

GLOSSARY

TERMS AND CONCEPTS

2015

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ISMPP

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ASSOCIATIONS, AGENCIES, ORGANIZATIONS

American Medical Writers Association (AMWA)

A professional organization for biomedical communicators in the United States. AMWA's mission is to promote excellence in the writing, editing, and production of printed and electronic communications to professional, regulatory, and public audiences. www.amwa.org

Contract research organization (CRO)

A company that assists biotechnology/pharmaceutical companies in the research, testing, and approval of products or technologies. CROs provide some or all of the following services: preclinical drug testing, clinical trial protocol development/study design, data collection, data management/analysis, and medical/regulatory/publication writing.

Drug Information Agency (DIA)

An independent, global, nonprofit, educational association supporting the pharmaceutical and medical device industries (www.diahome.org). Authoritative information is disseminated via meetings, conferences, online learning, and publications (e.g. Drug Information Journal and DIA Daily). Membership comprises professionals from industry, regulatory agencies, academia, and advocacy groups. Continuing education and certificate programs encompass a wide range of topics.

European Medical Writers Association (EMWA)

A professional organization for biomedical communicators in Europe. EMWA seeks to uphold standards of excellence in medical communications by providing networking opportunities to its members, furthering their professional development and promoting awareness of medical writing throughout Europe. www.emwa.org

European Medicines Agency (EMA)

A regulatory body that provides independent, science-based recommendations on the quality, safety, and efficacy of medicines and on more general issues relevant to public and animal health that involve medicines. www.ema.europa.eu/ema/

International Committee of Medical Journal Editors (ICMJE)

A group of medical journal editors that develops guidelines regarding preparation of manuscripts for publication in medical journals. These guidelines are described in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." www.icmje.org

International Society for Medical Publication Professionals (ISMPP)

A nonprofit professional association formed to serve the educational needs of those involved in publication planning and related activities in the pharmaceutical and biotechnology industries. There are both US and EU branches of this society. www.ismpp.org

Medical Publishing Insights and Practices (MPIP)

A committee jointly founded by members of the pharmaceutical industry and the International Society for Medical Publication Professionals (ISMPP) with the purpose to elevate trust, transparency, and integrity in the publishing of industry-sponsored studies. The current committee is comprised of representatives from the pharmaceutical industry, ISMPP, and journal editors. www.mpip-initiative.org

National Institutes of Health (NIH)

An agency of the [US Department of Health and Human Services](#), which is the principal federal agency responsible for conducting and supporting biomedical research. The goal of the NIH is to investigate ways of preventing, detecting, diagnosing, and treating all types of disease and disability. The NIH conducts its own research and also provides support to researchers throughout the world. The NIH comprises 27 institutes and centers, including the National Cancer Institute, the National Institute on Aging, the National Library of Medicine, and the Center for Scientific Review. www.nih.gov

National Library of Medicine (NLM)

The NLM, which is located on the campus of the National Institutes of Health in Bethesda, MD, is the world's largest medical library. The NLM collects materials and provides information and research services in all areas of biomedicine and healthcare. www.nlm.nih.gov

NICE

A UK agency established in 1999 to reduce variation in availability and quality of care provided by the National Health Service (NHS). NICE develops evidence-based guidelines on diagnosis, treatment, and prevention of disease and disseminates quality standards indicating when a treatment or procedure is considered clinically effective, cost effective, and safe. NICE issues technology appraisals, which are recommendations on use of medicines, medical devices, diagnostic techniques, surgical procedures, and health promotion activities. NICE also provides a variety of services to support public health and healthcare delivery in the UK.

www.nice.org.uk/about

www.nice.org.uk/about/what-we-do

www.nice.org.uk/guidance

The Pharmaceutical Researchers and Manufacturers of America (PhRMA)

An association of research-based pharmaceutical and biotechnology companies in the United States. The mission of PhRMA is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical/biotechnology research companies.

www.phrma.org

Professional, scientific, medical societies (also, names of specific societies)

Medical professionals form associations or societies to advance and disseminate learning for their medical interest. A society may be centered on a medical specialty, such as the American Academy of Neurology, or a specific condition, such as the Canadian Hereditary Angioedema Society. Professional societies are important for the publication planner because:

- They provide a means to reach highly targeted audiences
- They often publish journals on their specialty
- Often, the society's journal is tied in with an annual meeting that brings many members of the society together in 1 location for an exchange of scientific information
- They offer a venue for providing continuing medical education (CME)

The European Federation of Pharmaceutical Industries and Associations (EFPIA)

A professional group that represents the pharmaceutical industry in Europe. The mission is to support "modern, sustainable healthcare systems in Europe". www.efpia.eu/about-us/who-we-are

The International Publication Planning Association (TIPPA)

TIPPA is a for-profit, industry-run association that states that its mission is “fostering excellence in medical publications and communications within the biopharmaceutical industry”.

US Food and Drug Administration (FDA)

The federal agency in the Department of Health and Human Services established to regulate new foods and health-related products (including dietary supplements, drugs, cosmetics, medical devices, biologics, and blood products) in the United States. www.fda.gov

AUTHORS, AUTHORSHIP

Academic freedom

The right of students and teachers to express their ideas in school without religious, political, or institutional restrictions.

Acknowledgment (of contributions)

A statement of recognition of individuals who contribute to the development of a manuscript. According to the International Committee of Journal Editors (ICMJE), contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include people who provided technical help or writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Authorship

An author is generally considered to be someone who has made substantive intellectual contributions to a paper. According to the ICMJE, authorship is based on substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work by ensuring the questions pertaining to the accuracy of the work are examined and answered. Authors should meet all 4 criteria.

www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Conflict of interest

These occurs when an author, reviewer, or editor has financial or personal relationships that may be perceived to inappropriately influence his or her actions; such relationships are also known as dual commitments, competing interests, or competing loyalties. Conflicts of interest can take the form of financial relationships (such as employment, consultancies, stock ownership, honoraria, or paid expert testimony), personal relationships, academic competition, or intellectual passion.

Contributor

Persons or organizations that provide substantial collaborative input to a publication, but do not satisfy accepted authorship criteria. In medical publications, contributors may be sponsors, members of a publication steering committee, medical writers, or data monitoring committees. Ethical publication practices recommend listing contributors in a separate Acknowledgements section of the article.

Permissions should be obtained from each individual listed. If journal policy does not allow authors to include this information, it should be provided separately in the cover letter accompanying the submission.

Disclosure (by authors or opinion leaders)

The submission of facts and details concerning financial or personal relationships that might be considered to bias the work of an author or opinion leader.

Ghostwriter

Any professional who writes material that is officially attributed to another person or persons. Typically, this individual's role is not acknowledged in the published document. Current publication practices consider ghost authorship dishonest and unacceptable.

Guest author (ship)

An individual who is included as an author of a paper, even though that individual does not meet accepted criteria for authorship; the practice of including such individuals.

Medical writer

Writing professionals with diverse backgrounds and varied associations with the pharmaceutical industry or academic institutions. Many have advanced degrees in science or are, themselves, physicians. Regardless of their background, the medical writers' role is to produce manuscripts based on (1) scientific or clinical data, and (2) a thorough literature search to identify and assess relevant publications on the topic. Ideally, such writers collaborate with the designated authors at the beginning of the writing process and throughout the development of the manuscripts. In addition to their communication skills, medical writers generally are more familiar than investigators or sponsors with writing and publication guidelines, which are designed to ensure that articles are written according to generally accepted standards. A medical writer may also be referred to as a professional biomedical writer, a scientific writer, scientific information associates, or science public information officers.

Transparency

The increased visibility, or transparency, of clinical trials through the use of publicly available clinical trial registries and results databases, such as clinicaltrials.gov. Pharmaceutical companies, policymakers, medical practitioners, researchers, journal editors, and the general public have vested, and sometimes competing, interests in the information included in trial registries and results databases and the manner in which it is provided. The notification of ongoing clinical trials via use of public databases has greatly increased the transparency of clinical studies sponsored by pharmaceutical companies.

BIOSTATISTICAL TERMS

Absolute risk

Observed or calculated probability of an event in a population under study.

Absolute risk reduction (ARR)

Difference in risk of an event between 2 groups: $\text{risk}_1 - \text{risk}_2 = \text{ARR}$. Used to compute number needed to treat (NNT).

Accuracy

Degree to which a measurement or an estimate based on measurements represents the true value of the attribute that is being measured. (Contrast with precision.)

Analysis of covariance (ANCOVA)

Similar to analysis of variance, ANCOVA is a significance test for comparing the means of a quantitative variable between 2 or more groups. However, it takes into account measurements made for 1 or more other quantitative variables (covariates) that may influence the groups (confounders).

Analysis of variance (ANOVA)

Significance test for comparing the means of a quantitative variable between 2 or more groups; an extension of the t test for 2 independent samples. ANOVA classifies the total variance seen for the outcome variable into between-group and within-group compartments. The significance test is based on the null hypothesis that no difference exists between the groups, in which case the within-group and between-group variances would not differ (i.e., their ratio would be 1). This is the F-test, or variance ratio test.

Area under the curve (AUC)

The area under a receiver operating characteristic (ROC) curve. Often used in the context of diagnostic testing, the AUC can be interpreted as the probability of correctly detecting the individual with a specific disease and the individual without the disease with the diagnostic test, given that 1 is presented with 2 subjects randomly drawn from a population, when 1 subject is affected and 1 is not.

Confidence Interval (CI)

Range of values within which the “true” population parameter is believed to lie, with a given level of confidence. The narrower the interval, the more precise the estimate.

Confounder

A variable that can cause or prevent the outcome of interest, is not an intermediate variable, and is associated with the factor under investigation. Unless it is possible to adjust for confounding variables, their effects cannot be distinguished from those of the factor or factors being studied.

Confounding

Distortion of the apparent effect of an exposure on risk brought about by the association with other factors that can influence the outcome. Situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure to other factors that influence the outcome under study.

Correlation

Linear association between 2 variables, measured by a correlation coefficient. The degree to which variables change each other.

Correlation coefficient

Measure of association that indicates the extent to which 2 variables have a linear association. This can take values between 1 and -1, indicating perfect positive and negative correlation. A correlation

coefficient of 0 indicates no linear association. See also Spearman rank correlation, Pearson product moment correlation, and Kendall tau.

Cost-benefit analysis

An economic analysis in which the costs of medical care and the benefits of reduced loss of earnings due to preventing premature death are considered. The general rule for allocation of funds in a cost-benefit analysis is that the ratio of marginal benefits (the benefit of preventing an additional case) to marginal cost (the cost of preventing an additional case) should be equal to or greater than 1.

Cost-effectiveness analysis

This analysis attempts to determine the costs and effectiveness of an activity or to compare alternative activities to determine the relative degree to which they will produce the desired objectives or outcomes.

The preferred action is the one that requires the least cost to produce a given level of effectiveness or provides the greatest level of effectiveness for a given cost. In health care, outcomes are measured in terms of health status.

Covariate

A variable that is possibly predictive of the event under study. A covariate may be of direct interest in the study, or it may be a confounder or effect modifier.

Cox proportional hazards method

This is a method for comparing survival time in 2 groups. The test assumes that the ratio of risks (or hazard ratio) of the event, at any point in time, is the same for the groups being compared. The outcome variable in the model is whether the event of interest has occurred; if so, after what period of time, and if not, the duration of follow-up. The model predicts the risk (or hazard) of the event at any point in time. Because no assumptions are made about the distribution of events, this is a semiparametric method. It is sometime referred to incorrectly as a Cox regression.

Cross-sectional study

Also known as a prevalence study; a study that examines the relationship between diseases or other health-related characteristics and other variables of interest as they exist in a defined population at 1 point in time (cross-section).

The relationship between a variable and a disease can be examined in terms of the prevalence of the disease in population subgroups defined by the presence or absence of the variable (or its level, for a continuous variable) or in terms of the presence or absence of the variable in individuals who have a disease versus those who do not. The temporal sequence of cause and effect cannot be determined in such a study, nor can disease incidence be determined.

Degrees of freedom

The number of independent comparisons that can be made between the members of a sample. It refers to the number of independent contributions to a sampling distribution.

Effect modifier

A variable whose effect on the outcome depends on the magnitude of a putative causal factor: depending on the value of the causal factor, the effect modifier may either decrease or increase the probability of the outcome.

F-test

Significance test used in analysis of variance to assess whether the population means of 2 or more groups are similar, by comparing between-group and within-group variability.

Kaplan-Meier method

Method of determining survival probability over a period of time, in which probabilities are calculated at the exact points in time at which an event of interest has occurred. This information can be used to plot a survival curve, in which the probability of survival remains constant until an event occurs, at which point the curve drops, yielding a characteristic step appearance. ([Kaplan EL, Meier P. Non parametric estimation from incomplete observations. J Am Stat Assoc 1958;53:457–81.](#))

Kendall tau

Nonparametric measure of association between quantitative or ordinal variables, based on ranks of the observations.

Linear regression

Regression analysis using linear models, in which the value of a parameter (y) for a given value of a factor (x) is assumed to be equal to $a + bx$, where a and b are constants. This equation can be plotted as a line showing change in y per change in x, with the y-axis intercept equal to a.

Logistic regression

Modeling used to predict the value of the outcome variable, given the value of the predictor, when the outcome variable is binary (yes/no, dead/alive) or categorical.

Median

That value in a distribution that divides the observations into upper and lower halves; the 50th percentile.

Null hypothesis

Statistical hypothesis that 1 variable has no association with another variable or set of variables, or that 2 or more population distributions do not differ from each other. In the case of a trial or experiment, the null hypothesis states that the observed differences between study groups are no greater than might have been observed by chance alone.

Number needed to treat (NNT)

The number of patients with a specified condition who must follow a specified regimen for a prescribed period of time to prevent the occurrence of a specific complication or outcome of the condition (e. g., the number of patients at risk for stroke who must be treated with a specific antihypertensive agent to prevent the occurrence of 1 stroke). Mathematically, it is the reciprocal of the absolute risk reduction, that is, the difference between occurrence rates in the treatment and placebo groups in a clinical trial. Because it depends on the risk of the occurrence of the event, the NNT will always be smaller in a high-risk population; that is, fewer individuals will need to be treated to prevent 1 event.

P value

This represents the probability that a given difference, or one that is greater, has been observed in a study sample, when in fact such a difference does not exist in the population from which the sample was drawn. The smaller the P value, the stronger the evidence to reject the null hypothesis (that no difference exists).

Pearson product-moment correlation (r)

Measure of the strength of the linear relationship between two quantitative variables, a parametric correlation. Use of this correlation assumes that one or both of the variables are normally distributed. If this assumption is not met, a nonparametric test, such as Spearman rank correlation, should be used.

Poisson regression

Statistical model to predict the value of the outcome variable given the value of the predictor, when the outcome is counts (per unit time or area) or rates.

Post hoc analyses, Ad hoc analysis

Analyses conducted after the end of a trial and related to endpoints that were not in the original protocol. These analyses are used to test a hypothesis on a subset of results to gain a better understanding of the initial endpoints.

Precision

The degree to which multiple measurements of the same attribute agree with one another; the standard error of measurement. Precision does not imply accuracy.

Receiver operating characteristic curve (ROC curve)

Graphic display of a quantitative diagnostic test. The graph is a plot of sensitivity or detection rate versus false-positive rate (1 – specificity). The better the test, the higher the detection rate and the lower the false-positive rate. The area under the curve is a measure of the performance of the test.

Relative risk (RR)

The ratio of the risk of disease or clinical event between an exposed and non-exposed group. Relative risk reduction (RRR) The proportion of the initial or baseline risk that was eliminated by treatment. As a formula, $RRR = (1 - RR) \times 100$.

SAS Institute

A company that provides a statistical software package (SAS/STAT®) commonly used for data analysis.
www.sas.com

Significance, clinical

A difference between treatment groups in a clinical trial that would be meaningful to the clinician.

Significance, statistical

Refers to the result of a test of significance. When the P-value is less than a certain value (commonly, but not always, <0.05), the difference between groups is declared to be statistically significant.

Spearman rank correlation (ρ)

A nonparametric correlation coefficient, calculated by computing the Pearson product-moment correlation coefficient for the association between the ranks given to the values of the variables involved, as opposed to the actual data values.

SPSS

A statistical software package, now part of IBM, commonly used for data analysis.
www.ibm.com/software/analytics/spss/.

Standard deviation (SD)

Measure of dispersion or variability of a set of measurements, representing the average distance of individual observations is from the mean. Mathematically, the SD is the square root of the variance.

Standard error (SE)

Measure of the degree of uncertainty in calculating an estimate from a sample; the standard deviation of an estimate. Its main determinants are sample size and variability.

t-test

Significance test used to compare the means of 2 different groups.

Type I error

Probability of deciding that a difference exists between study groups when, in truth, there is none; also known as α .

Type II error

Probability of deciding that no difference exists between study groups when, in truth, there is a difference; also known as β . $1 - \beta$ is power.

Variable

Any attribute, event, or phenomenon that can have different values.

Variability (y)

Measure of the variability of a set of measurements, defined by the sum of the squares of deviation from the mean divided by the number of degrees of freedom in the set of observations.

CLINICAL CONCEPTS

Active-controlled trial

A clinical trial in which the drug being evaluated is compared with another drug used to treat the same condition, rather than with placebo. This design is often used when several drugs are available for treatment and exposure of patients to placebo may be considered unethical.

Adverse reaction (event)

An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time.

Adjudicator

An individual or committee who reviews outcomes and events from a clinical trial, and resolves discrepancies in data that arise during investigator or independent review committee assessment.

Bias

Systematic error or deviation of results or inferences from truth. Common types of bias that may occur in clinical trials include selection bias (from the enrollment criteria), performance bias (from how the trial was conducted), attrition bias (caused by drop-outs or missing data), and assessment bias (based on the

statistical methods used or blinded assessments). In clinical trials, bias may be minimized by randomization and blinding.

Biosimilars

Officially approved subsequent versions of innovator biological products made by a different sponsor following patent and exclusivity expiry on the innovator product. Also known as follow-on biologics.

Blinding

In clinical trials, concealment of treatment assignment; ideally, both investigators and patients should be unaware of treatment assignment (double-blinding).

Case-control study

Observational study that compares individuals who have a specific outcome or clinical disease event (cases) to a matched group of individuals who do not (controls) to attempt to determine differences in the history of risk factors. This study design is often used in instances of rare diseases to suggest possible etiologies.

Clinical practice

In contrast to clinical research or clinical trials, clinical practice is the usual and customary management of patients by physicians or other practitioners.

Clinical trial

A planned experiment designed to assess the efficacy of a treatment in humans by comparing the outcomes in a group of patients treated with the test regimen (eg, drug, surgery, counseling) with those observed in a comparable group of patients receiving a control treatment (eg, placebo, usual care), in which patients in both groups are enrolled, treated, and followed up over the same time period. Clinical trials are essential for drug development and approval.

Clinical trial design

Most rigorous for phase 3 clinical trials. A hypothesis is established (e.g., drug X will reduce the incidence of clinical events or will have a greater effect on a specific measured parameter compared with placebo), desired level of significance is specified, power to detect a difference is specified, the primary (and possibly secondary and exploratory) outcome or outcomes are specified, sample size is determined, statistical analyses are prespecified, and study participants provide informed consent and are randomly assigned to treatment or placebo. Investigators and participants may remain unaware of the treatment assignment of any individual (double-blinding).

Clinical trial protocol

A formal study document that describes the background, objectives, hypotheses, study design, planned efficacy and safety measurements, data analysis plans (including sample size and power calculations), and administrative and regulatory considerations. Details of participant eligibility and exclusion criteria, and the study flow chart of timelines and measurements, are included. Each participating primary investigator signs an agreement to conduct the study in accordance with the protocol and within standards of Good Clinical Practice. In addition, the protocol is presented for approval to the Institutional Review Board of each participating clinical site. All investigators use the protocol and its amendments as primary reference documents throughout the study, and elements of the protocol are used in development of publications reporting the results of the trial.

Clinical trial registry

A central repository (usually posted online) of government- supported or privately supported clinical trials that are recruiting participants, are in progress, or have been completed. Depending on the registry, information posted may include the purpose of the trial, eligibility limitations, locations of study centers, and study center contact information. See, for example, www.clinicaltrials.gov (an NIH site), sites sponsored by individual countries or regions (for example, Australia, Canada, the United Kingdom, the European Union), or sites sponsored by individual drug companies. Many journals that participate in the International Committee of Medical Journal Editors (ICMJE) have required registration for clinical trials that started recruiting participants on or after July 1, 2005, if the investigators wish to have results considered for publication in these journals. For further details about the ICMJE position, see www.icmje.org/about-icmje/faqs/clinical-trials-registration.

Clinical trial report

Also known as a clinical study report; in general, a formally structured document (used as a basis for application to the FDA) reporting results of a clinical trial. These reports are typically generated by specialized writing staff and are entirely separate from (although using many of the same data as) peer-reviewed publications of trial results. The report is generated after trial data are collected and cleaned, and a “frozen file” is declared.

Clinical trial results

A more general description of findings from a clinical trial that discusses the effect of treatment on a prespecified outcome of interest. Two general types of analysis, intent to treat and per protocol (also known as completers), are used to examine the effect.

Clinicaltrials.gov

NIH-sponsored website for registration of clinical trials, mandated by FDA Modernization Act. See also clinical trial registry.

Cochrane review

A product of the Cochrane Collaboration, founded in 1993 as a group of healthcare specialists who review medical studies and the results of healthcare research. The goal of the organization is to assist people in making educated healthcare decisions by ensuring the accessibility of systematic reviews of the effects of healthcare interventions. Complete Cochrane reviews are available by subscription, either on CD-ROM or the Internet.

Cohort study

Observational study that assembles a large group of individuals, collects extensive information about these people at baseline, and follows up with the group for a period of time in an attempt to examine relationships between outcomes and risk factors. This differs from case-control studies in that the outcome events occur during the follow-up period. Some well-known cohort studies include the Framingham Study, the Seven Countries Study, the Physicians’ Health Study, and the Nurses’ Health Study.

Combination therapy

Treatment of a single condition with two or more drugs, sometimes combined in a single treatment, that have additive or synergistic effects. (Contrast with monotherapy)

Compassionate use

A method of providing experimental therapeutics before final FDA approval for use in humans. This procedure is used with very sick individuals who have no other treatment options. Often, case-by-case approval must be obtained from the FDA for "compassionate use" of a drug or therapy.

www.gpo.gov/fdsys/pkg/FR-2009-08-13/pdf/E9-19005.pdf

Data analysis plan, Statistical-analysis plan (SAP)

A description of how clinical data from a trial will be analyzed. The plan is prepared before the trial begins.

Data Safety and Monitoring Board (DSMB) or Data Monitoring Committee (DMC)

An independent committee composed of community representatives and clinical research experts that review data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB or DMC may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

Double-blind trial

In a clinical trial, assignment of participants to treatment groups and ascertainment of outcomes in such a way that participants and investigators are unaware of group assignment. This minimizes bias that could result from knowledge of treatment group assignment.

Drug therapy

Treatment of a clinical condition with a pharmacologic agent (or agents).

Drug use, Drug utilization

Prescribing, dispensing, and consumption of pharmaceutical agent(s). In our context, this does not apply to use of illicit substances.

Effectiveness

The extent to which a specific intervention produces a specific benefit in real-world conditions. (Contrast with efficacy.)

Efficacy

The extent to which a specific intervention produces a specific benefit under controlled conditions, as in randomized clinical trials. (Contrast with effectiveness.)

Empirical

Based on experimental or observational data, not on a theory.

Epidemiology

The branch of medical science that deals with the study of the etiology, incidence/prevalence, distribution and control of a disease in a population.

EQUATOR

An international initiative for promoting the transparent and accurate reporting of research studies, EQUATOR is best known for the provision and implementation of guidelines for reporting clinical studies and for monitoring the quality in reporting in the scientific literature. Many guidelines are advocated by EQUATOR, including CONSORT for randomized controlled trials of efficacy and safety, STARD for

studies of diagnostic accuracy, STROBE for epidemiologic studies, and PRISMA for meta-analyses of randomized controlled trials. www.equator-network.org/about-equator

Evidence-based medicine, Evidence-based practice

The use of the best available evidence to aid healthcare providers in making informed decisions about patient care. Operationally, evidence-based guidelines for the evaluation and management of a disease or group of related diseases are developed under the auspices of medical societies and/or governmental agencies using standardized processes for evaluating the quality and strength of the evidence for the benefits and risks of therapeutic interventions, diagnostic or screening procedures, and preventive measures. ([Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS \(January 1996\). Evidence based medicine: what it is and what it isn't. *BMJ* 312 \(7023\): 71–2.](#))

Head-to-head trial

Clinical trial in which 2 therapies are directly compared for the treatment of a condition in order to investigate whether there are significant differences in safety or efficacy between the therapies. effectivehealthcare.ahrq.gov/glossary-of-terms/?filterletter=h

Health economics and outcomes research (HEOR)

Research that aims to assess the relationship between the cost and the clinical and/or quality-of-life outcomes of health care interventions. HEOR is used by industry primarily to establish the value proposition of a drug, medical device, or procedure. HEOR is used by public sector agencies and payors to evaluate the cost effectiveness of treatment. Comparative effectiveness research (CER) is a branch of HEOR focusing on the relative cost effectiveness of two or more interventions for a given clinical condition.

Hierarchy of evidence

Not all evidence is created equal; the best evidence (that is, most free of bias or systematic error) to show a causal association between treatment and outcome comes from well-designed and well-conducted clinical trials or from meta-analyses of such studies. At the other end of the spectrum are personal observation, anecdotal evidence, and results of laboratory studies (because laboratory studies do not use clinical event end points).

In vitro study

A study conducted outside a living organism (e.g., cell lines).

In vivo study

A study conducted in animals or humans.

Incidence

Measure of new cases of a disease that occur during a specified period of time. (Contrast with prevalence.)

Indication, or disease state

A condition for which treatment is given; specifically, the approved use of a treatment.

Informed consent

The process of obtaining permission from an individual before enrolling them in a clinical trial. Healthcare workers are required to provide all facts and resulting consequences of a particular treatment to the

individual/the caregiver so that an informed decision can be made. The individual granting the consent must be able to understand and have the ability to make decisions after learning the key facts about a clinical trial before deciding whether or not to participate. [answers.hhs.gov/ohrp/categories/1566](https://www.answers.hhs.gov/ohrp/categories/1566); [ministryofethics.co.uk/?p=6](https://www.ministryofethics.co.uk/?p=6)

Intent-to-treat (ITT) analysis

A type of analysis of data from clinical trials in which data from all patients randomized to each treatment group are analyzed within the assigned group, regardless of whether they received or completed the assigned treatment. Considered to be the most conservative analysis because it preserves randomization (contrast with per-protocol analysis).

Level of significance

The prespecified probability of detecting a difference. Level of significance is usually set at 0.05; that is, 5 times out of 100 a statistically significant difference will be found by chance. See also type I error.

Mechanism of action

The way a drug works to modulate disease; effect of a drug at a cellular or tissue level.

Meta-analysis

A statistical analysis in which data from independent, usually similar studies (identified by systematic review) are combined (pooled) to produce the most precise estimate of the magnitude of effect of a given treatment; also a means of assessing consistency of effect among studies. Well-conducted meta-analyses that use data from well-designed and well-conducted clinical trials provide the highest level of evidence. A good meta-analysis should cover all relevant studies, evaluate the presence of heterogeneity and use sensitivity analyses to confirm the main findings.

Monotherapy

Treatment of a disease or condition with a single agent. (Contrast with combination therapy.)

Nonclinical research

Any research that does not evaluate disease outcomes in human subjects; includes laboratory studies (in vivo and in vitro), exploratory/applied research, and process development.

Noninferiority trial

A clinical trial intended to show that the effect of a new treatment is not worse than that of an active control by more than a specified margin.

Observational study

Nonexperimental study (i.e., not a clinical trial) in which participants cannot be assigned to specific interventions as in a clinical trial. Study types include cross-sectional (survey, database), case-control, and cohort (prospective or retrospective). None of these can be used to determine cause-and-effect associations; only clinical trials can provide this level of information. All observational study designs are subject to risk of bias. The strength of an observational study is that it more closely reflects real-world practice. See also individual study types.

Per-protocol analysis

Analysis of clinical trial data that includes data only from participants who were adherent to treatment throughout trial; because participants drop out of trials for nonrandom reasons, this analysis does not

preserve randomization and may lead to bias in inference. In general, not used for analysis of primary outcomes of placebo-controlled studies and may be more conservative than intent-to-treat analysis in head-to-head trials of 2 active agents (contrast with intent-to-treat analysis).

Pharmacodynamics

The study of the action of a drug in the body over a period of time, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion; biologic effects resulting from drug–biologic system interaction.

Pharmacoeconomics

The discipline that seeks to determine the economic outcome of using a drug. Pharmacoeconomic studies are needed to demonstrate to third-party payers and formulary committees that a new treatment is a better solution, economically, than current treatments.

Pharmacokinetics

The study of the processes of bodily absorption, distribution, metabolism, and excretion of drugs; typically described as a function of time.

Phases (drug development, product life cycle)

- Phase 1
Safety and pharmacologic profiles; earliest trial in humans, usually involving fewer than 100 participants. May include various doses or routes of administration, escalating doses to define the level at which unacceptable toxicity is encountered (the maximum tolerated dose).
- Phase 2
Pilot efficacy studies usually involving several hundred participants. For drugs, emphasis is on demonstration of safety and efficacy; for vaccines, emphasis is on immunogenicity. Participants may or may not be randomized to study and control groups.
- Phase 3
Major efficacy study that may involve thousands of study participants. Designed for definitive evaluation of safety and efficacy. Typically multicenter studies in which participants are randomly assigned to treatment and placebo groups, and investigators and patients remain unaware of treatment assignment. Often called pivotal studies because drug approval depends on the results.
- Phase 4
Conducted after approval and licensing of drug. May focus on specific pharmacologic effect, evaluation of long-term effects, or incidence of adverse events.

Pivotal study, pivotal trial

Typically phase 3 clinical trial, primary study of efficacy and safety of an intervention; basis of submission to regulatory agency for approval of treatment.

Placebo control

In a clinical trial, the group with which the treatment group is compared to determine efficacy of the intervention. As a consequence of randomization, participants in the group assigned to placebo are similar at the start of the study to participants assigned to active treatment, so that differences between the groups at the end of the study are a measure of treatment efficacy. Participants in the placebo group

receive inactive medication that is identical in appearance to the active treatment (to maintain blinding/masking).

Point estimate

That value with which observed data is most consistent.

Power

Ability of a study to demonstrate an association if one exists; one of the factors considered in study design/sample size calculation; probability of not making a type II error.

Prevalence

Total number of existing cases of a disease or condition at a specific point in time (contrast with incidence).

Primary outcome

End point of trial on which power/sample size calculations are based. Generally, but not always, the most clinically important outcome.

Quality-adjusted life-year (QALY)

Adjustment of life expectancy that reduces overall life expectancy by amounts that reflect the existence of chronic conditions that causes impairment, disability, or handicap.

Randomization

In a clinical trial, the mathematical process by which participants are allocated to treatment groups. In combination with blinding, randomized assignment minimizes bias and ensures that groups are similar at baseline of the study. As a consequence, differences between groups at the end of the study can be inferred to be due to the treatment given and not to characteristics of the people to whom the treatment was given.

Registry study

Studies conducted in a real-world setting with the intention of measuring the effectiveness of a product/device. Effectiveness refers to the performance of a product/device in the general population of patients and in the context of routine clinical practice (as opposed to efficacy which is a performance measure used in clinical studies, in a carefully selected patient population, and according to a strict protocol). Registry studies are observational (as opposed to clinical studies which are investigational). They offer both large-scale and long-term data collection at a far lower cost than traditional studies, and can help establish whether the results of these controlled clinical trials actually translate to everyday practice. The degree of scientific rigor can vary, according to the formality of data collection. If, however, inclusion/exclusion criteria are stipulated, together with well-defined case report forms and a rigorous audit system to ensure patient follow up, then their scientific validity can be considered more robust.

Safety (of pharmaceuticals)

The extent to which an agent does not cause harm to individuals who use it as treatment for a clinical condition or disease.

Sample size

The number of participants enrolled in a clinical trial, calculated in study design. Based on prespecified level of significance, power, rate of event in untreated population (or variability of measured outcome,

such as blood pressure or cholesterol, in untreated population), and magnitude of difference treatment is expected to make in population studied.

White paper

An authoritative report in the form of a call to action or a review paper highlighting an unmet need in a particular disease area. They are often part of an education program targeted at improving adherence to treatment by connecting clinical evidence, education and behavioral change.

CONGRESSES, CONFERENCES, CONVENTIONS, SCIENTIFIC MEETINGS

Abstract book (scientific meeting or congress)

A printed or electronic compilation of all of the abstracts presented at a scientific meeting. These may be available only at the meeting as a part of registration or as a supplement to a journal associated with the meeting organization. Late Breaking Clinical Trial abstracts may not be included in the abstract books.

Abstract deadline

Date by which an abstract must be submitted to be considered for presentation at a scientific conference or congress.

Advisory board (meeting)

Advisory board members are typically physicians, scientists, or other healthcare professionals who are invited to an industry-sponsored meeting to provide independent advice and recommendations on scientific or technical matters. The members often possess recognized expertise and judgment in a specific field and have the training and experience necessary to evaluate information or data objectively and to interpret its significance.

Analysis of scientific meeting attendance

A demographic evaluation of the attendees at a meeting. Analyses may include number of attendees, medical specialty, country of residence, gender, years in training, and so on.

Conference proceedings or congress proceedings

A summary of selected presentations given at a conference or congress. Proceedings may include copies of slide presentations, poster handouts, summaries of selected presentations, or online video interviews.

Dinner meetings

A meeting used to educate healthcare providers on new products, applications, or therapies. These meetings may include a modest meal, and a recognized speaker must present information with the objective to further knowledge.

Encore presentation

A presentation based on an abstract that has been presented at an earlier conference. Encore presentations provide an opportunity to share information with a wider audience. Conferences that accept encore abstracts and presentations typically include this information in the announcement for abstract

submission. The name of the conference at which the original abstract was presented should be indicated in the encore abstract and presentation. Permission to reproduce the abstract must be secured from the copyright holder.

Exhibitor prospectus (meetings)

Rules and regulations that govern exhibits at conferences and congresses. A prospectus may contain information on exhibitor registration, booth size, exhibitor setup dates and times, exhibit teardown dates and times, space rental fees, booth limitations, and so on.

Exhibits (meetings)

Industry-sponsored booths are used to promote products (commercial/promotional) or provide educational (scientific) information to meeting attendees.

Hospitality suite

A room in a hotel or in a congress or conference center in which conference participants may have access to computers, phones, or other business needs. Refreshment may be provided. The suite is usually sponsored by a pharmaceutical company or other organization.

Keynote address

A presentation at a congress delivered by a respected authority to establish enthusiasm for the main theme of the conference or to speak on a topic of particular interest to the attendees.

Late-breaker abstract (aka Late Breaking Clinical Trials Abstract)

Many conferences offer the opportunity to submit abstracts with newly available data after the end of the usual abstract submission period. These abstracts are judged separately and may have a lower chance of acceptance than regular submissions. In many cases, only a summary of the study and its objectives are required for these abstracts and the final data do not have to be included. The goal of a late breaking clinical trial abstract is to enable the results of the study to be presented in a public forum for the first time. If accepted, these abstracts are almost always an oral presentation.

Poster hall

The area within a conference or congress designated for the presentation of posters.

Poster session (moderated)

Time period during which authors present specified posters in a poster hall during a conference or congress. There is direct interaction with attendees, who can ask questions of the author.

Roundtable

A discussion format used to synthesize medical information that relies on verbal exchange among members of a group whose members have expertise in a specific topic(s). Roundtables can be informal discussions of topics, or can be more structured and have similarities to a scientific session at such a congress. In a publication context, this format can function as a mode of generating a published print or electronic document or article as its final product, which is sometimes peer-reviewed.

Satellite symposium

An industry-supported educational event held in conjunction with, but independent of, an organization's meeting or congress. These typically require approval by the congress planning committee.

Scientific congress, Conference, Meeting of a professional society

Organized meeting sponsored by a professional society to disseminate research and educational information that would be of scientific interest to the meeting attendees.

Sponsorship (of conference events)

Funding provided to an independent, third party organization for a specific event, activity, or program. The funder has no influence or control over the scope or content of these activities.

Symposium (official congress event)

Educational event held by the association sponsoring the congress or conference. The same association conducts and oversees the symposium. The association may ask for applications from cosponsors to encourage new ideas and topics of interest.

Technology suite

This is a room either in a hotel or within an industry-sponsored exhibit booth, used to be able to discuss new proprietary technologies in a private venue. Typically, confidentiality agreements are required to attend.

HEALTHCARE PROVIDERS AND INSURERS

Health management organization (HMO)

HMOs are healthcare organizations that promise almost unlimited healthcare for members who agree to use only those physicians in the HMO. The member does not have a choice of doctors in an HMO.

Managed care

Managed care refers to the concept of having a third-party payer reexamine healthcare use and make decisions on the optimal use of healthcare resources.

Medicaid

A US government program that provides free or low-cost health insurance coverage to low-income individuals and families (<http://www.medicaid.gov/>).

Medicare

The US government program that provides health insurance to the elderly, certain younger people with disabilities, and those with end-stage renal disease. Other insurance is usually needed to supplement Medicare coverage (<http://medicare.gov/>).

Payers

Insurers or other agencies that provide reimbursement to healthcare providers for medical services, procedures, or treatments. Payers may include managed care organizations, government, or private insurers.

Preferred provider organization (PPO)

A PPO is a healthcare insurer that gives a higher percentage of coverage to members who receive services from a certain group of subscribing physicians. The member is permitted to work with the doctor

in the group whom they prefer and to receive services from a provider outside the network in exchange for reduced coverage for those services.

Reimbursement

Reimbursement, as an issue in pharmaceutical marketing, refers to the willingness of insurers and other third party payers (such as Medicare or Medicaid) to pay for pharmaceutical products under their insurance plans.

JOURNALS

Acceptance to publication time

This is a part of the publication lead time and varies widely among journals. It describes the interval between acceptance of a paper by a journal and its publication, either online or in print.

Acceptance rate

The proportion of manuscripts, or abstracts submitted to a journal, or scientific meeting that is ultimately accepted. For manuscripts, it can range between 5% and 85% based on the type of article and prestige of the journal. This is the inverse of the rejection rate. The rejection rate for some electronic journals can be as low as 15%. These rates are often posted on the journals Web site. For meetings, the acceptance rate can be much higher but is typically not publicized.

Analysis of journal circulation statistics

Journal selection is a key skill in publication planning. Circulation statistics are an important indicator of a journal's suitability for a publication. Some of the items to look for are readership, geographic distribution, paid versus complimentary subscriptions, and distribution method.

Author guidelines

Every scientific journal establishes guidelines for authors that must be followed. The guidelines cover things such as acceptable word count and limits, manuscript style, the number, types, and formats of graphics that can be submitted, who must be acknowledged as authors and contributors, as well as other disclosures. Adherence to guidelines is the first sign to the initial reviewing editor that the author read the instructions. Rejection for failure to adhere to guidelines causes needless delay in publication. Publication planners and/or medical writers should work with the authors to ensure that the guidelines are met before submitting.

BPA audit (circulation and readership audit service)

BPA (originally the Bureau of Public Affairs, now the official brand name) is an impartial media-auditing system that provides objective reporting on journal circulation statistics (www.state.gov/r/pa).

Citation analysis

One indicator of the prestige or reputation of a journal is how many times its articles are cited by authors in other journals. This statistic is compiled in the publications of the Institute for Scientific Information (ISI). ISI publishes Journal Citation Reports and the SciSearch databases. These products index the citations in the bibliographies of journal articles and link them to the original citations.

Consolidated Standards for Reporting Trials (CONSORT)

CONSORT comprises a checklist and flow diagram to help improve the quality of reports of randomized controlled trials. It offers a standard way for researchers to report trials. The statement has been endorsed by a number of medical journals, including The Lancet, Annals of Internal Medicine, and the Journal of the American Medical Association. These journals require use of the checklist and flow diagram in manuscript submissions of trial data. The most recent version to the statement can be accessed and the flowchart downloaded at www.consort-statement.org. In addition to English, the statement is available in Chinese, Dutch, French, German, Italian, Japanese, Korean, Portuguese, Russian, and Spanish. Additional information may also be found through accessing the Quality of Reporting of Meta-analyses, Standards for Reporting of Diagnostic Accuracy, and Meta-analysis of Observational Studies in Epidemiology. www.consort-statement.org.

Cover letter

An introductory letter that accompanies an article during the submission to a journal. Journals often require a letter, but in other cases do not. Consult the journal's instructions to determine if one is required. For additional details, please see the ICMJE website:

www.icmje.org/recommendations/browse/manuscript-preparation/sending-the-submission.html

Digital object identifier (DOI)

Digital object identifier; a unique identifier given to a manuscript published online before appearing in print.

Editor (of medical publications)

There are several editorial officers with whom a publication planner should be familiar. Some larger journals will divide these responsibilities among different staff members. At smaller journals, 1 person may fill all of the positions.

- Editor or Editor-in-Chief: The officer ultimately responsible for the content and quality of a journal's publications. In the medical field, the editor may be an MD.
- Managing Editor: The managing editor of a journal works under the Editor or Editor-in-Chief and is responsible for the day-to-day editorial operations.
- Manuscript Editor: When an article is submitted to a journal, the first person who sees it is the Manuscript Editor. The Manuscript Editor is the person directly responsible for the review and acceptance process.

Electronic publishing

Most medical journals publish content on the Internet. Some will place the full content online at a site that is password protected for subscribers. Others put a limited amount of free content on their Web sites. There are journals that are completely electronic and have no print counterparts.

Good Publication Practices 3 (GPP3)

This guideline was updated in 2015 (*Battisti W, et al. Ann Int Med 2015; 163(6):461-464*) and extends GPP2 (*Graf C, et al. BMJ 2009;339:b4330*; original GPP: *Wager E, et al. Curr Med Res Opin. 2003;19(3):149-154*). GPP3 builds on the guidelines provided in GPP and GPP2 for ensuring that biomedical publications conform to high ethical standards. GPP3 includes several new sections including: guidance on the principles of good publications practices for industry-sponsored research and which data should be published, sharing of data, and plagiarism. GPP3 also provides further guidance on the ICMJE authorship recommendations and common authorship issues, clarifies appropriate payment and

reimbursement of authors, and adds further details on the role of medical writers.
(<http://www.ismpp.org/gpp3>).

Immediacy index (journal evaluation point)

A statistic provided by the Journal Citation Reports (JCR), the immediacy index is a measure of how quickly the “average article” in a journal is cited. The immediacy index tells how often articles published in a journal are cited within the same year. It is calculated by dividing the number of current citations to articles published in the same year by the number of articles published in the current year.

Impact factor (journal evaluation point)

Also a JCR statistic, the impact factor is a measure of the frequency with which the “average article” in a journal has been cited in a particular year. The impact factor can help evaluate a journal’s relative importance, especially when compared with others in the same field. It is calculated by dividing the number of citations to articles published in the most recent 2 years by the total number of articles published in the same time period. The impact factor statistic only relates to journals within a category and must be cited as such. The impact factor for a journal in JCR’s cardiology category is not comparable to an impact factor in the respiratory category.

Instructions for authors (journals)

See author guidelines.

Journal Citation Reports (JCR)

A citation analysis service published by Thomson Scientific. It facilitates evaluation and comparison of journals, including information on which journals are most frequently cited in a given field, journals with highest impact in a field, and journals with the greatest number of publications in a field. See also citation analysis, immediacy index, and impact factor.

Media kit (journals)

Journals that accept advertising prepare a media kit to present to potential advertisers. The kit contains circulation information, a sample issue, a rate card, and other information that bolsters the journal’s credibility as a venue for reaching a specific audience. This information is invaluable to the publication planner, and is often available online.

Meta-analysis of Observational Studies in Epidemiology (MOOSE)

These guidelines ([Stroup DF et al. JAMA. 2000;283:2008-2012](#)) provide recommendations for reporting syntheses of observational (nontrial) studies, including a proposed checklist. The intent is to make such meta-analyses more useful for authors, reviewers, editors, readers, and decision makers.

Online journal, online publication

An online journal with no print counterpart, being published via the Internet in electronic form only. Online journals are copyrighted, peer reviewed, and available for a fee to subscribers.

Open-access publishing

A publishing movement to disseminate scientific information freely. Open-access publications are available free via the Internet. There are no copyright restrictions. Many journals are peer reviewed, although some may not be. Authors may have to pay a fee to make their publication available via Open Access.

Page proofs

A draft of an article received from the journal that is laid out as the pages will appear in the journal, with figures and tables correctly placed, and so on. (Galley proofs contain the text in an uninterrupted column without figures and tables inserted.)

Peer review

Process by which content and/or methodological experts in a relevant field review submitted manuscripts for journals. The details of the process vary among journals. Reviewers critically evaluate the manuscript, provide written comments, and recommend whether it should be accepted or rejected.

PERQ/HCI

PERQ/HCI is a market research firm that conducts surveys of physicians to determine which medical journals they actually read. PERQ/HCL became part of Kantar Media in January 2010.
kantarmediana.com/healthcare.

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA - formerly QUORUM)

First published in 2009 and provides an evidence-based minimum set of items for reporting systematic reviews and meta-analyses. It is an update and expansion of the QUOROM Statement. Although it focuses on randomized trials, the PRISMA Statement can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. It contains a 27-item checklist and a four-phase flow diagram. It was published in [Moher D, et al. *BMJ* 2009;339:b2535](#) in addition to other journals, and may also be accessed at www.prisma-statement.org.

Publication lead time

Average time from submission of a manuscript to its publication in a specific journal. Most journals provide this information to contributors. See also submission to acceptance time and acceptance to publication time.

Publisher

An individual whose profession is publishing. See also publishing.

Publishing

The business or profession of the commercial production and issuance of literature, information, or other materials.

Quality of Reporting of Meta-analyses (QUOROM)

The QUOROM statement provides guidance for the reporting of meta-analyses of clinical trials, including a checklist and flowchart. It is analogous to the CONSORT statement and may be accessed online at www.consort-statement.org/QUOROM.pdf. The original source of the statement is [Moher D et al. *Lancet*. 1999;354:1896-1900](#). This statement was superseded by PRISMA in 2009 (see PRISMA).

Readership

A key journal evaluation point. It differs from circulation in that it seeks to measure to what degree the target audience actually reads the content of a publication as opposed to simply receiving it or otherwise being exposed to it.

Referee, Reviewer

Individual (peer) who critically appraises manuscripts submitted to a journal at the request of the editors of that journal. The reviewer assesses whether the submitted manuscript is of appropriate scientific quality and appropriate for the journal's audience. Reviewers may or may not be blinded to the names and affiliations of the authors. Conversely, the authors may or may not be blinded to the names of the reviewers. Authors submitting a manuscript can suggest or request specific reviewers in their field of expertise, but this practice varies, because it could help or hinder publication.

Standards for Reporting of Diagnostic Accuracy (STARD)

These guidelines are designed to improve the accuracy and completeness of reporting of studies of diagnostic accuracy to allow readers to assess the potential for bias in a study and to evaluate the generalizability of its results. The relevant checklist and flowchart can be accessed at www.stard-statement.org.

Submission package

Submitting an article to a journal involves more than just sending the manuscript. The contents of the submission package (specified in the author guidelines) may include the manuscript itself, a cover letter from the lead author, separate figures or table files, and specified disclosures, and acknowledgments. These may include the fact that the article has been sponsored by a pharmaceutical company and that assistance with writing was provided.

Submission to acceptance time

The average time between submission of a manuscript to a journal and acceptance of the paper for publication. This is a part of the publication lead time and varies widely among journals.

Supplement

An extra issue of a journal (beyond its standard publication cycle) that is devoted to a specific topic. Journal supplements are often financed by a commercial organization (such as a pharmaceutical company) or an organization representing for-profit interests. Supplements may be produced outside the normal editorial and peer-review processes of the journal. Supplements may also be used to publish abstracts or proceedings from a scientific congress. www.nlm.nih.gov/pubs/factsheets/supplements.html

Template (manuscript preparation)

A best practice in manuscript preparation is to use a template. This involves taking the author guidelines and incorporating each requirement into a template. The writer then writes to the guideline. Planners who use this practice say that it minimizes disagreements and confusion about content. Reference software such as EndNote provides some templates.

Throw-away journals

One way to distribute journals is simply to send them to a target audience without requiring paid subscriptions. The mode of distribution is called "controlled circulation." Throwaways have large circulations, and some manage to gain substantial readership. Their acceptance rate is normally high, the articles published in these journals may not undergo peer review.

MEDICAL, SCIENTIFIC BIBLIOGRAPHY

Bibliographic citation

A statement that gives a reader all of the information needed to find a document in a publication. For example, a journal article citation includes the names of the authors, article title, journal title, publication date, volume, and page numbers. The American Medical Association Manual of Style provides guidelines for citing most forms of written information.

Bibliography

In publication planning, the term bibliography is used in 2 senses:

1. A bibliography is the list of publications used as references in the preparation of a manuscript.
2. A product's bibliography is the body of information about the product entered into the published scientific literature.

BIOSIS

Provided by Thomson Scientific, this database compiles abstracts, meeting reports, and summaries in life sciences.

Brandon/Hill list

The Brandon/Hill Selected List of Print Books and Journals for the Small Medical Library is a selection guide to help librarians working in smaller health science libraries choose high-quality medical literature. The Brandon/Hill selected lists have always been based on the opinion of the compilers. There is no model or scientific method employed.

EMBASE (Excerpta Medica)

A comprehensive bibliographic database that covers the worldwide literature on biomedical and pharmaceutical fields. It is produced by Elsevier B.V. and has somewhat different coverage than Medline.

Index Medicus

A bibliographic listing of references to articles from biomedical journals worldwide. The National Library of Medicine indexes literature that has been judged most useful to Index Medicus users by a group of distinguished physicians, medical editors, and medical librarians. Materials selected for inclusion are indexed by highly trained literature analysts. Monthly issues consist of 2 volumes: Part 1 Subject A–P and Part 2 Subject Q–Z, Authors, and Bibliography of Medical Reviews. The cumulated contents of the 12 monthly issues are published as the annual Cumulated Index Medicus.

Literature searching

The first step in preparing a manuscript is to search for other scientific literature on the topic. The literature found is used to support the content of the article and is listed in the article's bibliography.

MEDLINE®

An online database of medical literature created by the National Library of Medicine. Articles are indexed using Medical Subject Headings (MeSH). Abstracts of published articles are available online at no cost on PubMed®. MEDLINE® is an important tool for publication planning because it offers a way for readers to find medical publications without actually subscribing to journals. Also see PubMed definition.

MeSH headings, keywords, meta tags

Computerized searching works by matching words typed into a search field with words that appear in a database entry. Often, the language used in a database entry is not of a type that describes its content well to searchers. Therefore, indexers will add terms to the database entry to increase the likelihood of an article's being found by a search. Articles in MEDLINE® are indexed using MeSH, which controls the terminology used to describe the published work (www.nlm.nih.gov/pubs/factsheets/mesh.html). MeSH terms are arranged alphabetically and in a hierarchy.

Some of the ways of increasing the chances of an article being included in a search are:

- **Meta tags:** Terms applied to a document when it is posted on the Internet. Users never see the meta tags, but they are searched when users type in their search terms.
- **Keywords:** Some journals require that authors supply a list of 5 or 6 keywords that describe the topic of their article.

These attributes are important in determining whether medical publications will be found by researchers and readers who do literature searching.

PubMed®

A resource developed and maintained by the National Center for Biotechnology Information (NCBI), at the US National Library of Medicine (NLM), a part of the National Institutes of Health (NIH). PubMed® is a free resource that is comprised of citations for biomedical literature – sources include MEDLINE, scientific journals and online books. Also see MEDLINE® definition.

Science Citation Index

Also known as SCI®, and is a service of Thomson Reuters, which provides access to current and retrospective bibliographic information, author abstracts, and cited references found in 3700 of the world's leading scholarly science and technical journals covering more than 100 disciplines.

PHARMACEUTICAL MARKETING

Advertising (pharmaceutical)

The practice of promoting the sale of a pharmaceutical drug through various media outlets. This practice is generally regulated individually in each country. In the US for example, FDA Title 21 of the US Code of Federal Regulations (21CFR 202.1) states that advertisements subject to Section 502(n) of the Food, Drug, and Cosmetic Act (FD&C Act) include advertisements published in journals, magazines, other periodicals, and newspapers; and broadcast through media such as radio, television, and telephone communications systems. The US FDA also regulates advertising conducted by sales representatives, on computer programs, through fax machines, and on electronic bulletin boards.

Brand

A name, term sign, symbol, or design, or combination that identifies the goods or services of one seller or group of sellers, to differentiate from its competitors.

Brand name drug

A drug marketed under a proprietary, trademark-protected name. The brand name must pass approval a regulatory authority, such as the FDA in the US and the European Medicines Agency (EMA) in Europe, for clarity and legal clearance to ensure its unique identify. A brand name drug is generally patented for a particular indication from 5-7 years.

Brand strategy

A strategy initiated with the product's positioning statement, verbal descriptors and key messaging, and differentiation. It creates an identity for the brand that captures its characteristics consistently and conveys a reason to believe in the brand. From this foundation, the identity and promise can be communicated to audiences in a consistent manner.

Brief summary

The FDA requires that a "brief summary" of prescribing information be provided in all print advertisements and includes all risks listed in the drug's prescribing information and at least one FDA-approved use of the drug. www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#B

Center for Device and Radiological Health (CDRH)

This division of the FDA is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products. www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/

Detailing (sales activity)

Performed by medical device or pharmaceutical field representatives, detailing is the job of educating healthcare professionals about the uses and benefits and risks of a particular product, and its key messages. Sales detailing must follow strict federal regulatory guidelines, consisting of compliance with FDA labeling.

Device representative (medical device)

These field representatives are responsible for the sale of medical devices to relevant customers (physicians or hospitals). They are also considered content experts and often support procedures when relevant. They can also be organized to specialize by specific target customer, for example, the referral physician network versus the specialist performing a procedure.

Direct-to-patient marketing

Marketing of prescription pharmaceuticals to the public, as opposed to health care professionals. In the US, such marketing may include print or broadcast consumer advertising, most commonly in the form of product claims advertising, which must include the generic and brand names, at least one approved use, and the most significant risks of taking the drug. Promotions in the US can also take the form of reminder advertisements or help-seeking advertisements; these types of advertising are not permitted to describe product uses, benefits or risks.

www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm)

Division of Drug Marketing, Advertising, and Communications (DDMAC)

A division of the FDA that seeks to protect the health of the American public by ensuring that information about prescription drugs is communicated truthfully, objectively, and accurately. This division is responsible for regulating and monitoring prescription drug promotional materials, hearing complaints

about regulatory violations, initiating action against entities that disseminate false or misleading materials, and ensuring that regulatory requirements are applied consistently and fairly.

www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm080806.htm

Drug representative (“rep”)

A pharmaceutical company employee who makes visits to healthcare professionals to educate them about a particular drug, along with its use, features, and benefits.

Focus group

A qualitative marketing research tactic in which the marketer obtains opinions from potential prescribers, patients, or caregivers to ascertain their opinions and attitudes toward a product, service, concept, advertisement, idea, or packaging. This is usually an interactive group of healthcare professionals led in discussion by a moderator. The marketer commissioning the focus group is not present in the discussion.

Intellectual property

Creations of the mind, such as inventions, literary and artistic works, symbols, names, images, and designs used in commerce. Intellectual property laws allow the originator of the expression of an idea to exercise exclusive rights of use. A patent is a type of intellectual property.

Joint venture

A legal organization that takes the form of a short term partnership in which the persons jointly undertake a transaction for mutual profit. Generally, each person contributes assets and share risks. Like a partnership, joint ventures can involve any type of business transaction and the "persons" involved can be individuals, groups of individuals, companies, or corporations. In the United States, joint ventures are governed by state Partnership, Contracts, and Commercial Transactions law. A joint venture is also treated like a partnership for federal income tax purposes. A joint venture corporation involves the same type of activity as mentioned above but within a corporate framework. Foreign joint ventures are subject to the international trade laws and the laws within the foreign countries.

Label

The label is the official description of a drug product in the countries for which it has received regulatory approval; it includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnant women, children, and other populations; and safety information for the patient. The approved label must also include the established name, proprietary name (if any), adequate directions for use, and adequate warnings. The approved product label, sometimes called the full prescribing information, is considered by approval agencies to be adequate directions for use and adequate warning.

Licensing agreement

A legal agreement by which a patent holder or drug developer allows another entity to use or market its patented product.

Life cycle

The marketing life of a product, from regulatory approval through patent expiration. For medical devices, life cycle refers to a product from approval through obsolescence. Strategy is likely to change as the product moves through the stages of its life cycle.

Marketing director (corporate officer)

The officer at a pharmaceutical company who is responsible for all communications and messaging about the company's products or a particular product. At a medical device company, the marketing director is responsible for the marketing, including marketing communications, forecasting, and sales support for a product or product family.

Marketing plan

The document created by a marketer that describes in detail the entire marketing strategy, tactics, and budget for a following year that will create the right program to meet a projected forecast. The marketing plan will include unit and revenue projections, direction for the sales force, and medical marketing plans.

Market research

A systematic and objective process used to gather and interpret qualitative and quantitative data in order to define the characteristics (such as size, location, and/or make up) of the market for a product or service. The process specifies the information required, the collection method, the way results are to be analyzed and communicated and their possible implications. Data collection can include both primary research (directly from a respondent) and/or secondary research (using sources such as governments, trade associations etc.). Subsequent marketing research provides further information to improve the way organizations make decisions based on objective, reliable data and insight. Such decisions can include the identification of marketing opportunities and the generation, refinement and evaluation of marketing strategies and tactics such as market segmentation and product differentiation.

Medical device

Any item that aids in diagnosis or achieves therapeutic goals (e. g., syringes, pacemakers, implantable defibrillators, catheters, magnetic resonance imaging machines).

Outcomes research

Research that seeks to understand the end results of particular healthcare practices and interventions. Findings are commonly used in reimbursement negotiations or managed care value statements. By linking the care people receive to the outcomes they experience, outcomes research has become the key to developing better ways to monitor and improve the quality of care.

Patent extension strategies

When a drug product patent expires, the pharmaceutical company loses its exclusive marketing rights to the drug, and generic versions are able to enter the marketplace. It is to the company's advantage to retain patent rights for as long as possible. Strategies to extend patent rights could include such approaches as applying for a new patent for a revised formulation, a unique manufacturing process, or a new indication. The extension, if granted, can last for a maximum of 5 years, but total market exclusivity time cannot exceed 14 years.

Patent life

The length of time that the pharmaceutical manufacturer retains exclusive rights to market a particular drug product. The length of a patent term is 20 years from the patent filing date. As patents are obtained before a product enters the market, the amount of time the company can market the drug exclusively is often shorter than 20 years. This time varies for medical devices.

Pharmaceutical research and development

The process of acquiring new knowledge through development of a chemical or protein or molecular structure that is carried through further scientific research into a new pharmaceutical product or an improvement to an existing product.

PDUFA

The Prescription Drug User Fee Act ([PDUFA](#)) is a law allowing the FDA to collect fees from drug manufacturers to fund the new drug approval process. The Act provided that the FDA was entitled to collect a substantial application fee from drug manufacturers at the time a New Drug Application (NDA) was submitted. In order to continue collecting such fees, the FDA is required to meet certain performance benchmarks, primarily related to the speed of certain activities within the NDA review process.

PDUFA date

The goal date, or target date, that is the deadline date agreed upon by the FDA and the sponsoring company filing a licensing/marketing application, in keeping with goals of a periodically reviewed model established via the latest agreed reauthorization of PDUFA (PDUFA V2) by FDA and the United States Congress.

Pink Sheet

A weekly newsletter published by Elsevier,. Coverage includes regulatory activities of FDA, FTC, and HCFA; Congress, industry news, such as mergers and acquisitions, new product introductions and executive changes; and financial news, such as companies' sales and earnings performance and stock activity. The publication covers research, manufacturing, distribution, and retail.

Postlaunch

The period of time after the product enters the market.

Premarket approval (PMA)

The FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury ([FDA PMA website](#)). Therefore, these devices require a PMA application under section 515 of the FD&C Act in order to obtain marketing clearance (www.fda.gov). PMA is the most stringent type of device marketing application required by the FDA.

Premarket notification (PMN or 510k)

Device manufacturers who wish to show that their device is a “substantial equivalent”, i.e.at least as safe and effective, to an approved device that is not subject to a PMA (see above) are required to submit a PMN to the FDA. In this submission device manufacturers are required to compare their new device with one or several similar devices that are legally marketed. A device determined to be a “substantial equivalent” to an existing device can then be marketed in the US. ([FDA PMN](#))

Prescribing information (PI)

FDA-approved information about a drug, including efficacy, safety, and dosing instructions.

Proactive vs reactive materials

Resources used in either scientific or commercial discussions with members of the scientific or payer communities. Proactive materials are resources (slides, published papers, etc.) that may be shared to inform members of the scientific or payer communities upfront. Reactive materials are used to answer unsolicited questions raised by members of the scientific or payer communities during these discussions. Whether proactive or reactive, commercial discussions must relate directly to information within a product's label.

Product launch

This is the entry of the pharmaceutical product into the marketplace after regulatory approval.

Product life cycle (prelaunch through end of patent protection)

The life of the drug, from the earliest clinical trials until the expiration of patent. For medical devices life cycle refers to a product from approval through obsolescence.

Promotion

Marketers and manufacturers promote drug products through advertising, sales programs, and many other tactical programs in which messages and educational information is provided to potential prescribers, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs. Promotional messages can also be directed to the consumer in direct-to-consumer advertising. DTC advertising is intended to motivate the consumer to ask their physician about a particular area of health. Promotional activities must comply with FDA regulation.

Quick response code (QR code)

Two-dimensional matrix barcode that is readable by QR scanners, mobile phones with a camera, and smartphones. This image encodes information, which can be text, a website location (Uniform Resource Locator or URL), or other data. In medical publications, QR codes may be included in poster presentations and manuscripts.

Research and development (R&D)

The process of acquiring new knowledge through research and translating that knowledge into a new pharmaceutical product or medical device or an improvement to an existing product.

TrialTrove

A product of CiteLine, [TrialTrove](#) is a proprietary database of up-to-date information about ongoing clinical trials in the pharmaceutical and biotechnology industries. TrialTrove provides subscribers with information about the design and progress of ongoing trials, targeted patient populations, and the market implications of competitive research and development activity.

Washington Legal Foundation vs. Henney (1999)

The district court found that the FDA had overstepped its bounds in preventing drug manufacturers from distributing to doctors independent journal articles that described off-label uses of pharmaceuticals or medical devices. Distributing off-label information outside DDMA 21 CFR 99 is permissible but should involve the company's regulatory and legal departments to weigh benefits and risks. ([Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 - Dist. Court, Dist. of Columbia 1999.](#))

PHARMACY

Formulary

A formulary is a list of drugs preferred for use by a healthcare organization such as a hospital or HMO. A drug formulary typically includes less costly medications that are effective for treating a disease/condition. Drugs not included in a formulary may be approved by the plan for use by an individual patient after an appeal, prior authorization, or at a higher co-pay.

Formulary committee (often referred to as “P&T”, short for Pharmacy and Therapeutics committee)

The formulary committee is a multidisciplinary team composed of pharmacists, physicians, and administrators who decide the placement of a drug on a formulary.

Hospital pharmacy

A pharmacy typically located in a hospital. Hospital pharmacies dispense single doses of drugs ordered by prescribers for hospital inpatients. In some cases, hospital pharmacies may fill prescriptions for outpatients.

Online pharmacy

A pharmacy that receives prescriptions over the internet or in some cases by mail or fax. Drugs are dispensed to the patients by mail.

Prescriptions and prescribing

An instruction written by a licensed medical practitioner that authorizes a patient to be dispensed a prescription drug or provided a medical device or service (e.g. laboratory test). Prescription drugs are licensed for use by regulatory bodies (e.g. FDA) but their use requires a prescription from a licensed prescriber. Prescribing is the act of recommending a treatment to an individual patient.

Retail pharmacy (community, chain, supermarket, other)

A pharmacy with a physical location where customers can “walk-in” their prescriptions or pick-up refills. Retail pharmacies are typically part of a retail store and may offer customer focused services (e.g. immunization).

Specialty pharmacy

A pharmacy that dispenses medications and services for patients with chronic, complex, or rare diseases/conditions (e.g. infertility, transplant, multiple sclerosis).

PHYSICIANS AND SCIENTISTS

Healthcare professionals (HCPs) other than MDs

Medical practitioners, physician assistants, pharmacists, dentists, nurse practitioners, nurses, and other individuals authorized to administer or dispense pharmaceutical products.

Key opinion leader (KOL)or Key thought leader (KTL)

A specialist in a field who is regarded as a leader by his or her peers. Typically KOLs/KTLs have published and presented extensively in their area and serve on national and international guidelines committees.

Medical science liaison (MSL)

A representative of a device or drug company, typically those with advanced degrees, who serve as an expert in the application and research surrounding a drug or medical device. MSLs may support investigational or marketed products, and are not compensated based on product sales. They serve the company as an interface with health care providers/customers, especially opinion leaders, at a “peer-to-peer” level. In some cases, they are the interface for investigator-initiated research studies.

Medical specialty

An area of specialization in diagnosis and treatment of disease (e.g. pediatrics). There are several organizations in the United States that certify physicians in various medical specialties. These organizations are the American Board of Medical Specialties ([ABMS](#)) and the American Medical Association ([AMA](#)); the American Osteopathic Association Bureau of Osteopathic Specialists ([AOABS](#)); the American Board of Physician Specialties ([ABPS](#)) and the American Association of Physician Specialists ([AAPS](#)).

Pharmacist

A healthcare professional who prepares, compounds, and distributes medications prescribed by doctors and other health practitioners. Pharmacists advise physicians on appropriate drug use and effects of drugs. Pharmacists advise patients about the drugs they take and ensure that they avoid harmful drug interactions and take their medication properly.

PUBLICATION PLANNING

Agency publication team

The team representing 1 or more agencies providing publication support for a brand. Each agency could be involved in some aspect of publication strategy, publication planning, or implementation of the publication plan. The size and composition of the team vary considerably depending on the resources allocated to the product and needs of the client publication team. The agency team could include client services, medical writers, and scientific directors. Graphics and production personnel are not usually considered part of the publication team because they are typically a shared resource. Each agency publication team typically has 1 or 2 main contacts that coordinate the agency activities relative to a project.

Client publication team

The client team involved in providing input and decisions regarding the publication strategy, publication plan, and the actual publications (manuscripts, abstracts, posters, slide sets) under development. The size and composition of the team vary considerably depending on the resources allocated to the brand and needs of the team. Representatives from different departments may be members of the team (e.g. medical communications, clinical, commercial, medical affairs, biostatistics, health economics, public

relations, promotional & regulatory affairs, and epidemiology), but typically one individual leads the team, and is the main point of contact for the agency.

Communication strategy

The strategy that establishes a coordinated timeline for communication of all relevant messages through all venues, including publications, promotions, public relations, and others. The strategy identifies the brand messaging, the appropriate audiences, and the timing of these communications, as well as interactions between or among communication venues. The strategy should also prioritize all aspects of communications.

Continuing medical education (CME)

Coursework provided to medical professionals for CME credit. Publications (usually evidence-based, or strength of recommendation taxonomy [SORT] reviews) provide continuing education (CE) or CME credit required by the profession for maintaining a license. These articles are peer reviewed and written with fair balance. They are accompanied by a set of questions that must be submitted to an accredited body (i.e., approved to issue CE or CME). The journal editorial board typically selects those articles that will be used for CE or CME. These articles may be solicited or unsolicited at the journal's discretion. CE and CME credits can also be derived from non-publication activities. CME specifically targets physicians. CE targets any of the health professions.

Gap analysis

Evaluation of published literature or publication plan, or both, to identify target informational needs that are not being addressed by the plan or by the data expected from a clinical program.

Journal circulation statistics, analysis of

Evaluation of the audience of journals (e.g., numbers and types of subscribers, individual vs institutional).

Key point summary

A brief description in the form of a list or paragraph containing the main concepts the article is intending to convey.

Medical education

The most general goal of medical education is to improve the quality of healthcare. Medical education ensures that the healthcare professional prescribes a product appropriately, allowing the patient to gain optimal therapeutic benefit. In the broadest sense, medical education can include information on disease state, route of delivery, mechanism of action, therapeutic options, action plans, and physician/patient communication skills.

Needs assessment

A systematic process to acquire an accurate, thorough picture of the strengths and weaknesses of a current situation in order to improve it, meeting both existing and potential future challenges. The process is intended to collect and examine information, and then utilizes that data to determine any discrepancy between the current and desired situation. Prioritization, plan development and resource allocation are often considered so that the agreed objectives can be achieved. In the context of publication planning, a literature 'gap analysis' can be considered a type of needs assessment.

Outline

A written plan for the content of a medical publication that is developed prior to the first draft. Outlines are often formatted as bulleted lists, which detail the specific information to be included in the introduction, methods, results, and discussion of the manuscript.

Outsourcing (publication planning or writing)

The use of an external vendor (usually a medical communications agency or freelance writer) to oversee 1 or more aspects of the publication process, including publication strategy, publication planning, or execution of the publication plan. Outsourcing provides a means to increase and decrease manpower over the course of the publication plan.

Pharmacoeconomist, health economist (publication team member)

The pharmacoeconomics and outcomes research member of the publication team quantitates the value of a brand. The economic outcomes measures used include cost-of-illness analysis, cost-minimization analysis, cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis. Humanistic outcomes measures, including health status, patient satisfaction, work outcomes, and patient-based assessments, are considered in the analysis of effectiveness. The goal of pharmacoeconomics and outcomes research is to ensure wise, fair, and efficient allocation of scarce healthcare resources.

Publication plan

The document indicating the timing of specific publications (abstracts, primary articles, review articles, supplements) associated with the clinical study data or disease-state reviews. The publication plan should include the aspects of each study or review to be communicated, scientific messages to be communicated, authors, target audiences, target scientific congresses, target journals, and important benchmarks against which the publications are timed. The publication plan is a dynamic document and changes with internal and external events that affect the product and therapeutic area.

Publication plan execution

Administrative, medical writing, and editorial support required for the production of the publications constituting the publication plan. The timing and content of the publications are in accordance with the publication plan.

Publication planner

A member of the client or agency team who is involved in constructing, maintaining, or overseeing the execution of the publication plan.

Publication planning

The act of creating the publication plan, which indicates the publications to be targeted toward specific audiences through identified venues at designated times. The publication plan is the mechanism through which the publication strategy concepts are put into concrete projects.

Publication planning agency

An agency that provides 1 or more services, including publication strategy development, publication planning, and publication implementation. The publication planning agency typically is represented on the publication team by 1 or more members.

Publication planning software

Software that facilitates the publication-tracking processes. The program links each clinical study publication to the appropriate clinical study and links all publications to key scientific messages. The program allows tracking of all manuscripts and all presentations at scientific congresses. The program should maintain a bibliography of all publications executed in the publication plan. Ideally, the software should also provide extensive publication information on scientific congresses and journals, and track the publication review process.

Publication review (Internal review of publications)

The review of a late draft of a publication by non-authors to ensure that the content is medically and scientifically accurate, complete, and transparent (balanced between benefit and risk). Often, these reviews are conducted by members of the publication team who are not authors but who are employed by the sponsor; their work is typically not acknowledged in the publication. However, if the publication has no authors from the employer of the reviewer, such reviews should be acknowledged within the publication unless the review was only conducted to ensure that intellectual property rights were protected, and no feedback was provided to the authors.

Publication strategy

The articulation of the goals of the publication plan and the rationale for these goals.

Publication team (agency and client)

The team that oversees the progress of publications, makes decisions regarding the publication strategy and plan, and prioritizes execution of the plan. The publication team meets regularly, typically on a monthly or quarterly basis.

Secondary publications

These publications typically contain subsets of data from large clinical trials and are targeted to specific audiences. Data may be specific for a region or country, or for a patient population such as the elderly or children. Target audiences may include physicians, nurses, pharmacists, payers, and others.

SWOT analysis

An analysis of the strengths and weaknesses of a product, the opportunities available, and the threats faced. Taken together, these can be used to facilitate the development of a publication strategy for a product.

Timelines (publication, congress)

A diagram or table indicating when events occur for each publication. These events include availability of the data, completion of outlines, preparation of various drafts, and submission and anticipated publication dates. Also included are key benchmarks (e.g., launch date, congress abstract deadline and meeting dates).

REGULATORY, ETHICAL ISSUES

Abbreviated New Drug Application (ANDA)

This type of application contains data, that when submitted to the [FDA's Center for Drug Evaluation and Research, Office of Generic Drugs](#), provides for the review and ultimate approval of a generic drug product. Generic Drug Applications are called “abbreviated” because they are generally not required to include preclinical (animal) and clinical trial (human) data. The sponsors are only required to demonstrate that the product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to the American public.

Approval letter

An official communication from FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product.

Biologic License Application (BLA)

Biologic products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm that manufactures a biologic for sale in interstate commerce to hold a license for the product. A [biologics license application](#) is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical effects of the biologic products. If the information provided meets FDA requirements, the application is approved and a license is issued, allowing the firm to market the product.

Committee on Publication Ethics (COPE)

Established in 1997, [COPE](#) is a London-based organization that provides a forum for publishers and editors of peer-reviewed scientific journals to discuss issues concerning the integrity of the scientific record. It encourages members to report, document, and initiate investigations into possible ethics violations within the scientific publishing community.

Corporate integrity agreement (CIA)

Detailed and restrictive agreement, usually lasting five years, imposed on providers by the [Office of Inspector General](#) (OIG) when serious misconduct (fraudulent or abusive type action) is discovered through an audit or self-disclosure. Compliance initiatives, such as training, designating a compliance officer, developing detailed processes, and implementing of a communications hot line, are built into the CIAs and are designed to ensure that fraudulent behavior does not occur again.

Food and Drug Administration Amendments Act of 2007 (FDAAA)

This act was signed into law September 27, 2007 as a reauthorization of [PDUFA](#). Title VIII of the act concerns clinical trial databases. The new law expands the national clinical trial registry to include more clinical trials and more information about those clinical trials than was mandated by the Food and Drug Administration Modernization Act (FDAMA) of 1997. A new national clinical trial results database will be established, and the registry and results databases will be linked. The new law contains certification requirements and provides for civil monetary penalties.

Food and Drug Administration Modernization Act (FDAMA)

Enacted in 1997, [FDAMA](#) amends existing laws to improve the regulation of food, drugs, devices, and biologic products. Among other things, FDAMA reauthorizes PDUFA, modernizes biologic product regulation, and streamlines the approval of drug and biologic manufacturing changes.

Internal review (of scientific content)

The process by which a publication is reviewed within the sponsoring company. This review is generally performed by representatives from medical affairs, clinical research, legal, and publications departments. Representatives from marketing may be included, but typically provide a courtesy review.

Institutional Review Board (IRB)

In some countries, this may also be known as an Ethics Review Board (ERB). The IRB or ERB is independent of the sponsor of the clinical trial that reviews and approves the study protocol on ethical treatment grounds to ensure that trial participants' rights and welfare are protected. The IRB or ERB monitors the clinical trial from inception through completion.

www.fda.gov/ForConsumers/ConsumerUpdates/ucm134723.htm

Investigational drug

An active drug that is being studied in a clinical trial.

Investigational New Drug Application (IND)

A request to conduct clinical research for the use or evaluation of an unapproved drug in humans. After completing preclinical testing, a company files an IND with the US Food and Drug Administration to begin to test the drug in humans. The IND becomes effective if the FDA does not disapprove it within 30 days. The IND shows results of previous experiments; how, where and by whom the new studies will be conducted; the chemical structure of the investigational drug; how it is thought to work in the human body; any toxic effect found in the animal studies; and how the compound is manufactured.

Investigator

A healthcare professional responsible for the conduct of a clinical trial at a trial site and who coordinates with the study sponsor and the IRB. 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.

Labeling (regulatory)

All labels and other written, printed, or graphic matter on a medication or any of the medication's containers or wrappers, or that accompany the medication, such as prescribing information. The labeling of a medication includes a description of the uses for which the medication has been approved by the government for the country or region where the drug will be marketed.

Marketed drug

A drug product for which marketing authorization has been granted in at least 1 indication in a particular country by a government health agency. Once initial marketing approval is obtained, subsequent research may be ongoing for additional indications or formulations or as part of required safety follow-up.

Medical affairs (corporate officer or department)

Department in a pharmaceutical company focusing on scientific development such as phase 4 studies, investigator-initiated studies, publications, and educational and research grants.

New Drug Application (NDA)

An application used to request FDA approval to market a new drug for human use following completion of all applicable phases of clinical trial development. When the sponsor of a new drug believes that enough evidence on the drug's safety and efficacy had been obtained to meet FDA's requirements for approval, the sponsor submits to FDA a new drug application ([NDA](#)). The application must contain data from specific technical viewpoints, including chemistry, pharmacology, medical, biopharmaceutics, and statistics.

If the NDA is approved, the product may be marketed in the United States. This is also required by medical devices seeking approval of a combination device. In the EU the equivalent is the Marketing Authorization Application (MAA).

New molecular entity (NME)

A new molecular entity is an active ingredient that has never before been marketed in the United States in any form.

Off-label drug use

The prescribing of medication by a physician or other healthcare provider for a use other than that which the medicine has been approved for marketing by a government health agency.

Over-the-counter drugs (OTC)

The US FDA defines OTC drugs as those that are safe and effective for use by the general public without a doctor's prescription.

Patient package insert (PPI)

An insert that contains information for patients' understanding of how to safely use a drug product.

Publication of negative results

The publishing of clinical research with outcomes other than those hypothesized in the trial protocol.

Regulatory issues

The national regulatory agencies, such as the FDA in the United States and the EMA in Europe, have strict guidelines on what clinical trials must be done to establish a product's safety and efficacy, what is legitimate to say in marketing claims for the product, and other aspects of pharmaceutical marketing. Any question of the legality of a marketing matter is a regulatory issue. These are usually addressed by a company's legal department.

Regulatory submissions (specific documents)

Submission of a comprehensive package including all data needed for the approval and commercialization of a drug or device.

Risk evaluation and mitigation strategy (REMS)

A strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of the drug outweigh its risks. The FDA often requires a REMS to include a goal to inform or educate patients or health care providers (prescribers and/or pharmacists) about the risks associated with a drug.

Safe harbor

When a publication containing off-label information for an approved product is reviewed through the DDMAC process (outlined in 21 CFR 99), off-label discussions of this publication can occur as long as they are conducted in good faith.

Sunshine Act

A number of United States Acts of Congress that focus on transparency in various professional, government and/or industry contexts that require a physician (“covered recipient”) to report annually to the Secretary of Health and Human Services his or her identity, business address, specialty, and National Provider Identifier, along with the amount, description and nature of any payment or transfer of value he or she has received. If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the physician must also supply its name, in addition to any other nature of the transfer of value, as defined by the Secretary. Failure to report such items subjects the physician to a fine. www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf

Supplemental New Drug Application (sNDA)

Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). The supplement type refers to the kind of change that was approved by FDA. This includes changes in manufacturing, patient population, and formulation.

Therapeutic Equivalence (TE)

Drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.

Drug products are considered to be therapeutically equivalent only if they meet these criteria:

- They are pharmaceutical equivalents (contain the same active ingredient or ingredients; dosage form and route of administration; and strength).
- They are assigned by FDA the same therapeutic equivalence codes starting with the letter “A.” To receive a letter “A,” the FDA:
 - Designates a brand name drug or a generic drug to be Reference Listed Drug (RLD).
 - Assigns therapeutic equivalence codes based on data that a drug sponsor submits in an ANDA to scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the Reference Listed Drug).

Transparency (in reporting on drug development)

Pharmaceutical companies and other researchers show transparency by posting information about their trials on publicly accessible clinical trials registries at inception and by the publication of results, both positive and negative. In addition, authors of papers describing the results of industry sponsored clinical trials declare any potential conflicts of interest to journal editors and describe their role in the conduct of the trial and development of the manuscript. The involvement of professional medical writing assistance in the development of publications should also be acknowledged.

SCIENTIFIC PUBLICATION TYPES

Abstract (scientific meeting or congress)

A brief summary of a study (clinical research, trial, survey, case report) presenting the objectives, methods, results, and main conclusions. Abstracts are often restricted by word limits, character count, or size limits (must fit within a specified space).

Abstract (journal)

A short synopsis of a journal article that is generally fewer than 300 words and appears just before the full article text. It may be structured (divided into sections with standard headings such as Objective, Methods, Results, Conclusions) or unstructured (a single paragraph).

Biostatistics

The application of statistics (ie, collecting, summarizing, and analyzing data) to study results, usually in the field of medicine.

Book chapters

An edited book is one that is divided into book chapters, each of which is written by a different author or group of authors. Individual chapters are generally authored by specialists.

Case report, Case study

A clinical report of an individual patient, which usually describe patient presentation, diagnosis treatment and/or follow-up. These may be accompanied by reviews of similar cases in the medical literature.

Case series

A clinical report of multiple patient cases, which may include cases with similar presentations, symptoms, diagnoses, or treatment. No control group is included. Extensive case series may be geographic or population-based.

Drug monograph

A comprehensive written account of a specific drug that often includes the disease background for which the drug is indicated, pharmacology and pharmacodynamics of the drug, efficacy and tolerability data, and prescribing information.

Formulary kit

A collection of information about a drug that includes the drug monograph; educational materials for patients and clinicians; key trials, articles, or case studies; and frequently asked questions about the drug. These are presented to members of the formulary committee to assist in their decision making.

Late-breaking abstract

Any abstract reporting results that became available for public dissemination after the regular abstract submission deadline has passed. It must be of critical importance to the clinical and/or scientific community and/or the public.

Letter to the editor (as a publication plan document)

A proactive or reactive brief communication in a journal stating an opinion regarding a controversial aspect of therapy or a recent publication. These communications typically appear in a separate section of the journal. If the letter addresses a recent publication, then there is usually a response from the author or authors of that publication that accompanies the letter to the editor.

Original research

Development of a study that uses the scientific method (purpose, methods, results, conclusion) to determine the effect of a procedure, drug, device, or test.

Platform presentation, Oral presentation (or presenting a scientific paper at a conference)

A brief (10–15 minutes) oral presentation of scientific research based on a submitted abstract. Fewer abstracts are accepted for an oral presentation than for a poster. Not all scientific meetings accept abstracts for oral presentation.

Poster

A poster expands on data presented in an accepted abstract and usually contains an introduction to the research, methods, results, and conclusions. Posters are large printed pieces hung up in a poster hall during specified times. Each congress or conference specifies the dimensions for posters displayed at their meeting. Publication managers should check the size specifications carefully before printing posters. Posters should contain visual depictions of the data (tables and figures) in addition to text. At some congresses, posters may be unattended, on display for a specified time, while at other an author is required to stand by the poster during a prespecified time to answer questions from delegates, or to give a presentation [see Poster session (moderated)].

The expanded content from a poster may not be published, and as such, should not be cited. This information does not qualify as “prior publication” by medical journals, so in general, posters would not jeopardize publication of a manuscript describing the same objective or objectives.

Primary manuscript

A manuscript based on original research in which the author states the purpose of the study, a detailed description of the methods used, the results of the study, typically the primary and key secondary endpoints, and a discussion of those results.

Publication bias

Publication bias is a tendency to publish positive results (i.e., those that identified that something happened) over negative results (i.e., those that identified that something didn't happen). Positive (statistically significant) results are more likely to be published, to appear in English, to be published quickly and multiple times, and to be cited by others. In this way, positive results can easily become overrepresented in the literature.

Review article

Summary of current research of a clinical topic through a critical assessment of existing literature and data. Reviews may be solicited (invited) or unsolicited (uninvited).

Secondary manuscript or publication

An article that draws on the findings of the primary manuscript (see above) to further describe a product or outcomes from a study or clinical trial. Secondary publications may contain data that were excluded

from the primary publication because of word count or space limitations. Types of secondary publications are review articles or articles on subset analyses (see below).

Slide kit

A set of slides providing information on a product, disease state, or clinical topics to specific audiences such as healthcare providers or formulary decision makers.

Style manuals

A resource that is used to enforce correct grammatical style and a uniform way of discussing topics in a certain discipline. For example, the American Medical Association (AMA) Manual of Style is used by authors, writers, and editors in the medical field to ensure that works written and published in medicine have the same style (e.g., abbreviations, citation standardization, terminology, units of measure, reference style, and statistics). Journals may require use of one particular style manual, which may be described in the “instructions for authors.” Other style manuals may include the Chicago Manual of Style, CSE (Council of Biology Editors), and APA (American Psychological Association).

Subset analysis, subset manuscript

The analysis of data from trials for specific patient groups. The groups may be based on age (e.g., children, elderly) or other relevant patient demographic or disease characteristics, (those with comorbidities or receiving other medications). The publications resulting from these subset analyses can be an opportunity to further increase healthcare providers’ understanding of the product.

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