

SOUTHWEST ONCOLOGY GROUP

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COST CONTAINMENT

POLICY STATEMENT

The Southwest Oncology Group recognizes both the increasing costs of medical care and the efforts to contain these costs. It is the policy of the Group to minimize costs incurred to patients, government agencies, and the health insurance industry associated with the performances of Group trials. In addition, there is expense to the individual treating sites and to the Southwest Oncology Group itself related to the collection of unnecessary data, and the Cost Containment Policy aims to reduce such costs. This will be done without sacrificing standards of care or patient safety by eliminating those diagnostic procedures and ongoing laboratory and imaging techniques not critical to patient management or study endpoints in Group protocols. In some cases, when required to collect specific data points in order to meet NCI or FDA requirements (and when additional external support is provided), these general guidelines may not apply within a specific study.

STUDY PARAMETER GUIDELINES

1. Imaging studies (CT, radionuclide, MRI) should not be at fixed intervals unless necessary for tumor measurement or determination of progression. If imaging is necessary, the following guidelines apply:
 - For studies that use "Response Rate" as the primary endpoint, link physical measurements of tumor to cycles of treatment. In general, imaging studies for tumor measurement should be performed every other cycle (i.e., every eight weeks on a four week treatment schedule; every six weeks on a three week treatment schedule) unless more frequent studies are clinically indicated.
 - If "Time to Progression" is the primary endpoint, the imaging should be scheduled at specific times, rather than linked to cycles, to overcome irregularities in tumor measurement timing caused by treatment delays.
 - In randomized trials, tumor measurements should be required at the same intervals for all treatment arms.
 - PET (or PET/CT) is not a validated measure of response and should not be used to measure response to therapy. PET is considered standard of care for staging of some specific types of cancer (such as primary lung cancer) and therefore could be used to determine protocol eligibility in these specific cancer types.
2. Pretreatment laboratory tests must not be mandatory unless required for disease or toxicity assessment, or to determine patient eligibility prior to study entry.

3. The Southwest Oncology Group does not collect and store data on clinical laboratory tests that are not directly related to an endpoint of the study. Laboratories used to indicate toxicity, and validated markers of tumor response may be requested with the following guiding principals:
 - Laboratory tests of minimal utility in performing disease assessment or evaluating toxicity should not be used, nor should those that duplicate the function of other tests (e.g., LDH, SGPT, BUN or urinalysis) be routinely requested. Therefore, in studies where SGOT is collected, SGPT or LDH should not be required. Urinalysis or BUN will not be required when serum creatinine is required.
 - The collection of specific electrolytes should only be performed routinely in studies where treatment may induce electrolyte abnormalities. Serum protein determination, with the exception of myeloma proteins, is of little use in monitoring general status, tumor status or toxicity, and should be discouraged.
 - For laboratories requested to evaluate toxicity, the CTCAE grade of laboratory abnormalities will be collected on Case Report Forms, and not the lab value itself, unless the pre-defined study endpoints require the actual laboratory value.
 - Tumor response markers should be validated response markers used commonly in the treatment and evaluation of cancer patients (such as PSA, CEA, CA 15-3, CA-125), and in these cases the actual value may be collected.
 - The time limit for baseline laboratory studies will generally be within 28 days prior to registration. It is understood that this is a maximum time frame. Shorter time frames will be used for those patient populations or investigational agents where safety concerns may be a greater issue.
4. EKGs, while appropriate in pretreatment evaluation in many protocols, are of little use in monitoring general status, tumor status or toxicity. Repeat EKGs on a routine basis should be discouraged except in the setting of some cardiotoxic drugs known to induce arrhythmias or prolong the QT interval. Even in doxorubicin therapy, EKGs are of little use in predicting CHF; routine repetition should be avoided.
5. Upon circulation of the first draft of each study, Study Coordinators are given the following instructions:

"You will notice that the Study Calendar (Section 9.0) is completely blank. We have instituted a 'zero-based calendar' approach to protocol development. Please decide which tests and evaluations (and the appropriate time intervals) are absolutely necessary for the evaluation of patients for this particular protocol. We are interested in study parameters that deal only with patient safety and endpoint documentation. We are attempting to prevent duplication of effort and contain costs for protocol patients."