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"Clinical Trials Dictionary: Terminology and Usage Recommendations"

Curtis L. Meinert, 2012, 441 pages, Wiley, $135

Review by Norman M. Goldfarb

"Clinical Trials Dictionary: Terminology and Usage Recommendations" is an insightful and meticulous guide to clinical research that is organized like a dictionary. The author is passionate about the use of language for ill purpose, as evidenced by the usage recommendations and an essay about the language of euphemism, critiicism, intimidation, division, usurpation, equivocation, etc.

The dictionary defines over 2,600 words, including the following:

> **halo effect** *n* – 1. A positive effect due to the attention one receives; effect having more to do with being the focus of study than with the reason for study; Hawthorne effect. 2. A coloring of observations of a person due to a positive aura of the observer; the effect produced by such coloring in an observation or report. 3. A tendency to recall past events and experiences in a positive light; such a tendency involving the more likely recall and reporting of positive events or experiences than negative events or experiences; a tendency in which positive events or experiences are emphasized and negative events and experiences are de-emphasized. **syn: Hawthorne effect rt: bias, Heisenberg effect, placebo effect, placebo reactor** *Usage note:* The term is typically reserved for instances in which the effect is positive or beneficial, as suggested by the modifier halo. The term, especially when used in the sense of defn 1, has connotations similar to placebo effect. Placebo effect is due to suggestion and supposition, whereas halo effect is due to attention.
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> **informed consent** *n* – A decision by a person or the person's parent, spouse, guardian or representative to submit to some procedure or to be enrolled in a research project, after being informed of its purpose, possible risks and benefits, and the consequences of refusing to consent. For trials, generally a consent, given after being informed of the purpose of the trial, why the person is eligible for enrollment, the treatments being evaluated and their potential risks and benefits, the method of treatment assignment, the level of treatment masking, and the options for treatment and care if consent is not given. rt: deconsent, deferred consent, documented consent, oral consent, post-assignment consent, reasonable person consent model, reconsent, signed consent, written consent *Usage note:* Usually the modifier "informed" is more an expression of hope than of fact. Its use is best reserved for settings in which there are steps built into the consent process to ensure an informed decision based on evidence of comprehension of what is involved, or for settings in which the decision can be demonstrated to have been informed.
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> **subject** *n* – [ME, fr ME, fr L *subjectus* one under authority & *subjectum* subject of a proposition, fr masc & neut, respectively, of *subjectus*, pp of *subiere* to subject, lit to throw under, fr *sub-* + *jacere* to throw] study subject (defns 1, 2, 3, and 4) *Usage note:* The term is widely used in human research, especially in experimental settings. The primary difficulty with the term for persons being studied in the setting

of trials has to do with the implication that the persons are research objects. The term carries the connotation of subjugation and, thus, is at odds with the voluntary nature of the participation and requirements of consent. In addition, it carries the connotation of use without benefit, a misleading connotation in many trials and, assuredly, in treatment trials. Even if such a connotation is correct, the term suggests a passive relationship with study investigators when, in fact, the relationship is more akin to a partnership involving active cooperation. Avoid by using more humanistic terms, such as human being, person, patient or participant.

triple-masked trial *n* – A double-masked trial in which data analyses done for treatment effects monitoring are presented to the individual or group responsible for such monitoring in a way that conceals the identity of the treatment groups. *Usage note:* Avoid because single- and double-masked relates to treatment administration. The masking of the monitoring body relates to evaluation of results and has nothing to do with treatment administration.

two-armed bandit outcome adaptive assignment *n* – A method of outcome adaptive assignment in which the treatment assignment probability for a particular treatment is a function of the observed treatment difference in outcomes of those already enrolled in the trial; motivation being to minimize the number assigned to the inferior treatment. [Zelen 1969[275]; Smith and Pyke, 1965[235]; Robbins, 1956[217]; 1952[218]].

The book is available at bookstores.

Reviewer

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