

SWOG
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Policy Memorandum No. 18
Subject: Data Evaluation Policy and Procedure
Departments Affected: All

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DATA EVALUATION POLICY AND PROCEDURE

POLICY

The SWOG Statistics and Data Management Center (SDMC) performs evaluations on data submitted for every patient registered to a SWOG protocol.

The purpose of data evaluations is to ensure that patients are eligible, properly stratified, and treated according to protocol requirements. The data are further evaluated to assess response to treatment, conduct consistency checks across forms for accuracy and completeness, and identify protocol deviations.

PROCEDURE

SWOG protocols require that the Initial Forms Set (IFS) be submitted within the timeframe specified in the protocol. The composition of the IFS varies among protocols. Most require submission of the onstudy form, the baseline tumor assessment form, baseline specimens, as well as a baseline abnormalities form for studies involving an Investigational New Drug. Some protocols also require copies of baseline operative reports, pathology reports and other forms (e.g. patient completed questionnaires). To ensure that IFS data are received in a timely manner, expectations are posted at the time of registration and resolved once submitted. All remaining data must be submitted according to protocol requirements at the specified time points documented in Section 14.0.

SWOG studies utilizing Medidata Rave (new activations after 04/01/2012) as its electronic data capture system (EDC) will have expectations resolved nightly upon successful submission of the form. Rave allows users to upload source documents such as operative and pathology reports within the EDC.

For studies activated prior to 04/01/2012, forms must be submitted online from the SWOG CRA Workbench at swog.org. Exceptions to this (e.g., the operative reports, pathology reports scans and lab reports) still require fax submission. On receipt of faxed forms, the SDMC routes the information to data entry for expectation resolution. Forms submitted via the web resolve expectations as part of the submission process.

If any information required for data evaluation is unclear, the Data Coordinator will generate queries requesting correction or clarification. Queries are emailed to the site PI and head CRA monthly and are also available within the applicable EDC and on a report on the SWOG CRA Workbench. Reply/clarification is required within 30 days.

The Data Coordinator for the study performs data evaluations according to the following guidelines:

Eligibility Review

The Data Coordinator will determine that the eligibility criteria are documented on the onstudy and other required forms. Dates of required onstudy tests must be documented and the timing of these tests are outlined in the study protocol. The goal is for this review to take place within 60 days of patient registration.

1. Onstudy Form

The Data Coordinator verifies that data on the form supports patient eligibility and stratification. If any data item on the onstudy form conflicts with eligibility requirements, the patient will be ineligible. Patients who are incorrectly stratified at registration may be ineligible if the correct stratum was closed at the time of registration or the incorrect stratification caused improper treatment assignment.

2. Baseline Tumor Assessment Form (if applicable)

The Data Coordinator will verify that disease meets the criteria specified in Section 10.0 of the protocol and confirm assessment dates are within the allowed range.

3. Ancillary Forms

Some studies require submission of ancillary forms such as operative reports, pathology reports, etc., to supply documentation of eligibility and stratification. The Data Coordinator will determine whether the information on these forms adequately supports eligibility and stratification.

On Protocol and Off Treatment Information

The Data Coordinator conducts reviews while the patient is on protocol and evaluates progression and off treatment data.

1. Treatment Forms

The Treatment Forms are reviewed to ensure the correct treatment and dosing requirements were given according to protocol specifications in Section 7.0. BSA is recalculated at each assessment, dose modifications or additions/omissions are reviewed and consistency checks are performed between assessment periods. Significant dosage deviation (>10%) will be communicated to the institution. Treatment must have begun after registration (see Policy No. 12 for noted exceptions). For NCORP studies, treatment and various intervention forms and patient questionnaires are reviewed for adherence to the study intervention.

2. Adverse Event Forms

The Adverse Event Forms are reviewed to ensure that adverse events were assessed at each reporting period. If there were dose modifications indicated on the Treatment Form due to an adverse event, the Data Coordinator will check to see if the applicable event was reported on the Adverse Event Form. For NCORP studies, adverse events may be collected on Side Effect Forms or other study forms, if applicable.

3. Follow Up Tumor Assessment Forms (if applicable)

The Data Coordinator verifies that all target and non-target lesions are documented and followed consistently using the same assessment type since baseline. If applicable, response is assessed at each follow up interval. Calculations are checked to ensure if a response to treatment was obtained and/or if progression time points are accurate. For NCORP studies, study follow-up is reviewed from a variety of study-specific forms and/or questionnaires.

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4. Off Study Data

Off Treatment Forms are reviewed to confirm the reason for removing the patient from study, to verify the patient was removed per protocol guidelines and to verify that the documentation on the form is consistent with data previously provided. All data, including progression, recurrence and second malignancy data are reviewed from the Follow Up and Notice of Death Forms.

These procedures are considered a preliminary evaluation of data prior to final review by the responsible Study Chair (see Policy No. 11 which identifies the Job Description of a Study Chair).