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SUE STILES PROGRAM IN INTEGRATIVE ONCOLOGY at UCLA Jonsson Cancer Center

Understanding the Language of Clinical Trials

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The language of Clinical Trials is sometimes difficult to understand. While the words and phrases are in specific meanings derived from the disciplines of statistics and bio-statistics, and include medical terms, meanings may be unfamiliar to patients and family members. This glossary is intended to assist patients generally, but it does not include language that may be specific to trials for a particular disease.

Underlined words found in any definition are included in this glossary.

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A

Accrual – 1. Process of enrolling patients in a trial. 2. Number of patients enrolled, or planned for enrollment.

Adjuvant – Treatment secondary to the primary treatment. *Eg:* Chemotherapy after surgery is *adjuvant* usually prescribed in hope of preventing recurrence or further spread of disease. *Cf:* [Neo-Adjuvant](#).

Arm – One of the treatment groups of a [randomized](#) trial. The majority of randomized trials have 2 a., but

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B

Best Supportive Care – Treatment to control, prevent and relieve complications and side effects and to [improve quality of life](#).

Blind – Aspect of randomized trial in which the patient is not told the arm of the trial to which he is assigned.

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C

Clinical – 1. Reference to the treatment of humans, rather than animals or laboratory studies. 2. General term for a physician.

Cohort – A group of patients within the same [arm](#) of a trial.

Complete Response (CR) – Condition post treatment in which no trace of detectable disease remains, though some patients with a *c.r.* may be "cured."

Control – The [arm](#) of a [randomized](#) trial in which participants receive the standard treatment or a [placebo](#).

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D

Disease Free Survival (DFS) – Length of time post treatment, the patient survives without evidence of [Progression Free Survival](#).

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Dose Limiting Toxicity (DLT) – Appearance of side effects during treatment that are severe enough to dosage or strength of treatment agent, or to prevent continuation of treatment at any dosage level.

Double Blind – Aspect of a [randomized](#) trial in which neither the participant nor the investigator knows if patient is assigned. Purpose is to eliminate any bias in reporting of results.

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E

ECOG Status – Scale for measuring [performance status](#), developed by the Eastern Cooperative Oncology Group (ECOG). Scores of "0" or "1," and trials enrolling patients with status of "3" are rare. See [Karnofsky Status](#) and :

End Point – The goal of a trial: *i.e.* what the trial is attempting to find out. Clinical trials must clearly define end points. Often includes [response](#) rate, survival and [toxicity](#).

Evaluable Disease – One or more tumors which are known to be present, but which cannot be measured. Examples: pleural effusion, ascites. Cf: [Measurable disease](#).

Exclusion Criteria – Factors which will prevent enrollment in a trial. Commonly, age, performance status, and [criteria](#).

Experimental – The [arm](#) of a [randomized](#) trial in which patients receive the investigational therapy. Cf:

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F

Food and Drug Administration (FDA) – United States government agency with jurisdiction over many products. All Clinical Trials must have FDA approval before enrolling patients.

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G

Grade – 1. In clinical trials, a numeric scale used to rate the severity of [toxicity](#) associated with a treatment. Grades are separately rated from "0" to "4." "0" = side effect not present. "1" = present but minor. "2" = present, moderate significant effect. "3" = potentially life threatening effect. "4" = severe. G. "3" or "4" toxicity usually results in further treatment being stopped. If resumed, treatment may be at lower dosage or frequency. 2. Scale used to refer to the levels of aggressiveness of a disease.

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H

Histologic Confirmation – Laboratory examination of tissue from biopsy or surgical procedure to determine tumor type and disease type. Many trials require *histologic confirmation* of disease as a condition of enrollment.

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I

In vitro – Latin. Literally "in glass." Refers to laboratory testing of a drug or combination of drugs.

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In vitro – Latin. Out of the body. Another description of laboratory testing.

In vivo – Latin. Literally "in life." Refers to laboratory testing of therapy on animals (often mice or rats) or humans in a clinical setting.

Inclusion Criteria – Factors which must be present in order for patient to enroll in a trial.

Commonly included are age, [performance status](#), [measurable disease](#), and aspects of medical and treatment validity all criteria must be met for enrollment in a trial.

Informed Consent – Process of informing a patient about the potential risks and benefits of participating in a trial without his *i.c.* The process includes discussion with the physician-investigator and also a coordinator. If the patient agrees to participate, an *i.c.* document outlining in plain language what treatment and benefits of participation, and the alternatives to participation, is signed by the patient and is witnessed.

Institutional Review Board (IRB) – A review panel which approves trials prior to initiation to assure compliance with scientific standards, and that the [Informed Consent](#) is adequate. At UCLA, there are 2 such Boards: The *Committee (HSPC)* and the *Institutional Scientific Peer Review Committee (ISPRC)*, and both must approve enrollment of participants.

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K

Karnovsky Status – A [performance status](#) scale which rates the severity of symptoms and degree of disability (no symptoms) to 0% (deceased). See [ECOG Status](#), see also Appendix 1.

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L

Lesion – 1. Pathologic tissue change. 2. An individual site or point in a multifocal disease.

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M

Maximum Tolerated Dose (MTD) – Highest dosage of a drug, drug combination or other treatment that a patient can tolerate. Usually determined by [Phase I Trial](#).

Measurable Disease – Tumor or tumors which can be clearly measured for size. *Eg:* lung nodules that are larger than other tissue in radiologic studies, or lumps which can be felt or seen by the naked eye and measured. A [Phase I Trial](#), so that any [response](#) can be measured.

Metastasis – 1. "Secondary" tumor at a location remote from original, "primary" tumor site. Cancer cells travel from one site to another organ, and multiply at the second site, forming a new tumor. 2. Process by which such secondary tumors form. Adjective: *metastatic*.

Multicenter – A trial enrolling patients at several locations ("sites") simultaneously.

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N

Neo-Adjuvant – Initial treatment which is not the primary therapy. *Eg:* Chemotherapy or radiation prior to surgery in instances of locally advanced disease in the hope that the size of the tumor is reduced in order that it

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another therapy, or permit less radical treatment than otherwise might be required. Cf: [Adjuvant](#).

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O

Open Label – Type of trial in which both the investigator and the participant know which drug or combination they are receiving.

Many [Phase III Trials](#) are *open label*.

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P

Partial Response – A post treatment decrease in the size of a [measurable](#) tumor of at least 50%, but not a complete response.

Performance Status – 1. A measure of the level of activity of which a patient is capable. 2. By implication, a measure of the extent of disease. See [ECOG Status](#) and [Karnofsky Status](#).

Phase I Trial – Trial to determine the safety of a therapy or combination therapy not previously used in [vitro](#), [in vivo](#). *Phase I trials* typically enroll patients in [cohorts](#), with each successive cohort receiving an investigational therapy until [dose limiting toxicity \(DLT\)](#) is observed in a defined number of patients. The DLT is then defined as the [maximum tolerated dose \(MTD\)](#). Patients enrolled in Phase I trials have disease that is not standard therapies, and usually only [evaluable disease](#) is required.

Phase II Trial – Trial to determine the effectiveness of a therapy or combination therapy. Patients in a Phase II trial must have [refractory](#) disease, and must have [measurable disease](#) so that the [response](#) to the investigational therapy can be determined. Phase II trials of the same therapy are often conducted on several different types of disease to determine if the therapy is effective in more than a single type of cancer.

Phase III Trial – Trial to compare 2 or more treatments for a single type and stage of disease. The [end point](#) is usually survival or [disease free survival](#). Phase III trials are most often [randomized](#). Some Phase III trials compare the investigational therapy (the [experimental arm](#)) with the current [standard of care](#) or [best supportive care](#) (the [control arm](#)) or with another existing treatment for the same disease.

Placebo – Inert substance (eg: sugar pill) used as "therapy" for 1 [arm](#) of a [randomized](#) trial, most often used in a trial to compare two different treatments, patients will be given both a *placebo* with the appearance of one of the other of the therapies.

Progressive Disease – Term applied when disease is worsening, documented by tests showing that additional tumors have appeared. Some trials are limited to patients with *progressive disease* so that if a response is observed, it is assumed to be the result of the investigational therapy.

Progression Free Survival – Time during which the patient lives without any worsening of the disease.

Protocol – 1. Detailed plan of treatment including dose and schedule of any drug or other therapy used in the trial. 2. Synonym for "Clinical Trial."

Protocol Document – Written document which describes in detail the plan for conduct of a clinical trial, including a detailed description of how therapy will be administered, [inclusion](#) and [exclusion](#) criteria, criteria for treatment, and a schedule of tests to be performed prior to, during, and following treatment. Also include a consent form document.

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Q

Quality of Life – 1. Overall enjoyment of life and activities of daily living. 2. Measure of the ability to perform sense of well-being. Many trials include a *q.o.l.* survey, often including a patient diary.

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R

Randomized Trial – Clinical trial having at least 2 [arms](#). The decision as to which arm the patient is assigned usually by a computer program.

Refractory – Disease which is not responsive to standard treatment. *Refractory* is applied to a patient's disease has failed to respond to a standard treatment, or if the patient cannot tolerate a standard treatment.

Response – Decrease in the size of a tumor, post therapy. See [Complete Response](#) and [Partial Response](#).

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S

Stage – Measure of how far the disease has advanced in terms of size of the primary tumor, lymph node involvement ([metastasis](#)) to other sites in the body. Each cancer type has its own staging system. See Appendix 2.

Standard of Care – Generally accepted treatment for a disease or condition. Treatment which is not experimental approval.

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T

TLA – Three Letter Acronym. *Eg:* [DLT](#), [MTD](#).

Toxicity – Literally, the state of being poisonous. In Clinical Trials, *t.* is a reference to side effects of the treatment.

Tumor – A lump, swelling, or mass. A *t.* may be benign or malignant. *Synonym:* Neoplasm.

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U

Upper Limit of Normal (ULN) – Frequently used in setting [inclusion criteria](#) for participation in a trial. *D* normal limit for a given test the patient may be, and still qualify for inclusion in the trial. *Eg:* "Bilirubin < 2 times the upper limit of normal." (Bilirubin is a substance in the blood, and elevated by liver problems.)

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W

World Health Organization (WHO) Status – A [performance status](#) measure very similar to [ECOG status](#).

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ECOG PERFORMANCE STATUS SCALE and KARNOFSKY STATUS SCALE COMPARISON

ECOG STATUS	MEANING	KARNOFSKY STATUS
0	No symptoms, fully active, able to work.	100
1	Symptomatic, but not spending extra time in bed. Able to do light work.	90 or 80
2	In bed less than 50% of the time, unable to work, but able to care for self.	70 or 60
3	In bed more than 50% of the time, though not bedridden, limited self care.	50 or 40
4	Completely bedridden.	30 or 20

KARNOFSKY PERFORMANCE STATUS SCALE

KARNOFSKY STATUS	MEANING
100%	No symptoms.
90%	Able to carry on normal activity; minor signs or symptoms of disease.
80%	Able to carry on normal activity with effort; some signs or symptoms of disease.
70%	Cares for self, unable to carry on normal activity or do active work.
60%	Requires occasional assistance but is able to care for most of own needs.
50%	Requires considerable assistance and frequent medical care.
40%	Disabled; requires special care and assistance.

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30%	Severely disabled; hospitalization indicated, although death not imminent.
20%	Very ill; hospitalization necessary; active supportive treatment required.
10%	Moribund, fatal processes progressing rapidly.
0	Patient expired.

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THE STAGING OF CANCER

A number of systems for the staging of cancer, the measure of how far the disease has advanced in tumor, lymph node involvement and spread (metastasis) to other sites in the body, have developed over making therapeutic decisions and estimating prognosis.

Each disease site has specific tests that are required for proper staging. Staging without surgical exploration is clinical staging. When a biopsy is performed and subsequent pathologic testing follows, the result is histologic staging.

The American Joint Committee on Cancer has developed the TNM or Tumor-Node-Metastasis staging system. Several staging systems developed in the past. The American system is identical to the classification of International Union Against Cancer, which is helpful interpreting scientific research data. The classification is based upon the primary anatomic site and histology (microscopic appearance) share similar patterns of growth and extension. TNM is used individually for each site, because of the different behavior of tumors at different sites. For most cancers, the TNM classification is based with the anatomic extent of the disease. There are, however, some instances where other factors such as performance or the age of the patient are incorporated into the system.

"T" stands for "tumor." Small tumors are classified as "T 1" whereas locally advanced tumors with invasive growth are classified as up to "T 4." "N" stands for lymph "nodes." Tumors without lymph node involvement are classified as "N 0." Tumors with positive lymph node involvement have progressively higher values assigned, depending on the extent of disease. "M" stands for "metastases." If there is no progression of disease to other body sites, the patient is classified as "M 0." If disease has spread to one other organ site the classification would be "M 1," and increase for each additional site.

The TNM classifications are grouped into stages which are expressed as Roman numerals I to IV, with stage I being the most limited and stage IV disease the most extensive. The staging systems for each disease reflect the distinct behavior of the tumor and in any discussion of cancer staging it is well to remember the dandelion analogy: When a dandelion seed lands on a neighbor's lawn, a vacant lot across the street, or in a sidewalk crack, what grows there is a dandelion. A tumor which spreads, for example, from the colon to the liver and subsequently to the bone remains a colon cancer.

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Material contained in this Glossary is presented for information and education purposes only. It should not be used as a substitute for medical or other professional advice in the diagnosis or treatment of any disease or other health problem. If you have a health problem, please consult a physician or other qualified health care provider.

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