

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 Data Operations Center performs evaluations on data submitted for every patient registered to a protocol coordinated by SWOG.

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. Results of this review are communicated to the registering institution in writing. If an error is made in documentation, the institution may correct the error and submit an amended form.

PROCEDURE

SWOG protocols require that the Initial Forms Set (IFS) be submitted within 7 days of registration. The composition of the IFS varies among protocols. Most require submission of the onstudy form, the baseline tumor assessment form, 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 ancillary forms. To ensure that IFS data is received in a timely manner, due dates are posted at the time of registration and resolved once submitted. Pending items are defined as an institutions 'expectation'. All remaining data must be submitted according to protocol requirements at the specified time points documented in Section 14.0.

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

SWOG studies utilizing Medidata Rave (new activations after 04/01/2012) as its electronic data capture system will resolve expectations nightly. Rave allows users to upload source documents such as operative and pathology reports within the EDC, eliminating the need to fax any data.

If any information required for data evaluation is unclear, the Data Coordinator will generate queries requesting correction or clarification. Reply/clarification is required within 30 days. These requests are available any time under the Queries tab within the Data Submission link and a consolidated list of all outstanding queries is available within the Reports menu, both on the CRA Workbench. Since queries for Rave studies are attached to individual data items within a form, those requests are only accessible within Rave and the consolidated list of outstanding queries within the Reports menu on the CRA Workbench.

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

Onstudy and Eligibility Information

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.

If day 28, 42 or 56 falls on a weekend or holiday, the limit may be extended to the next working day.

1. Onstudy Form

The Data Coordinator verifies that the correct onstudy form is used and that the 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 considered ineligible. Some patients who are incorrectly stratified at registration will be considered ineligible if the correct stratum was closed at the time of registration or the incorrect stratification caused improper treatment assignment.

The Data Coordinator must calculate Body Surface Area using the Dubois and Dubois Formula. If the institution has incorrectly calculated BSA, the Data Coordinator should bring it to the institution's attention if the error will result in a significant dosage error (>10% deviation).

2. Baseline Tumor Assessment Form (if applicable)

The Data Coordinator will verify that target disease meets the criteria specified in Section 10.0 of the protocol, assessment dates are within the allowed range, and ensure the lesions noted match those listed as current disease on the onstudy form.

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 supports eligibility and stratification.

On Study and Off Treatment Information

The Data Coordinator conducts regular reviews while the patient is on study as well as evaluating progression and off study 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).

2. Adverse Event Forms

The Adverse Event Forms are reviewed to ensure that adverse events were assessed at each reporting period and identify missed intervals. 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.

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

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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.

4. Off Study Data

Off Treatment Forms are reviewed to confirm the reason for removing the patient from study and to verify that the documentation on the form is consistent with data provided on the on study forms. Progression 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).