Dictionary *for* Clinical Trials

Second Edition

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John Wiley & Sons, Ltd

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To Nikki, Anya *and* Huw

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Contents

Preface to the Second Edition

I had a simple hope (but perhaps a difficult one to achieve) that this *Dictionary for Clinical Trials* would be a helpful and pragmatic little reference book to a wide variety of people working in clinical trials. The first edition proved a great success. I am grateful to the various reviewers who made kind comments; I also respect one or two more critical reviewers who pointed out some shortfalls (indeed, one or two blatant errors); and I thank the many colleagues and friends who have given me positive feedback. Without doubt, one of the greatest compliments was from Professor Sakuma, who felt it worth the effort to translate the first edition into Japanese.

Overall that simple hope has been achieved but the science and business of clinical trials is still relatively young and fast-moving. I have therefore tried to update a little, to include terms that were only just emerging at the time of the first edition and to delete a few that are, perhaps, redundant. Of course, to the best of my ability I have corrected the known errors. I have also introduced numerous commonly used abbreviations (and their meanings). These were an intentional omission from the first edition (with only one or two privileged exceptions) but they now enjoy an equal status in this second edition.

I hope this second edition continues to be helpful to a wide variety of 'doers' and 'consumers' of clinical trials.

Preface to the First Edition

It is now fifty years since the British Medical Research Council published the results of a trial entitled 'Streptomycin treatment of pulmonary tuberculosis' (*British Medical Journal*, 30 October 1948, pp. 769–782). That study is widely regarded as the first randomized clinical trial. Earlier examples of non-randomized studies are cited, notably that of J. Lind (*A Treatise on the Scurvy*, 1753). Despite such a history and the enormous numbers of trials conducted and published in the last twenty or so years, many people do not consider 'clinical trials' as a discipline in its own right and, as such, the breadth of terms that should be covered in a dictionary of this kind is not well defined. Ultimately, the choice of entries is a personal one, guided by experiences of what I have had to learn and what my colleagues in various specialities of the clinical trials spectrum have struggled to understand. Additionally I have trawled clinical trial protocols, reports, regulatory guidelines and published manuscripts to try to cover the majority of terms that are likely to be encountered. A lot of the terminology of clinical trials is statistical: terms used for the design (blocks, randomization, stratification) and for the analysis (confidence interval, P-value, survival analysis, t test, to list but a few). I make no apology for the high proportion of statistical terms: those are usually the ones that are least well understood. Overall though, the content is broad and it is very difficult to summarize what is covered.

It is almost as difficult to summarize what isn't covered. This is not a dictionary of medical terms, of statistical terms, of epidemiological, ethical or data management terms. It does, however, contain elements of all those disciplines, the first three in particular. Many of the epidemiological terms included would not ordinarily be found in a clinical trial protocol or report; however, in the discussion of whether a clinical trial is appropriate for answering a particular medical question, or in discussion of trial results alongside other sources of evidence, the issue of other approaches such as case-control studies and cohort studies is likely to be discussed. I have not included specific diseases (a medical dictionary would be more appropriate) or names of clinical rating scales but I have included a variety of medical terms that are frequently assumed to be understood (terms such as acute, chronic, subcutaneous, etc.). Abbreviations

are not included, except in the few instances where a term is better known by its acronym than by its full name (COSTART and MedDRA are obvious examples). Nor are the names of professional or scientific societies, research institutions or regulatory authorities included.

The intended readership for this dictionary are all those people who work with clinical trial protocols and reports or who otherwise need to understand the use of language in this specialist area. Such a readership includes clinical trialists (those people who actually carry out the various administrative, clerical and scientific aspects), those who sit on ethics committees, those who work in regulatory departments or grant awarding bodies, doctors, nurses, pharmacists (and patients) reading clinical trial reports and so on. Trials sponsored by the pharmaceutical industry, as well as those conducted by academic institutions or by small groups of enthusiasts, all fall within the scope of this work, as do community-based intervention studies, vaccine trials, and studies of medical practice and medical devices. Necessarily, many entries will be more relevant to some types of trials and trialists than to others. I hope the coverage is adequate without being too cumbersome.

The style of explanations and definitions is aimed at being pragmatic and readable rather than purist. Pre-existing definitions (often in regulatory guidelines) have not necessarily been faithfully reproduced, although care has been taken to incorporate the essential meaning from relevant guidelines. As an example, the term 'adverse event' has a very specific definition within the International Conference on Harmonisation although the explanation given here is a little more brief. Further examples of pragmatism abound in the explanations of some statistical terms. Many statisticians may challenge the correctness of my explanations of analysis of covariance, Bayesian statistics or *P*-value, for example: I apologize to them in advance but hope that the explanations I have given will help those readers who understand little or nothing of such terms to at least gain a rough and ready grasp of their meaning. Similarly, 'ethics' is covered in a mere two lines: there are other related entries but the aim is to get the essential meaning across. Full and complete explanations of all the terms included would mean this work taking on the scale of a series of text books and that is not the intention. I hope that the explanations give here, put in the context where the word or expression has arisen, will allow most readers to unravel most uncertainties.

In my defence over accuracy and quality control I can claim that every single entry has been reviewed by a variety of my colleagues; and in their defence I acknowledge that every single error, discrepancy and inconsistency remains my responsibility.

The Ground Rules

The following is a brief guide to what's in and what's not in, and rules for cross-referencing related or alternative terms.

In general, *study* is used rather than *trial* except where the distinction is helpful (strictly speaking, study encompasses trial but many types of study will not be trials). Similarly, *trial* is taken to mean *clinical trial*. For example, *acute study* is listed, but not *acute trial* or *acute clinical trial*.

Phrases may sometimes be abbreviated but, I hope, without causing any difficulty in finding them. For example, *adaptive design* should be taken to encompass *adaptive trial design* and *adaptive clinical trial design*.

Where alternative terms may be used interchangeably I have tried to pick the most common term to define and its synonyms will simply direct you there with the symbol ≈. For example, *alpha error* simply says '≈ *type I error*' (where an explanation is given). The most important terms used within the definition of other terms are emboldened, as are references to contrasting terms (⇔ . . .) and related terms (⇨ . . .). I hope that sometimes giving an indication of contrasting or related terms may help understanding. It is inevitable, however, that some definitions will be circular: *active control* contrasts with (⇔) *placebo control*; *placebo control* contrasts with (⇔) *active control*. Ultimately, just as with all dictionaries, all definitions must use the terms herein to explain other terms and the circularity becomes inevitable.

Bibliography

There is a variety of books written about clinical trials, and several other dictionaries and glossaries that may prove helpful in defining terms and clarifying their use. The following titles have proved particularly helpful in compiling this dictionary and may serve as useful additional sources of reference.

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A

a posteriori after the event; generally referring to decisions made or actions taken after data or results of a study have been seen. ⇔ ***a priori***. ⇨ **Bayes' theorem**, **posterior distribution**

a priori before the event; generally referring to decisions made or beliefs held before data or results of a study have been seen. Such decisions or beliefs may be based on data from previous studies or subjective feeling based on informal clinical experience. ⇔ ***a posteriori***. ⇨ **prespecify**, **Bayes' theorem**, **prior distribution**

Abbé plot ≈ **L'Abbé plot**

abscissa ≈ ***x* axis**. ⇔ **ordinate** (or ***y* axis)**

absolute change the numerical difference between two numbers as in, for example, **change from baseline**. ⇔ **relative change**

absolute frequency the number of items or the number of occurrences of a specified event. Often abbreviated simply to frequency. ⇔ **relative frequency**

absolute risk the number of events (deaths, adverse reactions, etc.) divided by the number of individuals who could have experienced the event (or the number of people 'at risk' of the event). ⇔ **relative risk**

absolute value a numerical value that ignores any positive or negative sign; for example, the absolute value of $+3$ is $+3$; the absolute value of -3 is also $+3$

absorption the process by which drug enters the blood stream. ⇔ **clearance**, **elimination**

absorption study a study that measures the process of (particularly the time taken for) drug to be absorbed into the blood stream

accelerated failure time model a statistical model used in **survival analysis** that assumes the effect of one treatment is to multiply the median **survival time** for patients randomized to that treatment relative to that of patients randomized to another treatment. ⇔ **Cox's proportional hazards model**

acceptance error the error of accepting a statement (usually a **null hypothesis**) when that statement or hypothesis is false. ⇔ **rejection error**. ⇨ **producer's risk**, **Type II error**

acceptance region the values of a **test statistic** (for example, calculated values of t in a ***t* test** or of chi-squared in a **chi-squared test**) that lead to accepting the **null hypothesis**. ⇔ **rejection region**. ⇨ **critical value**

accountability taking responsibility for one's own actions. ⇨ **drug accountability**, **patient accountability**

accrual rate ≈ **recruitment rate**

accrue to gather or accumulate (often with respect to patients, data or information)

accumulate to collect more and more (usually patients, and usually in the sense of data, information, etc.) over time

accumulating data when more and more data are available as time progresses. Usually used in the context of **sequential analysis** or **group sequential analysis**

accuracy nearness of an **observed value** to its **true value** (even if the true value may never be known). Also used with respect to a measurement process to describe how closely that process measures the true quantity. ⇔ **precision**

accurate close to the **true value**. ⇔ **precise**

ACES **active control equivalence study**

active control a **comparator group** in a study that receives an **active treatment**. ⇔ **placebo control**

active control equivalence study (ACES) a study designed to show **therapeutic equivalence** between two active products

active ingredient the pharmacologically or biologically active parts of product (the tablet, capsule, etc.) ⇨ **formulation**, **presentation**

active treatment generally means a noninert pharmacological product or biological substance (not a **placebo**). The term is also sometimes used to describe the treatment of primary interest, rather than a comparator (but still active) treatment

actuarial method ≈ **life table analysis**

acute rapid onset and short lasting. A disease may be acute (for example chicken pox) as opposed to chronic (for example diabetes). Sometimes the term is used to describe part of a study that is used to treat immediate symptoms of the disease of interest, in contrast to a long-term **follow-up period** looking for relapse or long-term drug safety. Such a short-term part of a study is sometimes called the acute phase of the study. ⇔ **chronic**

acute episode short-term appearance of symptoms of an underlying **chronic**

(long-lasting) illness. For example, bronchitis may be a chronic illness with acute episodes

acute phase see **acute**. ⇔ **follow-up period**

acute study short-term study (usually of a long-lasting disease). ⇔ **chronic study**

acute toxicity study a study to investigate the short-term **toxicity** of a product, usually a single dose of a drug. ⇔ **repeated dose toxicity study**. ⇨ **reproductive and developmental toxicity study**

ad hoc one off. Something unique to a particular problem

adaptive design study procedures that change as the study progresses. An example is that of the **randomization** process changing as the study progresses and results become known. Such designs are used so that, if it appears that one treatment is emerging as superior to another, the **allocation ratio** can be biased in favour of the treatment that seems to be best. ⇨ **dynamic allocation**

adaptive inference conclusions that can be made as data and information accumulate. Although this seems obvious, in many studies conclusions are drawn only once at the end of the study; adaptive inference may draw conclusions as the study progresses

adaptive randomization ≈ **adaptive design**

adaptive treatment assignment ≈ **adaptive design**. ⇨ **minimization**

additive model a statistical model where the combined effect of separate variables contributes as the sum of each of their separate effects. ⇔ **multiplicative model**. ⇨ **interaction**

ADE **adverse drug experience**

adequate and well controlled a term describing a comparative study that is sufficiently large, properly **randomized** and **blinded**

adherence the extent to which patients (or sometimes investigators) follow the study **protocol**. ⇨ **compliance**

adjust to modify (usually the estimate of a **treatment effect**) to account for differences in patient characteristics between treatment groups. ⇨ **adjusted estimate**

adjusted estimate an estimate of a **parameter** as would have been observed at some specified value of another variable. For example, high blood pressure (and its treatment) may be related to age and so we may wish to estimate the effect of a drug on people of different ages. ⇨ **analysis of covariance**

adjuvant therapy extra treatment given to enhance the effect of a **monotherapy**. For example, sensitizing drugs to enhance the effect of radiotherapy. ⇨ **concomitant medication**

administer to give (in the sense of giving treatment)

administrative review a review of (usually accumulating) study data where the purpose is to monitor practical aspects of the study's progress (such as **recruitment rates**, shipment of laboratory samples, etc.) ⇔ **interim analysis**

admission criteria ≈ **inclusion criteria**

ADR **adverse drug reaction**

ADROIT **Adverse Drug Reaction Online Information Tracking**

adverse drug experience (ADE) ≈ **adverse event**

adverse drug reaction (ADR) ≈ **adverse reaction**

Adverse Drug Reaction Online Information Tracking (ADROIT) a database kept of **adverse reactions** to marketed products

adverse event (AE) any (usually) unwanted effect that a subject experiences while taking a drug. Note that **causality** is not implied. ⇔ **adverse reaction**

adverse experience ≈ **adverse event**

adverse reaction ⇨ **adverse event** but note that **causality** to a particular drug is implied

adverse treatment effect ≈ **adverse reaction**

advocate to support a given argument, opinion or point of view

AE **adverse event**

aetiology the cause of a disease or the study of disease causality

agency ≈ **regulatory authority**

aggregate to combine separate data values into groups of **aggregate data**

aggregate data data that have been grouped in categories. For example, all ages of patients in the range 0 to 5 put into one category, ages 6 to 12 in another category, etc.

agonist a drug that enhances or activates the effect of a natural body chemical or of another drug. ⇔ **antagonist**

algorithm a written description of a mathematical equation or **decision rule**. It is usually written partially in words (although not necessarily in complete and proper sentences) rather than just a set of mathematical expressions

all patients treated analysis usually the same as **intention-to-treat analysis**, but would exclude any patients who did not receive any study treatment

all patients treated population all of the patients who have received any study medication ⇔ **intention-to-treat population**

all subsets regression a method of deciding which variables should be in a **regression model**. ⇨ **backward elimination**, **forward selection**

allocate to assign (typically a treatment to a patient) either by **randomization** or by some other method

allocation ratio in a **parallel group study** the ratio of the number of patients

allocated to one treatment group relative to the number allocated to another treatment group. Most often, the ratio is 1 : 1, or **equal allocation**

alpha (α) the probability of making a **Type I error**. ⇔ **beta** (β). ⇨ **significance test**

alpha error ≈ **Type I error**

alpha level ≈ **alpha (α)**

alpha spending function a method in **sequential studies** such that the times when **interim analyses** are performed do not need to be specified in advance. The number of, and timing of, interim analyses can be flexible

alphanumeric data that may be alphabetical (a, b, c, . . . , A, B, C, . . . , including special symbols such as +, £, %) or numeric (0, 1, 2, . . . 9)

alternate allocation a method of assigning treatments to patients whereby the first patient receives Treatment A, the second receives Treatment B, the third Treatment A, the fourth Treatment B and so on in a predictable (alternating) manner. ⇔ **random allocation**

alternative hypothesis (H_1) this is usually the point of interest in a study. It is generally phrased in terms of the **null hypothesis** (of no treatment effect) not being true. If the objective of a study is to 'compare Drug A with placebo' then the null hypothesis would be that there is no difference between the two treatments and the alternative hypothesis would be that there *is* a difference

alternative medicine approaches to medicine such as homeopathy, acupuncture, herbal medicines, etc., considered by many people to be non-conventional medicines

altruism putting the interests of the individual first; specifically in clinical trials, putting the interests of the individual before those of the research project. ⇨ **collective ethics**, **individual ethics**

amendment ≈ **protocol amendment**

ampoule ≈ **vial**

analysis the process of summarizing data or problems, describing them clearly (possibly including plotting data) and drawing conclusions

analysis by administered treatment a strategy where data are summarized and conclusions drawn based on the treatment that patients were actually given (not necessarily the treatment they were assigned to receive). ⇔ **analysis by randomized treatment**

analysis by assigned treatment ≈ **analysis by randomized treatment**

analysis by randomized treatment a strategy where data are summarized and conclusions drawn based on the treatment that patients were supposed to be given (the treatment they were randomized to receive), regardless of

what they actually took. It is very similar to the term **intention-to-treat**. ⇔ **analysis by administered treatment**

analysis of covariance (ANCOVA) a statistical analysis method that is an extension of **analysis of variance**. It allows estimates of **treatment effects** to be adjusted for possible **covariates** as well as **factors**

analysis of variance (ANOVA) a statistical analysis method that allows comparison of two or more treatment groups and estimates of **treatment effects** to be adjusted for other possible **factors** such as race, gender, treatment centre, etc. It is a very general method covering a very broad range of techniques and can be used in a great variety of situations. Because of this, to describe a method of analysis as being 'analysis of variance' is rarely sufficient to adequately describe what analysis has actually been carried out

analysis policy ≈ **analysis strategy**

analysis population the set (often subset) of patients recruited to a study who are subsequently included in the data analysis. Examples are the **all patients treated population**, **per protocol population**

analysis strategy this combines the decision whether to use an **all patients treated analysis**, an **intention-to-treat analysis**, a **per protocol analysis**, or some other policy, and considerations such as whether to use, for example, **parametric methods** or **nonparametric methods**, **Bayesian inference** or **frequentist inference**

Anatomical Therapeutic Chemical (ATC) a classification system of **indications** for drugs and biologics which describes the action that the product has (Table 1).

ANCOVA **analysis of covariance**

anecdotal evidence unsubstantiated evidence that cannot be strongly relied on. It is usually considered as more informed than mere opinion and often used as a means of generating ideas and research questions

aneugen a substance that causes **toxic effects** on DNA. ⇨ **clastogen**

angular transformation a transformation applied to data that are of the form of **proportions** to allow use of statistical methods based on the **Normal distribution**. Where the proportion is p, the transformation is $y = \arcsin(\sqrt{p})$. ⇨ **logistic function**, **probit transformation**

animal model results from experiments in (nonhuman) animals, used to extrapolate results to humans

animal study a study carried out in (nonhuman) animals. ⇨ **preclinical study**

ANOVA **analysis of variance**

antagonist a drug that prevents or reverses the effect of a natural body chemical or of another drug. ⇔ **agonist**

Table 1 Anatomical Therapeutic Chemical codes

Code	Drug acting on which part of the body?
A	Alimentary tract and metabolism
B	Blood and blood forming organs
C	Cardiovascular system
D	Dermatological
G	Genito-urinary system and sex hormones
H	System hormonal preparations (excluding sex hormones and insulins)
J	Anti-infectives for systemic use
L	Antineoplastic and immunomodulating agents
M	Musculo-skeletal system
N	Nervous system
P	Antiparasitic products, insecticides and repellents
R	Respiratory system
S	Sensory organs
V	Various

antedependence model a statistical method for analysing a series of **repeated measurements** on the same individuals. The method describes the data based (partly) on earlier measurements

applicable regulatory requirements requirements of a **regulatory authority** that are either general to all studies or apply specifically to the experimental or geographical circumstances relevant to a particular study

approval the process of an individual or group of individuals with appropriate authority agreeing to a request. This may take the form of approving a **protocol**, a submission to a **research ethics committee**, a submission to a **regulatory authority**, etc.

approximate close to the **true value**. Note that the 'true' value may not be known and the interpretation of 'close' may vary from one situation to another, so this is a rather vague term

approximation a method of estimating a **parameter** that gives an **approximate** answer

archive to keep a historical record in secure conditions to confirm the data obtained and the procedures that were followed during the course of a study. ⇨ **backup**

arcsin transformation ≈ **angular transformation**

area under the curve (AUC) a **summary measure** of data that have been collected repeatedly over time. The data are plotted with time on the ***x***

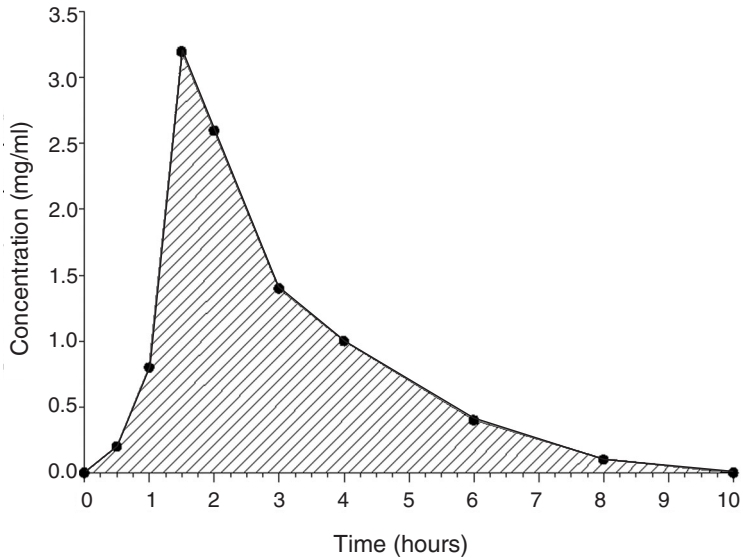

Figure 1 Area under the curve. Plot of serum concentration of drug on ten occasions up to 10 hours after administration. The area under the curve is shaded. Other features to note are $C_{max} = 3.2$ mg/ml and $t_{max} = 1.75$ hours

axis and the measurement on the ***y* axis**. The area is that between the line connecting the data points and the x axis (Figure 1)

arithmetic mean $\approx$ **mean**

arm synonym for group (as in **randomized group**)

artefact an aspect of data that is not substantiated in other data sets and is not a real effect

ascending order data sorted so that the smallest value comes first, the larger values later and the largest value last. This can be applied to **alphanumeric** data (by sorting into alphabetic order with special rules for including numbers and special symbols) as well as **numeric** data. $\Leftrightarrow$ **descending order**. $\Rightarrow$ **ranked data**

ascertainment bias bias caused due to the manner in which data are collected. For example, surveying the general incidence of health problems near a doctor's surgery would probably lead to an unreasonably high

proportion of respondents indicating less than perfect health; in contrast, surveying near a health club might lead to an unreasonably low proportion of respondents with impaired health

ASCII a standard set of **alphanumeric** characters that is widely transferable between different computers. It stands for American Standard Code for Information Interchange

assay a procedure to measure the quantity of a chemical (usually drug) in a sample (usually of blood or urine)

assay sensitivity a term used particularly in **equivalence** trials and **non-inferiority** trials. It describes the ability of the trial to show treatment effects, if they exist. For example, a very imprecisely measured **endpoint** may fail to show a difference between treatments, even if it exists. A study using such an endpoint would be said to have poor (or no) assay sensitivity

assent agreement to something in a passive way and not after thorough consideration of the advantages and disadvantages. Note that clinical trials usually need subjects to **consent** to take part, not just assent

assessment measurement of the state of disease. This may be a measurement of blood pressure, severity of depression, **quality of life**, etc.

assign ≈ **allocate**

assigned treatment the treatment that a patient is due to receive based on a **randomization** (or other) procedure

associate an assistant (often in the sense of a **subinvestigator**)

associate investigator ≈ **subinvestigator**

association a means by which two items are linked. For example, there is a link (or association) between smoking and lung cancer. ⇨ **correlation**

assumption a state (often a feature of data) that is taken as true although there may not be sufficient evidence to guarantee that state. A common assumption is that data come from a **Normal distribution**

asymmetric not symmetric, as in not evenly split around the middle. The term is often used about **distributions** of data that are **skewed**

asymptote a value that is never achieved but that is approached more and more closely. For example, repeatedly dividing a number by two will get closer and closer to zero but will never actually attain that value: in this case, zero is the asymptote

asymptotic method a statistical method that assumes there is a large sample of data and which may not be suitable with small samples

ATC **Anatomical Therapeutic Chemical**

atopy indicates that an allergic disease such as asthma, eczema, etc. is hereditary rather than being a spontaneous new case

attenuation making extreme results or statements less extreme and more typical of the norm

attributable risk ≈ **risk difference**

attribute characteristic or feature (usually of a patient). All variables (age, sex, pulse, serum calcium, etc.) are attributes

attrition loss; often used to describe loss of patients' data in long-term studies due to patients withdrawing for reasons other than those of meeting the study's **primary endpoint**

AUC **area under the curve**

audit a systematic review of data and operational details or study procedures. ⇔ **inspection**

audit certificate a certificate to confirm that a study has been audited

audit report a report (written or verbal) describing the findings of an **audit**. Such findings are usually restricted to points that do not meet expected standards of quality or completeness (rather than all aspects that do meet the expected standards)

audit trail a list of reasons and justifications for all changes that are made to data or documents, and of all procedures that do not comply with agreed study procedures

auditor a person responsible for carrying out an **audit**

autocorrelation correlation between **repeated measurements** taken successively in time from the same subject

autoencoding an automatic (usually by computer) method of assigning **codes** to data, for example codes for drugs or **adverse events**

autoregressive a description of a process that produces data collected sequentially in time when each data point is potentially related (or **correlated**) with the previous one(s)

average informal term for the **mean**

average absolute deviation ≈ **mean absolute deviation**

average deviation ≈ **average absolute deviation**

axis the scale (***x* axis** or ***y* axis**) on a graph

B

back titration reducing the dose of a drug until a desired effect is seen. ⇔ **up titration**

backup a reserve (often used in the sense of a reserve copy of data) kept under secure conditions in case of loss or corruption of the original. A more readily available and less permanent version of an **archive**

backward elimination a method of finding which **variables** should be kept in a **regression model** by first including all possible variables and then removing ('eliminating') those that are deemed not useful. ⇔ **forward selection**, **all subsets regression**

backward stepwise regression ≈ **backward elimination**

bacterium single-celled microscopic organism; the cause of many diseases

Balaam's design a type of **crossover design** where patients are **randomly** assigned to receive treatments A and B in one of the sequences AA, BB, AB or BA

balance the state of being equal, usually with reference to the number of subjects in each **treatment group**. ⇨ **balanced design**

balanced block part of an experiment (one **block** of it) such that within that block, the effect of each treatment is estimated with equal **precision**

balanced design an experiment in which the effect of each of the treatments is assessed with equal **precision**, usually by having the same number of subjects in each treatment group. Note that, in **crossover designs**, balance refers to there being as many **treatment sequences** AB as there are BA

balanced incomplete block design an experiment in which not all treatments being compared are represented in every **block** but where, overall, the occurrence of each treatment across all the blocks is the same (or **balanced**)

balanced randomization a **randomization** method which ensures that the effect of each treatment is estimated equally precisely, usually by assigning the same number of patients to each treatment group. ⇔ **unequal randomization**

balanced study a study that uses **balanced randomization**

bandit design ≈ **adaptive design**

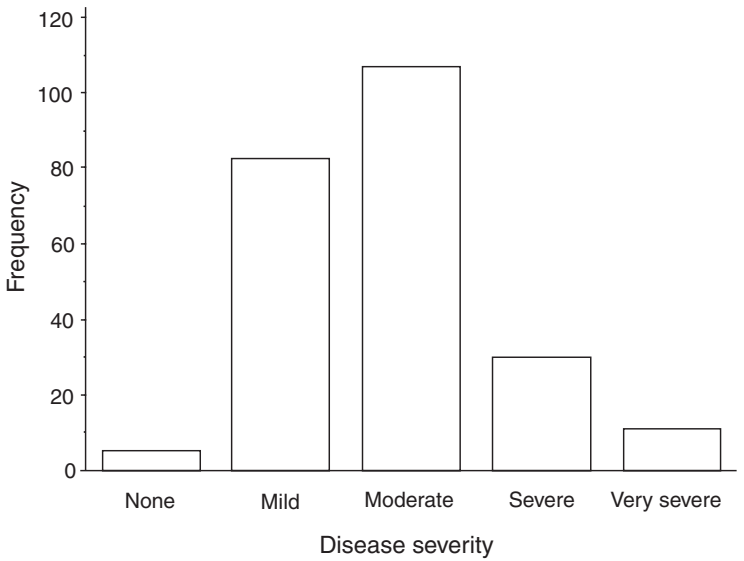

Figure 2 Bar chart. The number of patients who fall into each of the five categories is represented by the height of each bar

bar chart a graphical method of showing the number of subjects that fall into each of two or more **categories**. The height of each 'bar' is proportional to the number of subjects within that category (Figure 2). ⇨ **histogram**

bar diagram ≈ **bar chart**

Bartlett's test a method of testing the **null hypothesis** that several **variances**, each estimated from different groups of subjects, are all equal

baseline the moment in time that subjects are **randomized** or otherwise **assigned** their study medication. It is also used to refer to periods of time after a study has started but before randomization has occurred

baseline characteristic a measurement taken on a subject at the beginning of a study. Note that 'beginning' is generally taken to be at, or as near as possible to (and ideally before), the time of **randomization**. ⇨ **demographic data**

baseline comparability the process of, and results of, deciding if groups of

patients assigned to different treatment groups (usually by **randomization**) are similar with respect to **demographic data** and severity of disease

baseline data ≈ **baseline characteristic**

baseline hazard function in **survival analysis**, the **hazard function** for a subject in the **control group** (or a group arbitrarily chosen to be referred to as the control group)

baseline testing ⇨ **baseline comparability**

baseline visit usually the very first **visit** that subjects attend in a study. If **randomization** does not occur at visit 1 then 'baseline visit' may be used to refer to any visit before (and including) the visit at which randomization occurs

Basic a computer programming language. ⇨ **C**, **C++**, **Fortran**, **Visual Basic**

Baskerville design a method for finding the most preferred of several treatments. Each subject is **randomly** assigned to a **sequence** of treatments but the length of time each patient receives each treatment is dependent on their own personal choice. If a subject is completely satisfied with the first treatment they receive then they would not change and would not receive any of the other treatments. In contrast, if a patient is not happy with any of the treatments being compared they would quickly pass through the entire possible set of treatments and finish the study

batch process to work on a large number of documents all at once, rather than to handle each document as it arrives. This is a common term in **data management** but it applies to computerized systems as well as manual systems

batch validation to validate a large number of documents (usually data) as a **batch process**

baud rate the speed at which data are transmitted electronically, measured as the number of binary digits sent per second. A baud rate of 64 000 means 64 000 binary digits are sent per second

Bayes factor the ratio of the **posterior belief** to the **prior belief**. This can be seen as a measure of how the **strength of evidence** in favour of a given **hypothesis** has changed, given new data, relative to the prior belief. ⇨ **Bayes' theorem**

Bayes rule the action one takes that gives the maximum **utility**

Bayes' theorem a way of moving the thinking about the **probability** of data, given an **hypothesis**, to the probability of an hypothesis being true or false

Bayesian general statistical methods based around **Bayes' theorem**