

COMMONLY USED CLINICAL RESEARCH TERMS

These clinical terms were sourced from the following documents/websites -

- 1 <http://www.cdisc.org/glossary/CDISC2008GlossaryVersion7.0.pdf>
- 2 <http://writing.colostate.edu/guides/research/glossary/>
- 3 <http://www.amfoundation.org/medresearch.htm>

Accuracy	A term used in survey research to refer to the match between the target population and the sample. ²
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. ¹
Analysis variable	Variables used to test the statistical hypotheses identified in the protocol and analysis plan; variables to be analysed. ¹
Apparency	Clear, understandable representation of the data. ²
Bias	Situation or condition that causes a result to depart form the true value in a consistent direction. Bias refers to defect in study design or measurement. ¹
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 of bias. ¹
Case Series	A type of case study that reports on at least five cases. This type of study is useful for indicating that a trend may be present and deserves more formal study. ³
Case Study	The collection and presentation of detailed information about a particular participant or small group, frequently including the accounts of subjects themselves. ²
Causality	The relation between cause and effect. ²
Causal Model	A model which represents a causal relationship between two variables. ²
Causal Relationship	The relationship established that shows that an independent variable, & nothing else, causes a change in a dependent variable. Establishes, also, how much of a change is shown in the dependent variable. ²
Central Tendency	These measures indicate the middle or centre of a distribution. ²
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. ¹

Cohort	Refers to a group of subjects who have some defining characteristic in common and who remain part of this group over an extended period of time. The common characteristic is suspected of being a precursor or risk factor for a disease or health effect. Since the direction of inquiry in cohort studies are forward in time, they are prospective studies. ³
Confidence Interval	Eg. 95%CI is a 95% probability that the true value of a variable (mean, rate etc) is contained within the interval. The 95%CI is the range of values in which it is 95% certain that the true value lies for the entire population. ¹
Confidence Interval	The range around a numeric statistical value obtained from a sample, within which the actual, corresponding value for the population is likely to fall, at a given level of probability. ²
Confidence Level	The specific probability of obtaining some result from a sample if it did not exist in the population as a whole, at or below which the relationship will be regarded as statistically significant. ²
Confidence Limits	(Same as confidence interval, but is terminology used by Lauer and Asher.) "The range of scores or percentages within which a population percentage is likely to be found on variables that describe that population" (Lauer and Asher, 58). Confidence limits are expressed in a "plus or minus" fashion according to sample size, then corrected according to formulas based on variables connected to population size in relation to sample size and the relationship of the variable to the population size--the larger the sample, the smaller the variability or confidence limits. ²
Confirmability	Objectivity; the findings of the study could be confirmed by another person conducting the same study. ²
Confounding Variable	An unforeseen and unaccounted-for variable that jeopardizes reliability and validity of an experiment's outcome. ²
Construct Validity	Seeks an agreement between a theoretical concept and a specific measuring device, such as observation. ²
Content Validity	The extent to which a measurement reflects the specific intended domain of content. ²
Context sensitivity	Awareness by a qualitative researcher of factors such as values and beliefs that influence cultural behaviours. ²
Continuous Variable	A variable that may have fractional values, e.g., height, weight and time. ²
Control Group	A group in an experiment that receives not treatment in order to compare the treated group against a norm. ²
Convergent Validity	The general agreement among ratings, gathered independently of one another, where measures should be theoretically related. ²

Correlation	1) A common statistical analysis, usually abbreviated as r , that measures the degree of relationship between pairs of interval variables in a sample. The range of correlation is from -1.00 to zero to +1.00. 2) A non-cause and effect relationship between two variables. ²
Covariate	A product of the correlation of two related variables times their standard deviations. Used in true experiments to measure the difference of treatment between them. ²
Credibility	A researcher's ability to demonstrate that the object of a study is accurately identified and described based on the way in which the study was conducted. ²
Criterion Related Validity	Used to demonstrate the accuracy of a measuring procedure by comparing it with another procedure which has been demonstrated to be valid; also referred to as instrumental validity. ²
Data	Recorded observations, usually in numeric or textual form. ²
Deductive	A form of reasoning in which conclusions are formulated about particulars from general or universal premises. ²
Dependability	Being able to account for changes in the design of the study and the changing conditions surrounding what was studied. ²
Dependent Variable	A variable that receives stimulus and measured for the effect the treatment has had upon it. ²
Deviation	The distance between the mean and a particular data point in a given distribution. ²
Discrete Variable	A variable that is measured solely in whole units, e.g., gender and siblings. ²
Discriminate Validity	The lack of a relationship among measures which theoretically should not be related. ²
Distribution	The range of values of a particular variable. ²
Equivalency Reliability	The extent to which two items measure identical concepts at an identical level of difficulty. ²
Experiment	Experimental Research A researcher working within this methodology creates an environment in which to observe and interpret the results of a research question. A key element in experimental research is that participants in a study are randomly assigned to groups. In an attempt to create a causal model (i.e., to discover the causal origin of a particular phenomenon), groups are treated differently and measurements are conducted to determine if different treatments appear to lead to different effects. ²

External Validity	The extent to which the results of a study are generalizable or transferable. See also validity ²
Face Validity	How a measure or procedure appears. ²
Factor Analysis	A statistical test that explores relationships among data. The test explores which variables in a data set are most related to each other. In a carefully constructed survey, for example, factor analysis can yield information on patterns of responses, not simply data on a single response. Larger tendencies may then be interpreted, indicating behaviour trends rather than simply responses to specific questions. ²
Generalisability	The extent to which research findings and conclusions from a study conducted on a sample population can be applied to the population at large. ²
Grounded theory	Practice of developing other theories that emerge from observing a group. Theories are grounded in the group's observable experiences, but researchers add their own insight into why those experiences exist. ²
Hypothesis	A tentative explanation based on theory to predict a causal relationship between variables. ²
Independent Variable	A variable that is part of the situation that exist from which originates the stimulus given to a dependent variable. Includes treatment, state of variable, such as age, size, weight, etc. ²
Inductive	A form of reasoning in which a generalized conclusion is formulated from particular instances. ²
Inductive analysis	A form of analysis based on inductive reasoning; a researcher using inductive analysis starts with answers, but forms questions throughout the research process. ²
Internal Consistency	The extent to which all questions or items assess the same characteristic, skill, or quality. ²
Internal Validity	(1) The rigor with which the study was conducted (e.g., the study's design, the care taken to conduct measurements, and decisions concerning what was and wasn't measured) and (2) the extent to which the designers of a study have taken into account alternative explanations for any causal relationships they explore (Huitt, 1998). In studies that do not explore causal relationships, only the first of these definitions should be considered when assessing internal validity. See also validity. ²
Interval Variable	A variable in which both order of data points and distance between data points can be determined, e.g., percentage scores and distances. ²

Interviews	A research tool in which a researcher asks questions of participants; interviews are often audio or video-taped for later transcription and analysis. ²
Link	In hypertext, a pointer from one node to another. ²
Matching	Process of corresponding variables in experimental groups equally feature for feature. ²
Mean	The average score within a distribution. ²
Mean Deviation	A measure of variation that indicates the average deviation of scores in a distribution from the mean: It is determined by averaging the absolute values of the deviations. ²
Median	The centre score in a distribution. ²
Mode	The most frequent score in a distribution. ²
Negative predictive value	The proportion of people with a <i>negative</i> test who have been correctly identified as <i>not</i> having the disease. ²
Nominal Variable	A variable determined by categories which cannot be ordered, e.g., gender and colour. ²
Normal distribution	A normal frequency distribution representing the probability that a majority of randomly selected members of a population will fall within the middle of the distribution. Represented by the bell curve. ²
Observational Studies	A study where one or more groups of patients or subjects are observed and characteristics about the patients are recorded. In this type of study, no intervention (e.g., drugs, procedures, or dietary restrictions) is introduced. Therefore, there are no control subjects. ³
Ordinal Variable	A variable in which the order of data points can be determined but not the distance between data points, e.g., letter grades. ²
Outliers	Data anomalies which are extreme from a univariate or multivariate perspective. ¹
Parameter	A coefficient or value for the population that corresponds to a particular statistic from a sample and is often inferred from the sample. ²
Phenomenology	A qualitative research approach concerned with understanding certain group behaviours from that group's point of view. ²
Placebo	A pharmaceutical preparation that contains no active agent. In blinded studies, it is generally made to look just like the active product. ¹
Population	The target group under investigation, as in all students enrolled in first-year composition courses taught in traditional classrooms. The population is the entire set under consideration. Samples are drawn from populations. ³

Positive predictive value (PPV)	The proportion of patients with a positive test result who are correctly diagnosed ie. The number of true positives divided by the total number who tested positive. ²
Predictive value	The proportion of people with a <i>positive</i> test results who have been correctly identified as <i>having</i> the disease. ²
Probability	The chance that a phenomenon has a of occurring randomly. As a statistical measure, it shown as p (the “p” factor). ²
Qualitative Research	Empirical research in which the researcher explores relationships using textual, rather than quantitative data. Case study, observation, and ethnography are considered forms of qualitative research. Results are not usually considered generalisable, but are often transferable. ²
Quantitative Research	Empirical research in which the researcher explores relationships using numeric data. Survey is generally considered a form of quantitative research. Results can often be generalised, though this is not always the case. ²
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 requirements. ¹
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. ¹
Quality of Life	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. ¹
Quasi-experiment	Similar to true experiments. Have subjects, treatment, etc., but uses nonrandomized groups. Incorporates interpretation and transferability in order to compensate for lack of control of variables. ²
Quixotic Reliability	Refers to the situation where a single manner of observation consistently, yet erroneously, yields the same result. ²
Random sampling	Process used in research to draw a sample of a population strictly by chance, yielding no discernible pattern beyond chance. Random sampling can be accomplished by first numbering the population, then selecting the sample according to a table of random numbers or using a random-number computer generator. The sample is said to be random because there is no regular or discernible pattern or order. Random sample selection is used under the assumption that sufficiently large samples assigned randomly will exhibit a distribution comparable to that of the population from which the sample is drawn. ²

Randomisation	Used to allocate subjects to experimental and control groups. The subjects are initially considered not unequal because they were randomly selected. ²
Range	The difference between the highest and lowest scores in a distribution. ²
Reliability	The extent to which a measure, procedure or instrument yields the same result on repeated trials. ²
Rigor	Degree to which research methods are scrupulously and meticulously carried out in order to recognize important influences occurring in an experiment. ²
Sample	The population researched in a particular study. Usually, attempts are made to select a "sample population" that is considered representative of groups of people to whom results will be generalized or transferred. In studies that use inferential statistics to analyze results or which are designed to be generalizable, sample size is critical--generally the larger the number in the sample, the higher the likelihood of a representative distribution of the population. ²
Screen/Screening	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 batter of tests. ¹
Selective Reduction	The central idea of content analysis. Text is reduced to categories consisting of a word, set of words or phrases, on which the researcher can focus. Specific words or patterns are indicative of the research question and determine levels of analysis and generalization. ²
Short-term observation	Studies that list or present findings of short-term qualitative study based on recorded observation. ²
Standard Deviation	A term used in statistical analysis. A measure of variation that indicates the typical distance between the scores of a distribution and the mean; it is determined by taking the square root of the average of the squared deviations in a given distribution. It can be used to indicate the proportion of data within certain ranges of scale values when the distribution conforms closely to the normal curve. ²
Study	Is a broad term inclusive of everything that can be examined objectively. Generally, there are two major classifications of studies, observational and experimental. ³
Survey	A research tool that includes at least one question which is either open-ended or close-ended and employs an oral or written method for asking these questions. The goal of a survey is to gain specific information about either a specific group or a representative sample of a particular group. Results are typically used to understand the attitudes, beliefs, or knowledge of a particular group. ²

Transferability	The ability to apply the results of research in one context to another similar context. Also, the extent to which a study invites readers to make connections between elements of the study and their own experiences. ²
Treatment	The stimulus given to a dependent variable. ²
Unique case orientation	A perspective adopted by many researchers conducting qualitative observational studies; researchers adopting this orientation remember every study is special and deserves in-depth attention. This is especially necessary for doing cultural comparisons. ²
Validity	The degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure. A method can be reliable, consistently measuring the same thing, but not valid. See also internal validity and external validity. ²
Variable	Observable characteristics that vary among individuals. See also ordinal variable, nominal variable, interval variable, continuous variable, discrete variable, dependent variable, independent variable. ²
Variance	A measure of variation within a distribution, determined by averaging the squared deviations from the mean of a distribution. ²
Variation	The dispersion of data points around the mean of a distribution. ²
Verisimilitude	Having the semblance of truth; in research, it refers to the probability that the research findings are consistent with occurrences in the "real world." ²