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Center for Clinical Trials

Department of Biostatistics
Department of Epidemiology
Department of International Health

Department of Medicine
Department of Ophthalmology
Oncology Center

Wednesday, 7 September 2005

Memorandum

To: Center for Clinical Trials Students, Staff, and Faculty

Fr: Curtis Meinert

Re: Tables 101: Glossary of terms and definitions

A value taught in writing and speaking courses in high school and college is use of different terms to mean the same thing. Hence, TV announcers tell us that the Yankees trounced the Orioles 10 to 1, that the twins beat the White Soxs 5 to 1, that Seattle had a cake walk in Oakland 14 to 0, and that the Devil Rays shut out Boston 1 to zip. Such variation may make things more interesting but not more understandable. Use of different words to mean the same thing is OK in everyday life, but not in research. (See essay in front matter to my dictionary on this topic). Establish terminology and nomenclature standards and stick to them.

One way to help ensure consistency in table production is via creation and maintenance of a glossary containing definitions, labels, and abbreviations used in study documents. The Document Master is responsible for creating and maintaining the glossary.

The glossary should be an official study document and should be included in monitoring reports and meeting materials.

(Sat 7:15am) 16 Jul 05 \Tables.101\Glossary.WPD

Enclosure
Glossary and Terminology Worksheet

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Tables Notebook
Chronologic file

[Tables] J:\Glossary.wpd / bjc

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Glossary and Terminology Worksheet

1 Study _____

2 Acronym ..... _____

3 Document master

Name _____

e-mail ..... _____

Phone no. ..... _____

Fax no. ..... _____

4 Defined terms (definitions adapted from Meinert's *Clinical Trials Dictionary*)

( ) **Baseline**: A time point or period from which subsequent measurements or activities are timed. ***Usage note***: Subject to varying uses in the context of trials. Typically, unless otherwise indicated, the term should be reserved for characterizations that are appropriately thought of as being at or prior to randomization.

( ) **Baseline period**: The period of time allowed for performing procedures needed to assess the suitability and eligibility of a study candidate for enrollment into a study, to collect required baseline data, and to carry out consent processes.

( ) **Dropout**: 1. A person who withdraws from a trial by an announced unwillingness to continue to submit to the required procedures for treatment, evaluation, or data collection or as deduced in retrospect from an unbroken series of absences from scheduled contacts for such treatment, evaluation, or data collection. 2. One who refuses or stops taking the assigned treatment; one who stops taking the assigned treatment and whose reason for doing so is judged not to be related to the assigned treatment. ***Usage note***: Subject to varying usage; best avoided in sense of defn 2. Most trials require continued data collection regardless of course of treatment.

( ) **Endpoint**: Event/outcome measure ***Usage note***: Best avoided because of misuse and potential for confusion. Most trials call for followup, and often treatment as well, over a defined period of time even in the presence of and following intercurrent events. As a rule, there are no endpoints in this operational sense of usage, except for death.

( ) **Enrolled**: The point at which a person is considered to have entered a study. ***Usage note***: Ambiguous when used in the absence of detail indicating the point at which enrollment occurs. Generally, in the case of randomized trials, that point is when treatment assignment is revealed to clinic personnel. Not to be confused with registration.

( ) **Lost to followup**: A person who cannot be contacted for followup. ***Usage note***: Typically, the characterization is applied to a person who is unwilling or unable to return to a study clinic for followup examinations, but such uses are best avoided because they imply that missing clinic visits is tantamount to being lost to followup. That is true for data that cannot be collected in any other way, but it is not true for data that can be collected by other means, eg, by telephone contact with the person. Do not use interchangeably with dropout or drop out. Even persons who refuse contact with study personnel can be followed for death.

( ) **Missed visit**: A scheduled visit not made within the specified time window. ***Usage note***: Subject to confusion when used in relation to contacts done by telephone or mail; limit use to visits of study participants to study clinics or visits of study personnel to a study participant's home.

( ) **Off study**: Of or relating to something done or to be done that is not part of a study protocol; off-protocol ***Usage note***: Subject to confusion; avoid. If used provide details to make nature of use clear.

( ) **On study**: Of or relating to something done or to be done that is part of a study protocol; on-protocol ***Usage note***: Not recommended for reasons stated for "off-study". A person can be "on-study" in regard to one aspect of a study protocol and off in regard to a different aspect. Avoid confusion by use of more exact terminology, or by accompanying detail to make context of use clear.

( ) **Randomization override**: A decision to proceed with randomization in the presence of contraindications for randomization.

( ) **Randomized**: The condition of having been assigned to a treatment via a random process; normally considered to have occurred when the treatment assignment is revealed to any member of the clinic staff, eg, when an envelope containing the treatment assignment is opened at the clinic.

( ) **Withdrawal**: 1. The removal of a person or observation unit from a lifetable analysis at the cessation of followup for that person or observation unit or at the occurrence of an indicated event. 2. dropout (not a recommended synonym) 3. One who has been removed from treatment (not recommended usage) 4. One who is not receiving or taking the assigned treatment (not recommended usage).

( ) Other

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_____

_____

5 Mnemonic treatment group designations

Test treatments

1 _____ 2 _____ 3 _____ 4 _____

5 _____ 6 _____ 7 _____ 8 _____

Control treatment

1 _____ 2 _____

6 Mnemonic clinic labels

1 _____	2 _____	3 _____	4 _____
5 _____	6 _____	7 _____	8 _____
9 _____	10 _____	11 _____	12 _____
13 _____	14 _____	15 _____	16 _____
17 _____	18 _____	19 _____	20 _____
21 _____	22 _____	23 _____	24 _____

7 Organizational units — Letter code

( ) Research group (RG) ..... _____

( ) Steering committee (SC) ..... _____

( ) Executive committee (EC) ..... _____

( ) Treatment effects monitoring committee (TEMC) ..... _____

( ) _____

_____

_____

8 Operational units — Letter code

( ) Clinics (Cl) ..... _____

( ) Coordinating center (CC) ..... _____

( ) Office of study chair (SO) ..... _____

( ) Project office (PO) ..... _____

( ) Reading center (RC) ..... _____

( ) Central lab (CL) ..... _____

( ) _____

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_____

9 Position names or titles

( ) Trial head

( ) Study chair

( ) PI (not recommended)

( ) _____

( ) Head of clinic
  ( ) Director
  ( ) PI (not recommended)

( ) _____

( ) Head of coordinating center
  ( ) Director
  ( ) PI (not recommended)

( ) _____

10 Visit designations — Letter code

( ) Screening visits (Sc) ..... _____

( ) Baseline visits (Bl) ..... _____

( ) Randomization visit (Rz) ..... _____

( ) Followup visits (FU) ..... _____

( ) _____ ..... _____

_____ ..... _____

_____ ..... _____

_____ ..... _____

11 Completed by _____

12 Date completed ..... __ __ Dy __ __ __ Mo __ __ __ __ Yr