



(Friday 8:08am) 4 August 2000

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Notation and terminology good practice policies and procedures (GPPP)

Definitions

currency term *n* - 1. A **term** having an underlying implied operational meaning or connotation (eg, terms such as **followup**, **mask**, or **randomize**). 2. A term having a precise meaning or definition (eg, **random** *adj*, *scientific*, **arithmetic mean**, and **variance**). 3. A term having an implied **scientific** or **research** value (eg, **case-control study**, **clinical trial**, or **experiment**). rt: **value-laden term**, **vacuous term**, **weasel term** *Usage note*: The careful worker and writer takes pains to avoid debasement of currency terms. A common form of debasement arises from use of a currency term in a loose lay sense, such as in *we performed **random** blood sugar determinations* or *we selected patients at **random*** when **haphazard** is the more appropriate term. Debasement also occurs whenever the worker or writer intermingles lay and scientific usage of a term without distinction, as in *patients **randomized** to treatment had **random** blood sugars at each followup visit*. Such indiscriminate usage is, at best, likely to confuse readers, and worst yet, cause them to question the **accuracy** and **precision** of that being reported. See also notes for **value-laden term** and **vacuous term**.

vacuous term *n* - 1. A **term** lacking in content or meaning. 2. A term used to convey an implied meaning without definition or supporting **data**, eg, **understudied** in the claim that *women and their diseases have been understudied relative to those of men*. rt: **currency term**, **value-laden term**, **weasel term** *Usage note*: Terms used to connote departure, as with **over** in **overmatch** or **under** **understudy** or **underrepresent**, are **value-laden** or **vacuous** when used as claims or assertions in the absence of definition or supporting **data**. See also notes for **value-laden term** and for **overmatch**, **underrepresent**, and **understudy**.

value-laden term *n* - A **term** carrying an implied **value** or conveying an implied value judgment (in the sense of good or bad, desired or undesired); candidate terms include **treatment failure**, **underrepresent**, **understudy**, **overrepresent**, **overstudy**, and **overmatch**. rt: **currency term**, **vacuous term**, **weasel term** *Usage note*: Good trialists take pains to avoid value-laden language in the discourse of their work. Success at avoidance requires constant vigilance over the course of a trial. The window of opportunity for avoidance is narrow, once a language convention is introduced into the lexicon of a trial. See also note for **vacuous term**.

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weasel term *n* - [fr the weasel's reputed reputation of sucking the contents out of an egg while leaving its shell largely intact] A **term** (word or phrase) used to equivocate some statement or position in order to retreat from or avoid taking a direct position or making a forthright statement. rt: **currency term, vacuous term, value-laden term** *Usage note: One of our defects as a nation is a tendency to use what have been called weasel words. When a weasel sucks eggs the meat is sucked out of the eggs. If you use a weasel word after another there is nothing left of the other* (Theodore Roosevelt, St Louis, 31 May 1916). The language of the researcher is sprinkled with terms intended to qualify or equivocate. Terms such as *maybe, perhaps, possibly, or probably* are useful in conveying doubt or uncertainty and, to that extent, have legitimate functions. However, they can also be used for equivocating. Avoid in tandem, eg, with *perhaps possibly* in *perhaps possibly the results are due to chance*. See also note for **vacuous term**.

P&P 1: Establish notation conventions during protocol development; institute editing procedures to ensure uniformity of notation throughout and during the trial; conventions to include the following:

- Treatment groups (eg, in CAMP: Bud, Ned, PBud, PNed, and Plbo for budesonide, nedocromil, budesonide placebo, nedocromil placebo, and placebo (PBud and PNed groups combined), respectively)
- Study visits (eg, Bl, Rz, and Fu for baseline, randomization and followup)
- Centers (eg, Cl for clinics, CL for central laboratory, CC for coordinating center, etc)
- Clinics (eg, Bal, Bos, and Mpls by city, or JHU, Hav, and UoM by institution)
- Organizational units (eg, SC for steering committee, EC for executive committee)

P&P 2: Establish conventions for numbering study visits relative to the point of randomization (eg, Bl1, Bl2, Rz, Fu1, Fu2, Fu3, etc).

P&P 3: Establish and maintain a glossary of official study abbreviations and nomenclature.

P&P 4: Establish and maintain language conventions for key terms and phrases; establish to provide the following:

- Generic name for person being screened for enrollment (eg, study candidate)
- Generic name for person enrolled into the trial (eg, study patient or study participant depending on whether the trial is a treatment or prevention trial; avoid *study subject*; see Dictionary for reasons)
- Generic name for experimental variable (usually, *treatment* or *intervention*; see Dictionary for discussion)
- Generic name for any value of the experimental variable (eg, study treatment)
- Generic name for treatment(s) being evaluated (eg, test treatment)
- Class name of treatment being evaluated (eg, drug, device, surgery)
- Generic name for control or comparison treatment (control treatment or comparison treatment, depending on design)

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- Specific name of control treatment (eg, placebo treatment in the case of a placebo-controlled trial)
- Generic name for treatment course represented in a particular treatment group (eg, treatment regimen; treatment arm (not recommended))
- Collective name for set of persons assigned to a particular treatment (eg, treatment group; study treatment group, not recommended)
- Conventions for indicating analysis is by treatment assignment (eg, *analysis by treatment assignment* or *analysis by intention to treat*)
- Generic name for operational units in multicenter trials (center; see usage note for *center* in Dictionary)
- Place where persons are seen for evaluation and data collection (eg, study clinic or study field site)
- Standing organizational unit in the trial (committee)
- The titular head of the study (eg, principal investigator or study chair)
- Head of a study center (center director or principal investigator; the latter not recommended in multicenter trials)
- Deputy head of a study center (eg, deputy center director or co-investigator; the latter not recommended because the title is likely to apply to others in a center as well)
- Collective membership of a study center (eg, study center staff)
- Collective membership of the study group (eg, research group or full research group)
- Variable (variable; as used in statistical literature)
- Parameter (parameter; as used in statistical literature)
- Study class (trial; less specific names such as study, project, or program not recommended)
- Treatment structure descriptors (parallel or crossed)
- Design descriptors, as applicable (randomized, controlled, placebo-controlled, masked (blind, not recommended), single-masked, double-masked, triple masked)
- Generic name for event or measure used for assessing treatment effect (outcome or outcome measure; endpoint not recommended)

P&P 5: Develop and maintain a list of terms and phrases not to be used (see my memo of 6 August 2000 entitled: Musing on the terminology of clinical trials)

P&P 6: School investigators in the vocabulary of trials; discourage use of confusing terms and troublesome or value-laden terms.

P&P 7: Establish and maintain editing procedures to avoid:

- Anthropomorphic expressions (eg, the study found; the study infers)
- Non-parallel sentence construction
- Double or triple negatives
- Constructions involving a positive or inclusive term with a negative or excluding term (eg, no smoking is permitted)
- Use of data as a singular (eg, data is being collected)

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- Use of criteria as a singular
 - Sloppy uses of placebo, random, or randomization
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