

SWOG

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Subject: Quality Assurance Program
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QUALITY ASSURANCE PROGRAM

PURPOSE

The SWOG Quality Assurance Program was developed to enhance the reliability and validity of clinical trials data from Group institutions through the use of routine monitoring procedures. Audits are designed to provide assurance that the data reported on the research records accurately reflect the data as reported in the primary patient record and to verify compliance with protocol and regulatory requirements. The Program also surveys data management practices at each institution in order to provide educational support to the clinical trial sites regarding issues related to data quality, data management, and other aspects of quality assurance.

QUALITY ASSURANCE SITE VISITS

Each SWOG institution will be audited at least once every three years but will remain at annual risk of an audit. Institutions will remain at risk for audit even if their membership in the Group is withdrawn or terminated since they have made a commitment to long-term follow-up of patients on study for as long as the patient remains alive.

- 1) To become full Group members, new probationary Member and Community Clinical Oncology Program (CCOP) institutions must undergo a successful on-site Quality Assurance Audit within 6-18 months of registering their first patient. After a successful Quality Assurance Audit, the institution will be placed in the normal rotation to be audited again within three years.
- 2) Member, CCOP and UCOP institutions will be audited on site. A number of patients equal to 10% of SWOG and CTSU accruals since the last audit, with a minimum of three, will be randomly selected for review. While most cases will be selected from accruals since the last audit, all patients accrued will be subject to selection.
- 3) A number of patients equal to 10% of SWOG and CTSU accruals with a minimum of three cases from each member affiliate will be selected. Cases from affiliates registering less than thirty subjects in three years may be reviewed at the same time as the cases from the Member institution with which the affiliate is associated. Affiliates registering greater than thirty patients in three years will be reviewed separately on-site.
- 4) Affiliate sites will have an on-site Pharmacy audit conducted at least once every other audit cycle if time and budget constraints allow.

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- 5) In most instances, the on-site audit will take one full day; however, if accrual is exceptionally large, two to three days may be required. The audit team will consist of at least one investigator, nurse or CRA, and a Quality Assurance representative from the Group's Operations Office.
- 6) Institutions will be verbally notified of the date of the Quality Assurance Audit approximately three to six months prior to the audit. The National Cancer Institute (NCI) will be notified in advance of all scheduled Quality Assurance Audits and may choose to attend an audit.
- 7) A list of the cases selected for the audit will be sent to the institution approximately four weeks prior to the audit to allow for preparation of records. Cases will be randomly selected with an emphasis given to the following types of studies: investigational, multi-modality, intergroup, cancer control, and those with high accrual.
- 8) The institution is required to produce the following data relevant to each case selected:
 - a. Hospital charts or legible copies
 - b. Research records (case report forms, eligibility checklists, etc.)
 - c. Clinic (outpatient) charts
 - d. Operative, pathology, and radiotherapy reports
 - e. Reports of other special studies as required by protocol
 - f. Documentation that the Institutional Review Board (IRB) has initially and annually reviewed and approved each protocol on the list including any protocol modifications
 - g. Originals of the signed and dated consent forms for each case
 - h. Drug Accountability Record Forms for investigational protocols including Shipping Receipts, Transfer Forms, and Return Forms
- 9) To facilitate preparation for the audit and assist the person at the institution responsible for collecting the requisite information, the document ***Site Preparation for an Audit*** has been developed. This document will be provided to the institution with the list of cases to be audited approximately four weeks before the audit. It is important that the person who is most familiar with the charts be present during the audit to assist the auditors in locating the documentation in the primary records. It is highly recommended that the person designated to assist the team review the primary records prior to the audit to identify and flag the source of the data reported. It is also recommended that the Principal Investigator and co-investigators be available on the day of the audit for clarification of issues raised by the auditors.
- 10) The audit consists of reviewing and evaluating three separate components: 1) conformance to IRB and consent form requirements, 2) the pharmacy and use of NCI DARFs, and 3) patient case review. During the audit, each of these components will independently be assigned an assessment of Acceptable, Acceptable Needs Follow-up, or Unacceptable, based on findings at the time of the audit.
 - a. Acceptable: No deficiencies, few lesser deficiencies, or major deficiencies that were addressed and/or corrected prior to the audit. No follow-up is required.
 - b. Acceptable, Needs Follow-Up: Multiple lesser deficiencies identified, or major deficiencies identified that were not corrected and/or addressed prior to the audit. Requires a written response and/or corrective action plan.

- c. Unacceptable: Multiple major deficiencies identified, a single flagrant deficiency identified, or excessive number of lesser deficiencies. Requires (as a minimum) a written response and/or corrective action plan and a reaudit of any component rated as unacceptable.
- 11) At the conclusion of the audit, the auditors will conduct an exit interview with the Principal Investigator and staff on the findings from the audit. This will hopefully clear up any questions which could have a direct influence on the final report submitted to the NCI.
 - 12) Auditors will prepare a case-by-case description of the discrepancies using the SWOG Quality Assurance Case Review Form. The auditors will compile and analyze the data, and a final report will be prepared and submitted to the NCI within ten weeks of the audit, where a review of the audit findings and Group recommendation is made. If the NCI has any comments or questions, the Operations Office is notified.
 - 13) A copy of the Quality Assurance Audit Report is sent to the Principal Investigator at the time it is submitted to the NCI. The Principal Investigator is responsible for notifying the IRB, co-investigators and affiliate investigators of the results of the audit. The Principal Investigator may challenge or respond to the findings in writing to the Group Chairman, but must respond to certain findings as set forth in Section 14 below. Results of all Quality Assurance Audits are reported to the SWOG Board of Governors.
 - 14) Institutions found to be “unacceptable” or “acceptable but requires follow-up” on any component are required to submit a written response and/or corrective action plan to the SWOG Operations Office within 21 days of receipt of the final audit report. The corrective action plan along with an assessment of acceptability by the Quality Assurance Department must be forwarded to the NCI within 45 days of the date of the final audit report. Failure to meet the NCI deadline will result in suspension of registration privileges at the member and affiliate institutions.
 - 15) A reaudit of any component rated as unacceptable will be conducted within one year after the unacceptable audit. An unacceptable rating for the same audit component on two consecutive audits will result in probation. Accrual will be suspended pending submission of a site improvement plan that addresses key infrastructural issues contributing to poor performance. An unacceptable rating at the second reaudit may result in termination from SWOG. This action will be done in consultation with the Group Chairman and NCI-Clinical Trials Monitoring Branch.
 - 15) If systematic or intentional misrepresentation of data is identified on an audit, the Group Chairman and the NCI will be notified immediately and an immediate repeat audit is scheduled by the Operations Office with the NCI and/or the FDA.