

Discipline Committees

The Statistical Center has focused a great deal of effort toward service to three Southwest Oncology Group active discipline committees: pathology, surgery, and radiation therapy. These committees require two kinds of support from the Statistical Center: (1) processing the results from the data reviews performed by the members of these committees, and (2) providing statistical design and analysis services in support of their scientific activities.

The review functions performed by the discipline committees are designed to answer questions of protocol eligibility (pathology and surgery) or protocol compliance (surgery and radiation therapy). The summary data, which result from these reviews, are an important part of the Group patient data evaluation system and are integrated into the patient evaluation forms along with other eligibility and compliance data. In addition, the review processes yield important detailed data regarding pre-treatment status (pathology), procedures performed (surgery and radiation therapy), or outcome (pathology and surgery). The study coordinators are provided with copies of these detailed data forms.

The specific elements of the Statistical Center data operations that are relevant to the support of these discipline committee functions include the following.

1. A master's level biostatistician is assigned as the statistical liaison to each discipline committee. This biostatistician is responsible for seeing that the review processing requirements of the assigned committee are implemented and functioning and for seeing that their respective committees are provided with the necessary summary data on the operation of the review process. These reports include information on the number of reviews performed, the performance of specific institutions, review summary outcomes for specific protocols, etc.
2. The discipline coordinator supports each discipline committee through a variety of functions, depending on the needs of each discipline committee. These include patient registration, data entry management, forms tracking, quality control, protocol compliance enforcement, protocol setup, and review of protocols with respect to discipline committee data processing.
3. The study description file (SDF) corresponding to each study registration that involves discipline committee participation contains specifications of the various review committee options. Most of these are processing steps to be executed at the time of patient registration to that study and others cause flags to be set in the database. The processing steps might include request for additional information, display of special notes, creation of expectations, validation of special eligibility requirements, etc. The database flags include indications that the patient is registered to a study involving one or more review processes, and the setting of these flags may depend on the treatment assigned.
4. The expectation system is used to notify institutions of the need to submit materials and/or forms required by the discipline review processes, and then to track the submission of the materials or forms; it also yields timeliness data for the institutions. The resolution of expectations is done as the forms or materials arrive by the discipline coordinator at the Statistical Center.

5. The primary returns from a review process are the summary results, that is, an indication of eligibility (pathology and surgery) or protocol compliance (surgery and radiation therapy). The data are entered as soon as the review is completed and returned by the respective reviewer. The summary data are entered by the Statistical Center discipline coordinator. The input procedures are highly structured and include the creation of notification of changes in eligibility status, automatic update of overall eligibility (if applicable), and the ability to make annotations.
6. Summary results of the discipline review, including annotations, are reported to the study coordinators in the evaluation forms sent to them for patient evaluation data review. In addition, copies of the detailed discipline review process forms are sent to the study coordinators as they become available.
7. For each Group Meeting there are reports prepared for the Radiation Therapy and Pathology discipline committees on the results of the review processing for that cycle. These reports include information on institutional timeliness, review-specific eligibility/deviation rates, review process timeliness, review process volume, etc.
8. The Statistical Center also provides support for the entry of whatever other discipline review committee data are generated.

Cytogenetics

The Southwest Oncology Group Cytogenetics Business Office was relocated from City of Hope National Medical Center to the SWOG Statistical Center in June 2002. The Business Office is staffed by one data coordinator and one statistician. Responsibilities of the SWOG Cytogenetics Business Office include coordinating the application and approval process for new cytogenetics laboratories. Another primary responsibility is the data entry of cytogenetics forms. Data entry time consumes about 30 minutes per case due to the volume of forms submitted per case. The data coordinator and biostatistician coordinate Cytogenetics Committee Meetings, prepare patient files for central reviews held at each semi-annual Group meeting, and assist committee members as necessary during the central review process. Database queries are generated and submitted as requested by the Cytogenetics Committee Chair and other members of the committee. A future goal for the Cytogenetics Business Office is to convert case report forms and data entry operations to web-based programs whereby participating laboratories will remotely submit cytogenetics data directly into the database. There are currently 4329 specimens in the cytogenetics database from 33 different SWOG trials. We receive 23 samples a month on average.