

## **Data Analyses and Reporting**

### **Data Reporting**

All open and most recently closed studies are described in the semi-annual Report of Studies, which forms the basis for much of the discussion in the Disease Committees at the Group meeting. Data are as current as possible, subject to printing deadlines and the need for data review by the study coordinators. A patient-driven evaluation system is utilized to smooth the workflow, rather than relying on batching the reviews every six months. The description of each study includes a summary face sheet, schema, accrual information by arm and by institution, stratification and description factors and toxicity information. Response and survival comparisons are presented only when approved by the Data and Safety Monitoring Committee.

Standard report modules extract data from the database and create these tables and a computerized worksheet program helps keep track of the Report contents. The Report of Studies includes chapters for each disease committee, and the cancer control research committee. An additional section contains information on accrual to all Group studies by institution and study type; data on institutional performance regarding timeliness and completeness of forms is also included.

### **Analysis of Studies**

Additional analyses, generally using SAS® after data have been extracted from the database, are typically necessary before a study can be published. A program to extract data from the Oracle® database and create a SAS® data set was written to assist in this process. SAS® version 6.07 procedure LIFETEST is used for log rank and stratified log rank tests, and the procedure PHREG is used for proportional hazards regression and testing alternative hypotheses. Dichotomous data are analyzed using the procedures FREQ and LOGISTIC. Locally developed analysis software is used when necessary, especially for Cox regression diagnostics and for recursive partitioning. In addition, faculty statisticians are involved in ongoing methodologic research for more efficient trials designs, and improved analytic techniques.

### **Inclusion of Women and Minorities as Research Subjects**

The Southwest Oncology Group is committed to the equitable inclusion of women and minorities in all trials. We have a Committee on Women and Special Populations, one of whose missions is the monitoring of accrual for sex, race/ethnicity, and age, and suggesting interventions if needed. Our work on accrual of women was presented at ASCO (Hutchins et al., 1994); overall, the Group accrues more women to trials than would be suggested by incidence due to our emphasis on breast cancer. A study of accrual to older populations (Hutchins et al., 1999) indicated that there is an under representation of patients 65 years of age or older in cancer treatment trials. In addition, we have investigated sex, race/ethnicity, and age as prognostic factors in several disease sites (Modiano et al., 1996; Dahlberg et al. 1994; Flaherty et al. 1996; Albain et al., 1990, 1991, 1991). All Phase III trials now contain an analysis of treatment effects by race/ethnicity and sex, and have accrual goals in subsets where warranted.