

## **Training Programs**

### **Clinical Trials Training Course (CTTC)**

The Data Operations Department at the Statistical Center, along with assistance from the Operations Office staff and experienced clinical research associates, conducts a one and a half day training course for new clinical research associates. This training course is held prior to each Southwest Oncology Group Meeting. Ninety-two clinical research associates from throughout the Southwest Oncology Group participated in the Spring 2002 course.

The training course provides an overview of the Southwest Oncology Group as well as information pertaining to topics such as the explanation of clinical trials, phases of studies, quality control, quality assurance, institutional review board procedures, and informed consent. Familiarization with the Southwest Oncology Group registration process, forms, and office procedures are also included. A practicum round-table discussion provides clinical research associates with practice of forms completion, toxicity grading, response assessments, and calculating laboratory values.

An explanation of data flow, the expectation system, patient follow-up, and toxicities are other topics discussed in the training. Volume I of the Clinical Research Manual, which details the administrative procedures of the Group, and Volume II, which describes the forms and coding guidelines of each disease committee, are available via the internet at [swog.org](http://swog.org). CTTC participants are oriented to the web-based manual during the training course. Copies are mailed to participants who do not have Internet access.

### **Study Coordinators Workshop**

Members of the Statistical Center staff, in conjunction with Operations Office Staff, conduct a yearly, half-day course for researchers planning to become Study Coordinators. This course is held the day prior to the Spring Group Meeting. Each year, approximately 35 investigators participate in this workshop.

The course provides training in the responsibilities of a Study Coordinator, and of the coordinated efforts of the Statistical Center and Operations Office. There are presentations on ethics, protocol development steps, clinical trials design, data flow, and study coordinator responsibilities during development, during study accrual, and during manuscript preparation. The final hour and a half is a practicum session, where participants are asked to review a mock patient chart, to introduce Group coding guidelines, data collection forms, and study coordinator patient evaluation responsibilities.

### **Ortho Young Investigators Training Course**

The Statistical Center and Operations Office give a twice-yearly intensive course to new investigators who show promise of providing future leadership to the group. This program, provided in part by support from the HOPE foundation and Ortho Pharmaceuticals, was established in 2000. Applications for the workshop must include a proposal for a clinical trial, and recommendations for a Southwest Oncology Group Investigator who will serve as a mentor to the Young Investigator. Selection is limited to four candidates per training session.

The sessions consist of a four-day program at the Operations Office, followed several weeks later by four days at the Statistical Center. Participants attend presentations of protocol development, statistical methods in clinical trials, an overview of data collection, data flow and data evaluation. A key goal of the program is to have the Young Investigator produce a complete protocol document that is appropriate for CTEP submission.

Thus far, 19 investigators have participated in this program. As of July 2002, five protocols have been activated, Lung S0022, Lung S0126, GI S0107, GI S0127 and Ovarian S0211. The remaining protocols continue in active protocol development.