

# <u>A B C D E F G H I J K L M N O P Q R S T U V</u> W X Y Z

# A

### **Adverse Event**

An adverse outcome occurring during or after the use of a drug or other intervention but not necessarily caused by it.

Related Terms Side Effect Serious Adverse Event Adverse Drug Event

# **Applicability**

The extent to which the study results or effects of the study are appropriate and relevant for use in a particular patient situation (e.g., patient characteristics, clinical setting, resources, organizational issues)

External Validity Internal Validity Validity Reference Population

Related Terms

g., patient enaractionates, enrical cetting, recourses, enganizational leades

# Attrition

The loss of participants during the course of a study due to withdrawals, dropouts, or protocol deviations which potentially introduces bias by changing the composition of the sample.

Synonyms Dropout

Related Terms Lost to Follow Up

# B

### **Baseline Data**

Data which measures the outcome of interest prior to initiating any change or intervention

Related Terms
Baseline Characteristics

# C

# Case(s)

A person having a particular disease, disorder, or condition

# **Case-Control Study**

A study which involves identifying patients who have the outcome of interest (cases) and patients without the same outcome (controls), and looking back to see if they had the exposure of interest

# **Case Report**

A study reporting observations on a single individual

Synonyms Case Study Single Case

Related Terms
Case History
N-of-1

### **Case Series**

A report on a series of patients treated in a similar manner without a control group







# **Ceiling Effects**

Participants' scores that cluster toward the high end of a measure due to limitations in the design of the instrument not the phenomenon being observed

Related Terms
Floor Effects

### **Clinical Question**

A question developed to explore a focused clinical topic which contains specific elements: a patient or population; an intervention or exposure; often a comparison; and a specific outcome

Synonyms PICO Question Health Question

# **Clinically Significant**

A result (e.g. a treatment effect) that is large enough to be of practical importance to patients and healthcare providers, regardless of the degree of statistical significance. Assessing clinical significance takes into account factors such as the size of a treatment effect, the severity of the condition being treated, the side effects of the treatment, and the cost.

Related Terms
Statistically Significant

# **Cohort Study**

An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A prospective cohort study assembles participants and follows them into the future. A retrospective (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present. Because subjects are not allocated by the investigator to different interventions or other exposures, adjusted analysis is usually required to minimize the influence of other factors (confounders).

Related Terms
Confounder

# Comorbidity

The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes. (A co-morbidity may be a confounder.)

Related Terms
Confounder
Morbidity

### **Concurrent Validity**

Concurrent validity is demonstrated where a test correlates well with a measure that has previously been validated. The two measures may be for the same construct, or for different, but presumably related, constructs.

Synonyms
Convergent Validity

# **Confidence Interval (CI)**

Quantifies the uncertainty in measurement. It is usually reported as a 95% CI, which is the range of values within which we can be 95% sure that the true value for the whole population lies.

The CI reflects the precision of the result (e.g., odds ratio, relative risk). Wider CIs indicate less precision, narrow CIs indicate more precision.

# Synonyms Confidence Limits Related Terms Measures of Statistical Uncertainty Precision

### **Conflict of Interest**

A situation in which an individual or group is involved in multiple interests (concerns), and one or more interests could possibly affect the motivation for an action or interpretation regarding another interest. Also, within the biomedical research and publishing enterprise, these conflicts may occur when investigators, authors, institutions, reviewers, and/or editors have financial or nonfinancial relationships with other persons or organizations (eg, study sponsors) or personal investments in research projects or the outcomes of projects that may inappropriately influence their interpretation or actions. Conflicts of interest can lead to biased design, conduct, analysis, and interpretation of study results.





### Confounder

A factor that is associated with both an intervention (or exposure) and the outcome of interest

Confounding is a major concern in non-randomized studies. Randomization is used to minimize imbalances in confounding variables between experimental and control groups.

Confounders may be unequally distributed among the groups being compared and, if so, may distort the true relationship of the study variable of interest.

Related Terms
Adjusted Analysis

# **Construct Validity**

Construct validity reflects the degree to which an instrument measures the characteristic being investigated.

Related Terms
Factor Analysis
Concurrent Validity
Predictive Validity

# **Continuous Quality Improvement (CQI)**

A system that seeks to improve the provision of services with an emphasis on future results. Like total quality management (TQM), CQI uses a set of statistical tools to understand subsystems and uncover problems, but its emphasis is on maintaining quality in the future, not just controlling a process. Once a process that needs improvement is identified, a team of knowledgeable individuals is gathered to research and document each step of that process. Once specific expectations and the means to measure them have been established, implementation aims at preventing future failures and involves the setting of goals, education, and the measurement of results. If necessary, the plan may be revised on the basis of the results, so that the improvement is ongoing.

Synonyms Quality Improvement (QI) Process Improvement (PI)

Related Terms
FADE
Total Quality Management
(TQM)
Six Sigma
PDSA
(Plan, Do, Study, Act)

# **Control Group**

RCT/CCT: A group that does not receive the experimental intervention. In many studies, the control group receives either usual care or a placebo. The arm that acts as a comparator for one or more experimental interventions.

Case-Control Study: The group without the disease or outcome of interest.

Synonyms Comparison Group Control(s)

# **Controlled Clinical Trial (CCT)**

In both RCT and CCT, the investigator assigns the intervention or exposure. However, in CCT, allocation to treatment and control groups is not fully randomized or is less rigorous (e.g., quasi-randomization, no randomization mentioned) and may introduce bias into the study.

Synonyms
Quasi-Experimental Study
Pseudo-Experimental
Study
Clinical Trial

Related Terms

Nonrandomized Controlled

Trial

### Correlation

The magnitude and direction (i.e., positive, negative) of the association between two different variables or phenomena

# Credibility

In qualitative research, a term used instead of validity to reflect whether the investigators engaged thoroughly and sensitively with the material and whether the investigators' interpretations are credible. Signs of credibility can be found not only in the procedural descriptions of methodology but also through an assessment of the coherence and depth of the findings reported.

Related Terms
Validity

# **Critical Appraisal**

The process of assessing and interpreting evidence by systematically considering its validity, results and relevance

Synonyms Appraisal Evidence Appraisal







# Cronbach's Alpha (α)

Cronbach's alpha is a measure of internal consistency (i.e., how closely related a set of items on a measurement instrument are as a group).

Related Terms
External Validity
Internal Validity
Validity
Reference Population

# **Cross-Sectional Study**

The observation of a defined population at a single point in time or during a specific time interval. Exposure and outcome are determined simultaneously.

Related Terms
Economic Analysis

# D

# **Decision Analysis**

A systematic approach to decision making under conditions of uncertainty used to calculate the optimal strategy from among a series of all alternatives.

A quantitative estimate of the relative merit of the alternative strategies.

Related Terms
Economic Analysis

# **Demographic Characteristics**

Information describing characteristics of study participants (e.g., gender, race/ethnicity, age, comorbidities, geographical location)

Synonyms
Demographic Data
Descriptive Data

### **Descriptive Study**

A study which describes the characteristics or existing distribution of variables or certain phenomena without attempting to establish causality

### **Discounting**

Makes current costs and benefits worth more than those occurring in the future. An opportunity cost to spending money now and a desire to enjoy benefits now exists versus the future (e.g., if money is invested wisely now, it will be worth more in a year).

### **Domain of Inquiry**

A general category of qualitative study and its boundaries. An area of study with similar intents, functions and meanings.

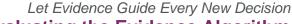
### **Dose-Response Relationship**

A relationship in which change in amount, intensity, or duration of exposure is associated with a change, either an increase or decrease, in a specified outcome.

# Ε

### **Economic Analysis**

A set of formal, quantitative methods used to compare two or more treatments, programs, or strategies with respect to their resource use and their expected outcomes





### **Effect Size**

The difference in outcomes between the intervention and control groups divided by some measure of variability, typically the standard deviation. Synonyms
Treatment Effect
Measure of Diagnostic
Accuracy

Related Terms

Odds Ratio Absolute Risk Reduction Relative Risk Relative Risk Reduction Number Needed to Treat Sensitivity Specificity Likelihood Ratio

# **Ethnography**

Qualitative Research: an approach to inquiry that focuses on the culture or subculture of a group of people to try to understand the world view of those under study

### **Exclusion Criteria**

The characteristics that render potential subjects ineligible to participate in a particular study or that render studies ineligible for inclusion in a systematic review.

### **Exposure**

A condition to which subjects are exposed (either a potentially harmful or a potentially beneficial one) that may have an impact on their health

### F

### **Face Validity**

The extent to which a measurement instrument appears to measure what it is intended to measure

### **Factor Analysis**

A set of statistical methods for analyzing the correlations among several variables in order to estimate the number of fundamental dimensions that underlie the observed data and to describe and measure those dimensions. Used frequently in the development of scoring systems for rating scales and questionnaires.

### **FADE**

A quality improvement model developed by Organizational Dynamics Institute (Wakefield, MA)

Four basic steps of the model include Focus, Analyze, Develop, and Execute (FADE). *Organization Dynamics Institute, Wakefield, MA* 

# Failure Mode and Effects Analysis (FMEA)

A failure modes and effects analysis (FMEA) is a procedure in product development and operations management for analysis of potential failure modes within a system for classification by the severity and likelihood of the failures. *Failure modes* are any errors or defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. *Effects analysis* refers to studying the consequences of those failures.





### **Field Notes**

Self-designed observational protocols for recording notes about field observations

### Floor Effects

Participant scores that cluster toward the low end of a measure, due to limitations in the design of the instrument not the phenomenon being observed

Related Terms Ceiling Effects

# Follow-Up (complete)

The observation over a period of time of study/trial participants to measure outcomes under investigation

Related Terms Ceiling Effects

### **Focus Group**

A small group selected from a wider population and sampled, as by open discussion, for its members' opinions about or emotional response to a particular subject or area.

# G

# **Grounded Theory**

The discovery of theory from data systematically obtained from social research

# Н

### Heterogeneous

A quality of being dissimilar in kind A state of having different characteristics and qualities Related Terms Homogeneity

# Homogeneous

Of the same or similar in kind

Related Terms Heterogeneity

### Incidence

The rate at which a certain event occurs, as the number of new cases of a specific disease occurring during a certain period in a population at risk

### Inclusion Criteria

A set of conditions that a person must meet in order to be eligible to participate in a research study

Related Terms Selection Criteria

### **Incremental Analysis**

Additional costs that one service or intervention imposes over another compared with the additional benefits it delivers





# **Intention to Treat Analysis**

A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol.

# Inter-Rater Reliability

The extent of agreement among raters on repeated ratings over time. There are a number of statistics which can be used to determine inter-rater reliability. Different statistics are appropriate for different types of measurement. Some options are joint-probability of agreement, Cohen's kappa and the related Fleiss' kappa, inter-rater correlation, concordance correlation coefficient and intraclass correlation.

Synonyms
Inter-Rater Agreement
Concordance

### Intra-Rater Reliability

The degree of stability exhibited when a measurement is repeated under identical conditions by the same rater. Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Lack of intra-rater reliability may arise from divergences between instruments of measurement, or instability of the attribute being measured.

# K

### **Key Driver Analysis**

Key driver analysis quantifies the relative influence of each causal variable onto perceived overall performance of a brand.

A correlational or regression analysis of survey variables which are expected to drive customer behavior in either a positive or negative direction.

# L

### Likelihood Ratio

The likelihood that a given test result would be expected in a patient with the target disorder compared to the likelihood that that same result would be expected in a patient without the target disorder

Related Terms Effect Size

# **Longitudinal Study**

A study of the same group of participants, processes, or systems at more than one point in time

(This type of study contrasts with a cross-sectional study, which observes a defined set of people at a single point in time.)

Synonyms Before-After Time Series

Related Terms
Cross-Sectional Study





# M

# **Measures of Statistical Uncertainty**

An estimate of the error in a measurement, often stated as a range of values that contain the true value within a certain confidence level, or the uncertainty of the result of a measurement expressed as a standard deviation

Synonyms
Precision
Measurement Error
Error Analysis

Related Terms
Confidence Interval
Standard Deviation

# Meta-Analysis

Performing statistical analyses to integrate and synthesize findings from completed studies and report a single pooled or summary estimate

# Meta-Synthesis

Synthesis of qualitative research involving the critical analysis of primary qualitative studies and synthesis of findings into a new theory or framework for the topic of interest

# **Mixed Methods Study**

Mixed methods research is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases in the research process. As a method, it focuses on collecting, analyzing, and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone.

# N

### **Narrative**

A qualitative study design that refers to distinct styles of generating, interpreting, and representing data as stories which provide insights into life experiences. It uses data collection methods whereby participants are asked to imagine or picture an event or sequence of events as a method of describing an experience.

### **Nonrandomized Controlled Trial**

A clinical trial in which the participants are not assigned by chance to different treatment groups. Participants may choose which group they want to be in, or they may be assigned to the groups by the researchers.

Related Terms
Controlled Clinical Trial

### Number Needed to Treat (NNT)

The number of people who would need to receive the experimental therapy to prevent one bad outcome or cause one additional good outcome.

Related Terms
Effect Size

### **Network Meta-Analysis**

Methodology used to evaluate different interventions across multiple clinical trials (randomized, controlled), including direct and indirect pairwise comparisons. A schematic network diagram may be used to represent associations or comparisons.

Related Terms Meta-Analysis Randomized Controlled Trial Systematic Review





# 0

# Odds Ratio (OR)

A measure of the odds of an event happening in one group compared to the odds of the same event happening in another group

Related Terms Effect Size

### **Outcome**

The variable(s) that the intervention is thought to change or influence (i.e. parameter, behavior or attitude)

Synonyms
Patient Outcome
Dependent Variable

### P

# **Pareto Analysis**

Pareto Analysis is a simple technique for prioritizing possible changes by identifying the problems that will be resolved by making these changes. By using this approach, you can prioritize the individual changes that will most improve the situation. Pareto Analysis uses the Pareto Principle – also known as the "80/20 Rule" – which is the idea that 20% of causes generate 80% of results. With this tool, we're trying to find the 20% of work that will generate 80% of the results that doing all of the work would deliver.

### **PDSA**

The PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act).

Synonyms
Small Test of Change

### p-Value

The probability that the null hypothesis is true. If a researcher finds the probability that the null hypothesis is less than 5 in 100, this is expressed as p < 0.05.

# **Phenomenology**

In qualitative research, an approach to inquiry that emphasizes the complexity of human experience and the need to understand the experience holistically as it is actually lived.

A philosophy and a group of research methods congruent with the philosophy

### **Power Analysis**

Procedure used for determining the sample size needed for a study

### **Precision**

Accuracy with which the population parameters have been estimated within a study

Also used to describe the degree of consistency or reproducibility of measurements with physiologic instruments





### **Predictive Validity**

An aspect of criterion validity.

The measurement's validity is expressed in terms of its ability to predict the criterion. An example is an academic aptitude test that is validated against subsequent academic performance.

### **Prevalence**

The proportion of a population having a particular condition or characteristic: e.g. the percentage of people in a city with a particular disease, or who smoke.

# **Prognostic Factors**

Demographic, disease-specific, or co-morbid characteristics associated strongly enough with a condition's outcomes to predict accurately the eventual development of those outcomes

Any factor (e.g., patient age, family history, lifestyle, stage of presentation) that is weighed in determining a prognosis

# **Prospective Study**

A study in which people are identified according to current risk status or exposure, and followed forwards through time to observe outcome.

Synonyms
Prospective Cohort
Study

# **Psychometric Study**

Evaluates the psychometric properties of a test instrument.

The word "psychometric" is used to describe any type of test which provides a reliable and valid measure of human traits such as aptitude, interest, and personality.

### **Purposeful Sampling**

In qualitative research, a sample which is intentionally selected according to the needs of the study. There are many variations (i.e., extreme or deviant case sampling, intensity sampling, maximum variation sampling, typical case sampling, snowball or chain sampling, theory-based sampling) and all may be seen as purposeful sampling.

Related Terms
Theoretical Sampling

# Q

### **Qualitative Research**

Qualitative research focuses on social and interpreted, rather than quantifiable, phenomena and aims to discover, interpret, and describe rather than to test and evaluate. Qualitative research makes inductive, descriptive inferences to theory concerning social experiences or settings, whereas quantitative research makes causal or correlational inferences to populations.

Synonyms
Qualitative Study

### **Quantitative Research**

The investigation of phenomena that lend themselves to test well-specified hypotheses through precise measurement and quantification of predetermined variables which yield numbers suitable for statistical analysis.

Synonyms

Quantitative Study





R

# Randomization

The random allocation of subjects of a clinical trial to the intervention and control groups using mechanisms, such as a random number table or a computer-generated random number list

Synonyms
Random Assignment

Related Terms
Random Allocation
Blinding

# **Randomized Controlled Trial (RCT)**

An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials, one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (e.g., in a household) or interventions are assigned within individuals (e.g., in different orders or to different parts of the body).

### Reference Standard

Any standardized clinical assessment, method, procedure, intervention or measurement of known validity and reliability which is generally taken to be the best available, against which new tests or results and protocols are compared.

Synonyms Gold Standard

### Relative Risk (RR)

The ratio (quotient) of the risk that an event will occur among the subjects exposed to a given factor and the risk that this event will occur among the subjects not exposed to this factor.

*Note:* A relative risk (RR) of 1 indicates that the risk is equal in the groups compared; an RR>1 indicates that the factor increases the risk; and an RR<1 indicates that the factor decreases the risk.

Synonyms Risk Ratio

Related Terms
Effect Size

# **Relative Risk Reduction (RRR)**

The proportional reduction in risk in one treatment group compared to another. It is one minus the risk ratio. If the risk ratio is 0.25, then the relative risk reduction is 1-0.25=0.75, or 75%.

Related Terms
Effect Size

# Reliability

The degree to which results obtained by a measurement procedure can be replicated. Lack of reliability can arise from divergences between observers or measurement instruments, measurement error, or instability in the attribute being measured.

Related Terms
Validity

### **Retrospective Study**

A study in which the outcomes have occurred to the participants before the study commenced.

*Note:* This type of study is more subject to bias than are prospective studies. Case-control studies are always retrospective, cohort studies sometimes are, and randomized controlled trials never are.

Related Terms
Prospective Study

### **Risk Factor**

An aspect of a person's condition, lifestyle or environment that affects the probability of an outcome (e.g., disease, variable of interest).



# Let Evidence Guide Every New Decision

# **Evaluating the Evidence Algorithm**

# Real World Data (RWD)

Data related to patient health status and/or the delivery of health care – may be collected from a variety of sources. Typically summarized as Real World Evidence. Differs from data collected primarily for research purposes.

Related Terms
Real World Evidence

# **Real World Evidence (RWE)**

Evidence about the usage and potential benefits or risks of a medical product or medication derived from analysis of Real-World Data and/or other study designs. May be observational / non-interventional study designs, which rely entirely on RWD

Synonyms
Observational Study

Related Terms
Real World Data

# S

# **Sample**

A selected subset of a population

### **Saturation**

Repetition of data obtained during the course of a qualitative study. Signifies completion of data collection on a particular culture or phenomenon. This evaluation criterion for a qualitative study asks the question: Was the data collected until there was no new information coming forth?

# Sensitivity

A measure of a screening/diagnostic test's ability to correctly detect people with the disease. It is the proportion of diseased cases that are correctly identified by the test.

It is calculated as follows:

Sensitivity = Number with disease who have a positive test / Number with disease

Synonyms
True Positive Rate

Related Terms
Specificity
Precision

### Six Sigma

Six Sigma is a business management strategy to improve the quality of process outputs by identifying and removing the causes of defects (errors) and minimizing variability in manufacturing and business processes. It uses a set of quality management methods, including statistical methods, and creates a special infrastructure of people within the organization. Each Six Sigma project carried out within an organization follows a defined sequence of steps and has quantified financial targets (cost reduction or profit increase).

### **SMART**

Specific, Measurable, Achievable, Realistic, Timely

### **Specificity**

A characteristic of the performance of a diagnostic test, defined as the proportion of persons with a negative test result among persons who do not have the disease.

It is calculated as follows: True Negatives ÷ (True Negatives + False Positives).

Related Terms
Accuracy
ROC Curve
Sensitivity
Effect Size





### **Standard Deviation**

A measure of the distribution of scores around the average (mean). In a normal distribution, two standard deviations above and below the mean includes about 95% of all samples.

# **Statistically Significant**

A result that is unlikely to have happened by chance. The usual threshold for this judgment is that the results, or more extreme results, would occur by chance with a probability of less than 0.05 if the null hypothesis was true. Statistical tests produce a p-value used to assess this.

Related Terms p-value

# Subgroup

An analysis in which the intervention effect is evaluated in a defined subset of the participants in a trial, or in complementary subsets, such as by sex or in age categories. Trial sizes are generally too small for sub-group analyses to have adequate statistical power. Comparison of sub-groups should be by test of interaction rather than by comparison of p-values. Sub-group analyses are also subject to the multiple comparisons problem.

Related Terms
Interaction
Multiple Comparisons
Stratification

### **Survival Curve**

A curve that starts at 100% of the study population and shows the percentage of the population still surviving (or free of disease or some other outcome) at successive times for as long as information is available.

# **Systematic Review**

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Synonyms Overview

### Т

### **Test-Retest Reliability**

Test-retest is a statistical method used to determine a test's reliability. The test is performed at least twice. In the case of a questionnaire, this would mean giving a group of participants the same questionnaire on two different occasions. If the correlation between separate administrations of the test is high, then it has good test-retest reliability.

Synonyms
Correlation Coefficient

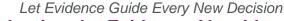
### **Theme**

Used to describe a structural meaning unit of data that is essential in presenting qualitative findings.

# **Theoretical Framework**

The basis upon which a study is guided; its purpose is to provide a context for selecting the study's variables, including how they relate to one another as well as to guide the development of an intervention in experimental studies.







# **TQM (Total Quality Management)**

An approach to the improvement of the provision of services based on the premise that the overwhelming majority of quality failures are the result of flaws in processes and that quality can be improved by controlling these processes. TQM involves creation of an organizational structure for identifying and improving processes, the use of data-based statistical analysis to study processes, and the empowerment of employees to take responsibility for their own tasks in a way that encourages both continuous learning and personal responsibility. In a health care setting, this means a shift from an emphasis on tasks to an emphasis on outcomes of care, which provide the data.

Synonyms
Continuous Quality
Improvement (CQI)

# U

### **Unit of Analysis**

The major entity that is being analyzed in the study It is the 'what' or 'whom' that is being studied. In social science research, typical units of analysis include individuals (most common), groups, social organizations and social artifacts.

Synonyms Statistical Unit

# V

### **Validity**

In health status measurement terms, validity is the extent to which an instrument measures what it is intended to measure. In critical appraisal terms, validity reflects the extent to which the study results are likely to be subject to systematic error and thus be more or less likely to reflect the truth.

In the context of a study, two types of validity are recognized: internal validity and external validity. In the context of measurement, there are several types of validity: construct validity, content validity, face validity, etc.

Synonyms
External Validity
Internal Validity

Related Terms
Methodologic Quality



# Let Evidence Guide Every New Decision

# **Evaluating the Evidence Algorithm**

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