2014 and Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol] See also privacy breach.	Serious Breach
C142687	serious risk		Risk of a serious adverse drug experience. [505-1(b) of FD&C Act (21 USC. 355-1(b)]	Serious Risk
C48297	server		A computer that controls a central repository of data, files, and/ or applications that can be accessed and/or manipulated in some manner by client computers. NOTE: A file server hosts files for use by client machines. A web server supports browser-based use of central applications.	Server
C70667	severe		An adjective for grading intensity on a relative scale describing a symptom, outcome or event. Note: The term 'severe' is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as 'serious,' which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a patient's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations. [After ICH E2A, B] See also serious adverse event and serious adverse drug reaction.	Severe
C28421	sex		Phenotypic expression of chromosomal makeup that defines a study subject as male, female, or other. Compare to gender.	Sex
C2861	side effects		Any actions or effects of a drug or treatment other than the intended effect. negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. experimental drugs must be evaluated for both immediate and long-term side effects. See also adverse reaction.	Side Effect
C142688	signal of a serious risk		Information related to a serious adverse drug experience associated with use of a drug and derived from-(a) a clinical trial; (b) adverse event reports; (c) a post-approval study; (d) peer-reviewed biomedical literature; (e) data derived from the post-market REMs. [505-1(b) of FD&C Act (21 USC. 355-1(b)]	Signal of a Serious Risk
C28233	single-blind study	single-masked study	A study in which one party, either the investigator or the subject, does not know which medication or placebo is administered to the subject; also called single-masked study. See also blind study, double-blind study, triple-blind study.	Single Blind Study
C51873	site 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. [ICH E6 1.35. 2.] See also investigator.	Site Investigator
C53489	SNOMED (Systematized Nomenclature of Medicine)		A structured nomenclature and classification of the terminology used in human and veterinary medicine developed by the College of Pathologists and American Veterinary Medical Association. Terms are applied to one of eleven independent systematized modules.	Systematized Nomenclature of Medicine
C20188	social circumstances		A set of concepts that results from or is influenced by criteria or activities associated with the social environment of a person. [NCI]	Social Circumstances
C17146	software		Computer programs, procedures, rules, and any associated documentation pertaining to the operation of a system.	Computer Program

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C142690	software validation		Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled. NOTE: Validating software thus should include evaluation of the suitability of the specifications to "ensure user needs and intended uses can be fulfilled on a consistent basis" (21 CFR 820.20). General Principles of software Validation; Final Guidance for industry and FDA staff, Jan 11, 2002. ISOIEC/IEEE 12207:1995 3.35; 21 CFR 820.20; 21 CFR 11.10(a); ISO 9000-3; Huber, I. (1999) See also validation, verification. Verification usually concerns confirmation that specified requirements have been met, but typically refers to the tracing of requirements and evidence of conformance in the individual phases or modules rather than suitability of the complete product. Validation is, "the evaluation of software at the end of the software development process to ensure compliance with the user requirements" (ANSI/ASQC A3-1978) and should not be thought of as an "end-to-end" verification.	Software Validation
C91996	software verification		The process that provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. NOTE: Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated [After 1. FDA General Principles of Software Validation; 2. ANSI/ASQC A3-1978; 3. ISO/IEC 17025:2017]	Device Software Verification Evaluation Method
C25683	source		1. The specific permanent record(s) upon which a user will rely for the reconstruction and evaluation of a clinical investigation. 2. Sometimes used as shorthand for source documents and/or source data. NOTE: Accuracy, suitability, and trustworthiness are not defining attributes of "source." The term identifies records planned (designated by the protocol) or referenced as the ones that provide the information underlying the analyses and findings of a clinical investigation. See also original data, certified copy. [After ICH E6, CSUICI]	Source
C125442	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; CSUCT]	Clinical Trial Source Data
C142752	source data verification		The process of ensuring that data that have been derived from source data accurately represent the source data.	Source Data Verification
C142693	source document verification (SDV)		The process by which the information reported by an investigator is compared with the source records or original records to ensure that it is complete, accurate, and valid. [Schuyl and Engel, 1999; Khosla et al., Indian J. Pharm 32:180-186, 2000] See also data validation.	Source Document Verification
C142692	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 medicotechnical departments involved in the clinical trial). See also eSource document, source, original data, certified copy. [ICH; CSUICI]	Source Document
C18101	special populations		Subsets of study populations of particular interest included in clinical trials to ensure that their specific characteristics are considered in interpretation of data (e.g., geriatric). [FDA]	Special Population
C142694	specified substance		Substance defined by groups of elements that describes multi-substance materials or specifies further information on substances relevant to the description of Medicinal Products. NOTE: This could include grade, units of measure, physical form, constituents, manufacturer, critical manufacturing processes (e.g. extraction, synthetic or recombinant processes), specification and the analytical methods used to determine whether a substance is in compliance with a specification. [After ISO 11615:2017, 3.1.77]	Specified Substance
C70793	sponsor		An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. NOTE: If there is also a secondary sponsor, the responsible entity would be considered the primary sponsor. A corporation or agency whose employees conduct the investigation is considered a sponsor and the employees are considered investigators. [After ICH E6, WHO, 21 CFR 50.3 (e), and after IDMP] See also secondary sponsor.	Clinical Study Sponsor

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C142695	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. NOTE: The term does not include any person other than an individual (i.e., 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. [21 CFR 50.3f] [ICH]	Sponsor-Investigator
C81893	standard		Criterion or specification established by authority or consensus for 1. measuring performance or quality; 2. specifying conventions that support interchange of common materials and information. NOTE: CDISC standards exist to support the exchange of clinical data, for example, at both the syntactic and semantic levels. See interoperability.	Standard
C53322	standard deviation		Indicator of the relative variability of a variable around its mean; the square root of the variance.	Standard Deviation
C94396	standard of care		A guideline for medical management and treatment.	Best Practice
C48443	standard operating procedures (SOPs)		Detailed, written instructions to achieve uniformity of the performance of a specific function. [ICH]	Standard Operating Procedure
C142696	standard treatment		A treatment currently in wide use and approved by FDA or other health authority, considered to be effective in the treatment of a specific disease or condition.	Standard Treatment
C115761	statistical analysis plan		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 E9]	Statistical Analysis Plan
C53206	statistical distribution		A group of ordered values; the frequencies or relative frequencies of all possible values of a characteristic. [AMA Manual of Style]	Statistical Distribution
C19044	statistical method		The particular mathematical tests and techniques that are to be used to evaluate the clinical data in a trial. [ICH E9; from the Center for Advancement of Clinical Research]	Statistical Technique
C61040	statistical significance		State that applies when a hypothesis is rejected. Whether or not a given result is significant depends on the significance level adopted. For example, one may say "significant at the 5% level." This implies that when the null hypothesis is true there is only a 1 in 20 chance of rejecting it.	Statistical Significance
C142628	stem		The prompt, question, or instruction in a PRO item. See also response option, item.	Patient Reported Outcome Stem
C142697	stochastic		Involving a random variable; involving chance or probability.	Stochastic
C142698	stopping rules		A statistical criterion that, when met by the accumulating data, indicates that the trial can or should be stopped early to avoid putting participants at risk unnecessarily or because the intervention effect is so great that further data collection is unnecessary.	Stopping Rules
C25689	stratification		Grouping defined by important prognostic factors measured at baseline. [ICH E9]	Stratification
C142699	structured data		Structured health record information is divided into discrete fields, and may be enumerated, numeric, or codified. examples of structured health information include: patient address (non-codified, but discrete field); diastolic blood pressure (numeric); coded result observation; coded diagnosis; patient risk assessment questionnaire with multiple-choice answers. Context may determine whether or not data are unstructured, e.g., a progress note might be standardized and structured in some eHR-s (e.g., subjective/objective/ assessment/Plan) but unstructured in others. [HL7 eHR-s FM Glossary of Terms, 2010].	Structured Data
C142700	structured product label (SPL)		The structured product labeling (SPL) specification is an HL7 ANSI-approved document markup standard that specifies the structure and semantics for the exchange of product information. [HL7]	Structured Product Labeling
C70756	study completion		As defined in the protocol, the point at which all protocol-required activities have been executed. NOTE: According to EU CTR, this should be a clear and unambiguous definition of the end of the clinical trial in question and, if it is not the date of the last visit of the last subject, a specification of the estimated end date and a justification thereof should be included. [REGULATION (EU) No 536/2014 Article 2.26]	Study Completed
C142702	study completion date		The date on which the final data for a clinical study were collected because the last study participant made the final visit to the study location (that is, last subject, last visit, or as otherwise defined in the study protocol). NOTE: See also study completion date data element on ClinicalTrials.gov.	Study Completion Date

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C51880	study coordinator		See clinical research coordinator.	Study Coordinator
C142704	study description		Representation of key elements of study (e.g., control, blinding, gender, dose, indication, configuration).	Study Description
C15320	study design		Plan for the precise procedure to be followed in a clinical trial, including planned and actual timing of events, choice of control group, method of allocating treatments, blinding methods; assigns a subject to pass through one or more epochs in the course of a trial. specific design elements (e.g., crossover, parallel, dose-escalation) [Modified from Pocock, Clinical Trials: a Practical approach] See Trial Design Model. See also, arm, epoch, and visit.	Study Design
C142705	study design rationale		Reason for choosing the particular study design.	Study Design Rationale
C93682	study design schematic		Schematic diagram (not tabular) of study design, procedures, and stages. [example: ICH E3 annexes iiia and iiib] Compare to schedule of assessments.	Study Schematic
C139171	study initiation date (date of first enrollment)		Date and/or date and time of first subject enrollment into a study, as verifiable by a convention that is consistent with authoritative regulatory criteria. Compare to study start date. [Modified from ICH E3]	Date of First Enrollment into Study
C142707	study 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). [ICH E6 Glossary]	Study Monitoring
C142710	study participant		A member of the clinical study population from who data are being collected. NOTE: This new term is used with growing frequency in some clinical documents and patient-facing ones like the informed consent form, Plain Language Summaries of study results, and publications. Subject or patient are terms used in regulatory guidelines, databases, other clinical research documents, or systems to refer to study participants. See also human subject, patient, vulnerable subjects, human subject, data subject, clinical research subject, participant.	Study Participant
C70833	study population		Persons enrolled in a study who meet the inclusion/exclusion criteria as specified in the study protocol.	Study Population
C142711	study publication date		The date of the publication of scientific articles or abstracts about a clinical study. NOTE: Institute of Medicine (IOM) Report: The committee noted support for open and free access to scientific publications immediately upon publication, as well as the requirement of the U.S. Food and Drug Administration (FDA) to make a summary of clinical trial results available to the public. [ClinicalTrials.gov]	Study Publication Date
C142713	study report completion date		The date at which the study report is considered final and will not be subject to any further change prior to submission. NOTE: For interventional studies of adults the study report completion date should be one year from the end of the LPLV, or end of study; for pediatric interventional studies this date should be six months. For non-interventional studies the study report completion date should be one year from the end of the LPLV, end of study, or end of data collection. [EU CTR]	Study Report Completion Date
C142714	study start		The formal recognition of the beginning of a clinical trial that is referred to in the clinical study report.	Study Start
C69208	study start date		The date of formal recognition of the beginning of a clinical trial that is referred to in the clinical study report. NOTE: For example, The date that enrollment to the protocol begins. See study initiation date. [ClinicalTrials.gov]	Study Start Date
C41161	study treatment		See intervention.	Protocol Agent
C142192	study variable		A term used in trial design to denote a variable to be captured on the CRF. See also variable.	Study Variable
C54622	sub-investigator		Any 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). [ICH] See also investigator.	Subinvestigator
C70735	subject completion		The case where a subject ceases active participation in a trial because the subject has, or is presumed to have followed all appropriate conditions of a protocol.	Subject Completed Participation in Study
C142717	subject data event		A subject visit or other encounter where subject data are collected, generated, or reviewed. [SDTM]	Subject Data Event

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C70731	subject identification code		A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data. [ICH]	Clinical Trial Subject Unique Identifier
C156639	subject monitoring		Act of tracking, reporting, and review of a clinical trial subject's status and/ or performance of required activities per protocol. NOTE: Examples include monitoring compliance with treatment and scheduled tasks, tracking measures of symptoms, self reported feelings, and/or behaviors. Subject monitoring supports managing of patient safety and well being by site staff as defined in a protocol. Compare with medical device, medical monitoring.	Subject Monitoring
C142638	subject trial contact		Any activity, anticipated in the study protocol, involving a subject and pertaining to collection of data. See visit.	Planned Trial Subject Contact
C21089	subject-reported outcome (SRO)		An outcome reported directly by a subject in a clinical trial. [Patrick, D.l., 2003] See also patient-reported outcome (PRO).	Patient Self-Report
C142496	submission model		A set of data standards (including SDTM, ADaM, and define.xml) for representing data that are submitted to regulatory authorities to support product marketing applications. NOTE: CDISC submission data consist of: tabulations that represent the essential data collected about patients; analysis data structured to support analysis and interpretation; and metadata descriptions.	Data Submission Model
C142722	superiority trial		A trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control). [ICH E9]	Superiority Trial
C142459	supplier		An organization that enters into a contract with the acquirer for the supply of a system, software product, or software service under the terms of a contract. [ISO/IEC/IEEE 12207:1995 3.30]	Computer System or Software Supplier
C142723	supporting variables		See variable. [FDA Drug Review Glossary]	Supporting Variable
C68772	surrogate endpoint		An endpoint that is used in clinical trials as a substitute for a direct measure of how a patient feels, functions, or survives. A surrogate endpoint does not measure the clinical benefit of primary interest in and of itself, but rather is expected to predict that clinical benefit or harm based on epidemiologic, therapeutic, pathophysiologic, or other scientific evidence. [NIH-FDA BEST (Biomarkers, Endpoints, and other Tools) Resource, https://www.ncbi.nlm.nih.gov/books/NBK338448/]	Surrogate Endpoint
C142724	surrogate marker		A measurement of a drug's biological activity that substitutes for a clinical endpoint such as death or pain relief.	Surrogate Marker
C142725	surrogate variable		A variable that provides an indirect measurement of effect in situations where direct measurement of clinical effect is not feasible or practical. [ICH E9]	Surrogate Variable
C17176	survey		Any means (e.g., questionnaire, diary, interview script, group of items) that is used to collect PRO data. NOTE: survey refers to the content of the group of items and does not necessarily include the training and scoring documents generally not seen by respondents. [from ISOQOL comments on PRO Guidance] Compare to instrument.	Survey
C156631	suspension (of a clinical trial)		An interruption of the conduct of a clinical trial by a Member State of the EU. NOTE: Similar to FDA "clinical hold". [after EU CTR]	Clinical Trial Suspension
C68836	synopsis		Brief overview prepared at the conclusion of a study as a routine part of a regulatory submission, summarizing the study plan and results; includes numerical summary of efficacy and safety results, study objective, criteria for inclusion, methodology, etc. [after ICH E3]	Synopsis
C54277	syntactic		The order, format, content of clinical trial data and/or documents as distinct from their meaning. NOTE: Syntactic interoperability is achieved when information is correctly exchanged between two systems according to structured rules whether or not sensible meaning is preserved. See also semantic, semantic interoperability.	Syntax
C25700	system		People, machines, software, applications, and/or methods organized to accomplish a set of specific functions or objectives. [ANSI]	System
C53231	t-test		A statistical test used to compare the means of two groups of test data.	t-Test
C125429	table of roles and responsibilities		A cumulative record documenting operational access and authorizations of study personnel to electronic systems used in eClinical trials.	Clinical Trial Roles and Responsibilities Matrix
C142727	tabulation dataset		A dataset structured in a tabular format. NOTE: The CDISC Study Data Tabulation Model (SDTM) defines standards for tabulation datasets that fulfill FDA requirements for submitting clinical trial data.	Tabulation Dataset

C67497	CDISC Glossary			
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C49692	target enrollment		The number of subjects in a class or group (including the total for the entire trial) intended to be enrolled in a trial to reach the planned sample size. Target enrollments are set so that statistical and scientific objectives of a trial will have a likelihood of being met as determined by agreement, algorithm, or other specified process.	Planned Subject Number
C142728	target population		Population of patients to which the indication of a medicinal product applies. NOTE: The term applies to investigational and authorized medicinal products. [After ISO 11615.2012]	Target Study Population
C142729	technology provider	technology vendor	A person, company, or other entity who develops, produces, and sells software applications and/or hardware for use in conducting clinical trials and/or in analyzing clinical trial data and or submitting clinical trial information for regulatory approval.	Technology Provider
C156630	temporary halt (of a clinical trial)		An interruption not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it. [after EU CTR]	Clinical Trial Temporary Halt
C45559	term		One or more words designating something. NOTE: In a controlled vocabulary, terms are considered to refer to an underlying concept having a single meaning. Concepts may be linked to several synonymous terms.	Term
C142719	termination (of subject)		Now considered nonstandard. See discontinuation.	Subject Termination
C142739	termination (of trial)		Premature discontinuation of a trial prior to plan. [EU Clinical Trial Directive]	Trial Termination
C142730	terminology		Set of concepts, designations, and relationships for a specialized subject area. NOTE: In the context of clinical research in human subjects, a standardized, finite set of terms (e.g., CDISC Terminology, MedDRA codes) that denote patient findings, circumstances, events, and interventions. See also glossary, vocabulary. Contrast with nomenclature.	Terminology
C101302	therapeutic area		A group of diseases which have common characteristics (such as pertaining to the same organ or organ group (e.g., cardiology, neurology, gastrointestinal diseases) or have similar pathophysiology (immunology, oncology) and often are belonging to the field of expertise of a specific medical specialty. NOTE: This term is sometimes used for an individual disease in an medical field of expertise.	Therapeutic Area
C49236	therapeutic intervention		See intervention.	Therapeutic Procedure
C70919	Tmax		The time after dosing when Cmax occurs.	Tmax
C67478	token		Physical key that provides access to a secure electronic system or location.	Token
C142497	transcription		Process of transforming dictated or otherwise documented information from one storage medium to another. NOTE: often refers explicitly to data that is manually transcribed from source docs or measuring devices to CRFs or to eCRFs.	Data Transcription
C82567	transition rule		A guide that governs the allocation of subjects to operational options at a discrete decision point or branch (e.g., assignment to a particular arm, discontinuation) within a clinical trial plan. See branch.	Transition Rule
C80450	translation		Converting information from one natural language to another while preserving meaning. Compare to mapping.	Translation
C142499	transmit		To transfer data, usually electronically. NOTE: In eClinical investigations data are commonly transmitted from subjects to clinical study sites, within or among clinical study sites, contract research organizations, data management centers, and sponsors, or to regulatory authorities. [modified from CSUICI].	Data Transmission
C142731	treatment benefit		The impact of treatment as measured by survival or a COA of how patients feel or function. Direct evidence of treatment benefit is derived from clinical trial effectiveness endpoints that measure survival or a meaningful aspect of how a patient feels or functions in daily life. NOTE: Treatment benefit can be demonstrated by an advantage in either effectiveness or safety, or both. [After FDA Clinical Outcome Assessment (COA) Glossary]	Treatment Benefit
C142733	treatment-emergent adverse event		An event that emerges during treatment, having been absent pretreatment, or worsens relative to the pretreatment state. [ICH E9]	Treatment-Emergent Adverse Event

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C142735	trial design element		A basic building block for time within a clinical trial comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element.[CDISC PRM Project] See also epoch.	Trial Design Element
C142736	Trial Design Model		Defines a standard structure for representing the planned sequence of events and the treatment plan of a trial. NOTE: A component of the SDTM that builds upon elements, arms epochs, visits; suitable also for syntactic interpretation by machines. [CDISC] See study design.	Trial Design Model
C15789	trial monitoring		Oversight of quality of study conduct and statistical interim analysis. [ICH E9]	Clinical Trials, Monitoring
C85838	trial site		The location at which clinical trial activities are conducted. NOTE: Synonym for investigative site, investigator site, site, site of the trial, study site. [ICH E6 (R2)]	Clinical Trial Site
C142737	trial statistician		A statistician who has a combination of education/ training and experience sufficient to implement the principles in the ICH E9 guidance and who is responsible for the statistical aspects of the trial. [ICH E9]	Trial Statistician
C66959	triple-blind study		A study in which knowledge of the treatment assignment(s) is concealed from the people who organize and analyze the data of a study as well as from subjects and investigators.	Triple Blind Study
C142740	trustworthy (electronic records)		An attribute of records (data and documents) and signatures submitted to regulatory agencies referring to their suitability for making scientific findings of safety and efficacy that underlie public policy decisions pertaining to market authorization. Two key dimensions that determine the trustworthiness of eClinical trial data are data quality and data integrity. [after 21CFR Part 11]	Trustworthy Electronic Record
C45726	type 1 (or type I) error	false positive	Error made when a null hypothesis is rejected but is actually true.	False Positive
C93283	type 2 (or type II) error	false negative	Error made when an alternative hypothesis is rejected when it is actually true.	False Negative
C142741	type 3 (or type III) error		Some statisticians use this designation for an error made when calling the less effective treatment the more effective treatment.	Type 3 Error
C142576	type of comparison		How treatment arms will be compared (e.g., safety, efficacy, PK/PD). May also include comparison to data from other studies or sources (e.g., historical control). [ICH E9, EudraCT (p.18)]	ICH Type Of Comparison
C142742	unblinding		Identification of the treatment code of a subject or grouped results in studies where the treatment assignment is unknown to the subject and investigators.	Unblinding
C142743	unequal randomization		See randomization.	Unequal Randomization
C142744	unexpected adverse drug reaction		An adverse drug reaction, whose nature, severity, specificity, or outcome is not consistent with the term or description used in the applicable product information (e.g., IB for an unapproved investigational product or PI/summary of product characteristics for an approved product, and/or scientific literature). [After ICH E6 (R2)]	Unexpected Adverse Drug Reaction
C142745	unexpected serious risk		A serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically or pathophysiologically related to an adverse drug experience identified in the labeling, but differs because of greater severity, specificity, or prevalence. [505-1(b) of FD&C Act (21 USC. 355-1(b)	Unexpected Serious Risk
C42743	uniform resource locator (URl)		Address of a web page, for example, appliedclinicaltrialsonline.com.	Uniform Resource Locator
C81930	use case		An explicit scenario designed to help in determining whether a system/process is capable of performing the functions required for a particular use. a use case might describe, for example, how a study coordinator would use a tablet computer to capture medical history data.	Use Case
C156628	use error (device)		User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm. [FDA, Applying Human Factors and Usability Engineering to Medical Devices]	Device Use Error

C67497 CDISC Glossary

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C142746	user site testing (UST)		Any testing that takes place outside of the developer's controlled environment. NOTE: Terms such as beta test, site validation, user acceptance test, installation verification, and installation testing have all been used to describe user site testing. User site testing encompasses all of these and any other testing that takes place outside of the developer's controlled environment. [from General Principles of software Validation; Final Guidance, section 5.2.6]	User Site Testing
C71756	valid		1. Sound 2. Well grounded on principles of evidence. 3. able to withstand criticism or objection. [FDA Glossary of Computerized System and Software Development Terminology]	Valid
C16237	validation	validity	Process of establishing suitability to purpose. NOTE: Validation is accomplished by planning how to measure and/or evaluate suitability to purpose; then executing the plan and documenting the results. [ICH E6] See also software validation.	Validation
C54166	variable		Any entity that varies; any attribute, phenomenon, or event that can have different qualitative or quantitative values.	Variable
C48918	variance		A measure of the variability in a sample or population. It is calculated as the mean squared deviation (MSD) of the individual values from their common mean. In calculating the MSD, the divisor n is commonly used for a population variance and the divisor n-1 for a sample variance.	Variance
C45513	verification		The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements. Compare to validation where suitability to purpose is also established.	Verification
C142501	verification of data		The checking of data for correctness or compliance with applicable standards, rules, and conventions. [FDA Glossary of Computerized system and software Development Terminology] See also source document verification (SDV).	Data Verification
C39564	visit		A clinical encounter that encompasses planned and unplanned trial interventions, procedures, and assessments that may be performed on a subject. A visit has a start and an end, each described with a rule. [CDISC Trial Design Project]	Patient Visit
C92442	vocabulary		Terms that function in general reference to concepts that apply over a variety of languages are words, and their totality is a vocabulary. See also controlled vocabulary, terminology.	Vocabulary
C142747	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 patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. [ICH]	Vulnerable Subjects
C142556	Warning Letter		A written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes, or other activities to be in violation of the Federal FD&C Act, or other acts, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice. [FDA]	FDA Warning Letter
C42872	washout period		A period in a clinical study during which subjects receive no treatment for the indication under study and the effects of a previous treatment are eliminated (or assumed to be eliminated).	Washout Period
C142748	web browser		A computer program that interprets HTML and other Internet languages and protocols and displays web pages on a computer monitor.	Web Browser
C142749	web page		A single page on a website, such as a home page.	Web Page
C142750	web server		A computer server that delivers HTML pages or files over the World Wide Web. See also server.	Web Server
C67518	website		A collection of web pages and other files. A site can consist of a single web page, thousands of pages, or custom created pages that draw on a database associated with the site.	Web Site
C48192	weighting		An adjustment in a value based on scientific observations within the data.	Importance Weight

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C142720	well-being (of the trial subjects)		The physical and mental integrity of the subjects participating in a clinical trial. [ICH]	Subject Well-Being
C49634	withdrawal		The subject-initiated act of discontinuing participation in a clinical study. NOTE: Withdrawal can range from the subject's complete withdrawal from study procedures and follow-up activities, to the subject's withdrawal from study-related interventions while the subject permits continued access to his/her medical records or identifiable information. Note that according to FDA regulations, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. See also discontinuation.	Withdrawal by Subject
C67498	within-subject differences		In a crossover trial, variability in each subject is used to assess treatment differences.	Intra Subject Variability
C20461	World Wide Web		All the resources and users on the Internet that are using HTTP protocols. Also called the web and www.	World Wide Web