

Data Operations

Patient Registration

All patients are registered using a computer program (WebReg), which interacts with the database during the registration. (Well-defined manual registration procedures exist for those times when the computer system is not available.) Registrations are performed either directly via the Web by institutional CRAs or by data operations staff using WebReg during the telephone conversation with the representative from the institution registering the patient. The main advantage of using WebReg is that the registration procedures are strictly enforced in a uniform manner for all registrations. Some of the other advantages and features of WebReg include:

1. The database is instantaneously updated with each registration.
2. There is validation of the status of the investigator and institution registering the patient. The approval status of the facility to perform radiation therapy (if applicable) is validated.
3. There is a review of previous registrations in cases where the patient is being registered to additional protocols or subsequent parts of a protocol.
4. Blinded treatment assignment is possible.
5. Registrations requiring randomization are dynamically balanced using the current database stratification counts. Post-registration modifications to stratification data instantaneously adjust the dynamic balancing algorithm.
6. Relevant study characteristics and special notes about the study, including stratum or treatment specific notes, are automatically presented during the registration.
7. A confirmation of registration is generated with copies for all relevant study participants. This confirmation includes a summary of the registration along with a list of expectations for forms submission.

WebReg is driven by a study description file (SDF), which contains the information needed to control the registration process and to load the database study description tables. There are one or more SDFs for each study. These are prepared by the data coordinator for that study with the consultation of the data coordinator's supervisor, the study statistician, and discipline data coordinators and biostatisticians when applicable.

Flow of Data

A single set of data forms for SWOG coordinated trials is mailed, faxed or web-submitted to the Statistical Center from the institutions where the data are collected. For non-SWOG coordinated intergroup studies, institutions submit data directly to that coordinating statistical center. Data forms are processed according to the following conventions:

- Illegible forms or those lacking required identifiers are returned to the institution.
- Faxed or mailed forms are routed to the data control technicians. Study Coordinators are mailed copies on an event-driven basis.
- Slide and/or block information (as applicable) for pathology reviews are entered into the database by the discipline coordinator. Materials are tracked in the database through the review process. All results (eligibility and detailed review results) are also entered in the database.
- Complete sets of radiation therapy materials are sent either directly to the Quality Assurance Review Center or to the central RT reviewer. The review results are entered into the database by the discipline coordinator at the SWOG Data Operations Center.
- Surgical summary forms (as applicable) are forwarded to the surgery study coordinator, along with operative records and pathology review forms.
- Upon completion of data entry, all forms are routed either first to the disease site data coordinator for a quality control review or directly to the electronic patient chart.

Data Entry

All newly activated trials use forms, which can be submitted electronically via the web. Entry of other Southwest Oncology Group data is accomplished in several ways. Most of our current forms were created using the commercial product Teleform[®], which produces forms that can be scanned directly into the database. Data entry of non-Teleforms is also done through the Teleform[®] software. Updates of last contact date, status, off-treatment date and expectation resolution are done through a separate in-house Visual Basic application. Data is sent to the database and a TIFF image of the form is then sent to the electronic patient chart.

Electronic File Organization

The Statistical Center organizes files so that all data for a patient are located in one electronic file.

Data within patients' charts are maintained with the most recent data at the top or on the left-hand side of Chart Manager as an incoming document. Electronic records are saved in a back-up database each evening, the security of which is detailed under data security and disaster recovery in the computing infrastructure section. The electronic filing system of data is stored by patient-specific numbers, then under study identification.