SWOG FORMS

Online data submission is mandatory for the majority of all active trials coordinated by SWOG. Forms may be completed via the CRA Workbench or via Medidata RAVE. The result is the immediate resolution of expectations, up to date patient survival status and the elimination of possible entry delays as a result of using standard mail or fax.

There are a few exceptions to what can be submitted online and must be sent via fax to the SWOG Data Operations Center data submission fax line (800-892-4007) or uploaded directly into RAVE:

- Discipline forms, or forms that need special routing
- Source documents (e.g. Op/Path reports)
- Amended data (if not amendable online)

General Forms and Guidelines

SWOG forms fall into three categories: forms used group wide across all disease sites, forms that are disease or discipline specific, and forms that are study specific. The overriding principle of forms design is to collect a minimal amount of data. Our basic data forms only contain those data required for registration, stratification, eligibility, safety and to meet the specific aims of the trial. Study specific data are included as required. An ongoing major goal of the NCI is to have consistent definitions of variables for all cooperative group trials. This is supported by the Common Data Element (CDE) review performed by CTEP for every phase III trial.

This chapter contains information about SWOG forms that are used across all disease sites, without particular attention to any discipline or disease process. Because of the complexity of some disease sites, there are guidelines provided that are specific to Leukemia, Lung, Lymphoma and Myeloma in the sub-sections of this chapter.

General Rules for Data Submission

The following rules apply to all forms across all disease sites.

- Each form submitted to the SWOG Data Operations Center must include the SWOG patient number, patient initials and the SWOG study number. All source documents - whether faxed or uploaded directly into RAVE - must be fully redacted and clearly identified on each page. Further, they must be oriented right side up and electronic images must be legible – Never use highlighters on source documents since highlighting often reproduces as redacted in electronic images.

- If data falls under one of the exceptions above and your data is sent via fax, please print legibly, using dark ink. Be sure to label every page with the SWOG patient number, patient initials and the SWOG study number or data received by fax will be rejected.

- Unless otherwise specified, check only ONE answer for each question on the form.

- If a portion of a date is unknown; default to the 15th if the exact day is unknown, default to June if the exact month is unknown. Include a note in comments section if default dates are used.

- Please always refer to Section 14 of the protocol for detailed data submission guidelines.

- Patient names must not be supplied on forms. This is to comply with a patient confidentiality initiative mandated by the NCI. Where older forms still list name, initials (L, F M) should be supplied instead. Patient name will only be collected at registration, and will be stored under an extra level of data base security at the SWOG Data Operations Center.

- Rounding (Tumor Measurements, Dosing and Labs): When rounding is used in reporting numerical digits on SWOG forms, it must be done to the nearest digit requested on the CRF (whole or decimal; round up for ≥ 5 and round down for < 5).

  Baseline Tumor Assessment and Follow-Up Tumor Assessment Forms request target lesion measurements be reported in centimeters to the nearest tenth (e.g. 1.5 cm). If the scan report provides a measurement of 2.78 cm (or 27.8 mm), it is acceptable to round the measurement as 2.8 cm. Similarly, rounding is acceptable for lab and test values and treatment dosing, as long as rounding the dose does not result in > 5% deviation from the calculated dose.

  Rounding is also allowed for any lab or test value related to eligibility **unless otherwise noted in the protocol.**

- When filling out the total dose received on a Treatment Form and the patient pill count diary conflicts with how many pills were left in the bottle, the actual pill count should take precedence in reporting. If the bottle and patient diary were not returned, enter the total dose based upon the verbal report of the patient. If the patient says no pills were missed, count the number of days since the last visit and then enter a comment on the form to document this is an estimate since the patient diary was not returned.

- Some studies use a Baseline Abnormalities Form to document existing conditions or continuing toxicities caused by prior treatment. The collection of this form, if required, will be noted in Sections 14.0 and 18.0 of the protocol. A baseline abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up ***for which a CTCAE term exists***. The Adverse Event Code is the appropriate CTCAE code for a baseline abnormality. The 'Other, Specify' options should only be used if there is not an appropriate adverse event term available.

  The Baseline Abnormalities Form is not used as a place to record the patient's medical history, diagnosis and/or pre-existing condition. For example, prior tonsillectomy or ongoing diabetes should **not** be recorded.

Information on SWOG Forms

The following items will automatically populate on the on-line forms once a patient is registered to a study:

***Study Number*:** The number of the protocol onto which the patient was registered.

***Protocol Step (Induction Number or Registration Step)*:** A protocol step is usually initiated by a registration via OPEN. For studies with only one registration step, the protocol step is coded *1*. For studies with multiple registrations, the protocol step is determined by the number of registrations. For these studies, subsequent registrations for crossover, consolidation, or maintenance steps will have different protocol step codes, e.g., *2*, 3.

***SWOG Patient Number*:** A 6-digit identification number assigned to the patient at the time of first registration to a SWOG protocol. This number identifies the patient in the SWOG Data Operations Center database and patient record.

The patient number remains the same for the patient regardless of the number of protocol registrations or the number of SWOG studies to which the patient is registered, unless the patient is registered to a FDA registration study, in which case a unique Patient ID will be given. Record this number accurately and legibly on uploaded or faxed data.

***Patient Name*:** Only initials should be visible (see above).

***Institution or Institution/Member*:** The name of the SWOG institution registering or currently following the patient if a transfer was made.

***SWOG Investigator or Physician*:** The name of the SWOG physician overseeing the patient's protocol therapy.

***Treatment Number*:** The treatment number is assigned at the time of registration and designates the treatment arm to which the patient is registered. Treatment numbers are found on the Confirmation of Registration.

Commonly Coded Variables

The following variables commonly appear on SWOG Forms. They are described in this section, but usually appear on disease specific prestudy/onstudy forms.

Weight: Record the patient's weight to the nearest tenth kilogram at time of registration. If the weight is given in pounds, convert to kilograms by dividing pounds by 2.2.

Height: Record the patient's height to the nearest centimeter at time of registration. If the height is given in inches, convert to centimeters by multiplying inches by 2.54.

BSA: Record the body surface area (BSA) for the patient as calculated at time of registration. BSA is calculated using the Dubois & Dubois method. It may be calculated using either a calculator or a table. The calculation must be to the nearest hundredth, i.e. 2.15 m^2. BSA should be recalculated after patient experiences weight gain or loss while on treatment. There is a BSA

calculator available on the SWOG CRA Workbench under the “Tools” link on the homepage. This is the recommended calculator to use for all SWOG studies.

Performance Status: Performance status is a measure of the functional ability of the patient. Record the performance status of the patient at time of registration. SWOG uses the Zubrod coding system for performance status:

Point	Description
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of limited self-care, confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care, totally confined to bed or chair.

If a patient's restrictions are not indicative of impaired health, e.g., a leg fracture not due to a pathologic fracture, adjust the performance status accordingly and record details of the functional impairment in the Comments section.

Date of First Pathologic Diagnosis: This item refers to the first histological/cytological diagnosis of the malignancy. The date of first pathologic diagnosis is the date the sample was obtained, i.e. the date the biopsy was done, even when the determination is made on review of evidence previously read as benign. In the absence of an exact date, the following estimates for date of first pathologic diagnosis may be used; indicate that date coded is an estimate in the Notes section.

- Date of admission when it is known that the diagnosis was made within one month prior to hospital admission.
- Date of admission when malignancy was diagnosed during that hospital admission.
- Date of first therapy for the malignancy.

Registration Form

The SWOG registration form is supplied for use as a worksheet, but is not to be submitted. Information on this form is reported at the time of registration.

Patient Characteristics

The following patient characteristics are collected at registration. If changes are required after registration, amend the confirmation of registration (using patient initials instead of name) reflecting the amended data, with a notation indicating that the data are amended.

Patient Name: Report the patient's full name. Use the patient's middle initial or middle name whenever possible. This is the only time patient name will be requested. All submitted forms should only report initials (LFM). Patient names are stored in a secured data base file. SWOG reports will only contain patient initials. If a patient name is changed, notify the SWOG Data Operations Center and the name will be changed in the database.

Date of Birth: Record month, day and year of the patient's birth date. Estimates are preferable to coding unknown for any portion of the item. When the exact birth year is unknown, an estimate should always be made.

Sex: Check the box to indicate the sex of the patient.

Race/Ethnicity: Report the patient race and ethnicity (as an example, Hispanic is not a race, but an ethnicity, according to the coding on page 5 and 6).

Method of Payment: Report the patient's type of medical insurance coverage.

Social Security Number: Report patient's Social Security Number. This number is kept in a secure computer file, separate from the clinical data. This is an optional but preferred field. Entries must be legitimate social security numbers. If you do not wish to provide a valid SSN, the field may be left blank.

Patient's Zip Code: Report the zip code of the patient's main residence.

Study Specific Data on the Registration Form

Information required at registration for randomization (Stratification Factors) will appear on the Registration Form. These variables are study specific. Be prepared to report the patient values for these variables when registering the patient. They may also be recorded on study specific forms.

SWOG Registration Form Sheet

Race Code Definitions:

White or Caucasian: a person having origins in any of the original peoples of Europe, Middle East, or North Africa.

Black or African American: a person having origins in any of the black racial groups of Africa.

Native Hawaiian or Other Pacific Islander: a person having origins in any of the original peoples of Hawaii, Guam, Samoa and other Pacific islands.

Asian: a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent. Including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

American Indian or Alaskan Native: a person having origins in any of the original peoples of North, Central or South America, and who maintains tribal affiliations or community attachment.

Ethnicity (Spanish/Hispanic Origin) options:
Hispanic or Latino
Not Hispanic or Latino
Unknown

Method of Payment options:

Private Insurance	No means of payment (no insurance)
Medicare	Other
Medicare and Private insurance	Unknown
Medicaid	Veterans Sponsored
Medicaid and Medicare	Military or Veterans sponsored (NOS)
Self-Pay (No insurance)	Military sponsored (including Champus and TRICARE)

Measures of Response using RECIST v. 1.1

Response Evaluation Criteria in Solid Tumors (RECIST v.1.0) was developed by the World Health Organization and mandated by the National Cancer Institute for use in SWOG solid tumor protocols on January 1, 2000. This has since been updated and *new* response evaluation criteria (RECIST v. 1.1) was released for use in SWOG protocols effective January 1, 2010. For studies using the RECIST v. 1.1 criteria, up to 5 'target' lesions overall are followed and recorded.

Please see Chapter 11 in this manual for guidelines for RECIST v. 1.1.

Disease Assessment

Most disease sites use standard Baseline Tumor Assessment (BTA) and Follow-Up Tumor Assessment (FUTA) forms to document disease assessment. Use the following guidelines when filling out these forms.

Site (for target lesions): Record the organ site, e.g. brain, liver, lung, skin, and when appropriate, a descriptive location, e.g. parietal lobe grain, right anterior liver, right lower lobe lung, left forearm.

Tumor Size: Record the longest diameter, in centimeters. When the tumor size is given in millimeters, divide by 10 to obtain centimeters.

Assessment Type: Use the assessment type codes listed on the bottom of the form (or in the dropdown in Rave) to record the test which was used to obtain the measurements recorded under

Tumor Size. If a study or test used to assess the malignancy is not included in the list, contact the Data Coordinator at the SWOG Data Operations Center.

Lymph Node?: Record Y (Yes) or N (No)

Assessment Date: Record the month, day and year that the test used to obtain the measurements was performed.

Site (for non-target disease): Record the organ site, (e.g. brain, liver, lung, skin) or type of disease (e.g. ascites, pleural effusion, lymph node enlargement). Be as specific as possible.

Extent: Indicate the degree of involvement or extent of the disease process in the space provided. Examples are location and/or size of pleural effusions; number of evaluable lesions in lung, bone or brain; or the value of laboratory tests.

Assessment Type, Date: As above, identify diagnostic procedures used in assessment of malignancy of non-target disease. When more than one study was used to evaluate a site, code the one which provided the most definitive information.

Negative Diagnostic Tests

Record the diagnostic tests and studies which were used to evaluate the patient for malignancy, but which were negative for malignancy. Also record the month, day and year the test(s) was performed.

Assessment Types

Clinical/Laboratory Evaluation

Palpation when the lesion was evaluated using manual palpation.

Physical Exam when a visible skin or mucosal lesion was measured.

Photography For skin lesions, documentation by color photography including a ruler to estimate the size of the lesion. When lesions can be evaluated by both clinical exam and imaging, imaging-based evaluation should be undertaken.

Endoscopy when the lesion was evaluated using endoscopic procedures such as bronchoscopy, gastroscopy, colonoscopy, sigmoidoscopy, or anoscopy.

Cystoscopy when disease is assessed by examination of the urinary tract with a cystoscope.

Radiologic Confirmation

Plain film/X-ray without contrast when the lesion was evaluated and measurement obtained using standard roentgenographic technique; e.g., chest X-ray.

X-ray Imaging when the lesion was evaluated and measurement obtained using standard roentgenographic technique with the addition of contrast media. For example, intravenous pyelogram, intravenous cholangiogram, upper GI series (barium swallow), or lymphangiogram.

CTEN = Contrast enhanced CT scan when the lesion was evaluated and measurement obtained using computed tomography of a specific section or region of the body.

CT scan without contrast When the lesion was evaluated and measurement obtained using computed tomography of a specific section or region of the body where IV contrast was not used, typically due to allergy or renal insufficiency.

MRIEN = Contrast enhanced MRI scan when the lesion was evaluated and measurement obtained using magnetic resonance imaging of a specific section or region of the body.

MRI = MRI without contrast When the lesion was evaluated and measurement obtained using magnetic resonance imaging of a specific section or region of the body where IV contrast was not used, typically due to allergy or renal insufficiency.

Radioisotope scan when the lesion was evaluated using procedures such as liver-spleen scan, brain scan, or lung scan. Radioisotope scans normally cannot be used to obtain bidimensional measurements for reporting measurable disease. On some older studies bone scan would also be in this category. If code 25 is not listed as an option for bone scan use 14.

Ultrasound when the lesion was evaluated and measurement obtained using ultrasound of a specific section or region of the body.

PET scan when the lesion was evaluated and measurement obtained using positron emission tomography of a specific section or region of the body.

PETCTEN = Contrast enhanced PET-CT scan When the lesion was evaluated and measurement obtained using combined positron emission tomography and computed tomography of a specific section or region of the body where IV contrast was used

PETCT = PET-CT scan without contrast When the lesion was evaluated and measurement obtained using combined positron emission tomography and computed tomography of a specific section or region of the body where IV contrast was not used, typically due to allergy or renal insufficiency.

PETMRI = PET-MRI scan When the lesion was evaluated and measurement obtained using combined positron emission tomography and magnetic resonance imaging of a specific section or region of the body

Spiral CT scan when the lesion was evaluated and measurement obtained using spiral (helical) computed tomography of a specific section or region of the body.

PET/Spiral CT when the lesion was evaluated and measurement obtained using combined positron emission tomography and spiral computed tomography of a specific section or region of the body.

PET/Conventional CT when the lesion was evaluated and measurement obtained using combined positron emission tomography and computed tomography of a specific section or region of the body.

Bone scan when the lesion was evaluated and measurement obtained using a bone scan of a specific section or region of the body.

RADNUC = Radionuclide Imaging When the lesion was evaluated and measurement obtained using nuclear medicine scan to provide images using radiotracers or radiopharmaceuticals, excluding PET scans; e.g., bone scans

Microscopic Confirmation

Histologic confirmation when the confirmation of the lesion was made using tissue obtained by biopsy which was examined microscopically.

Cytologic confirmation when there was cytologic confirmation of the lesion.

Other Assessments

Other as specified on the Baseline Tumor Assessment form. This code will be used to document tests for oncogene expression, as well as other tests. Specify in Comments section and indicate the lesion number.

Diagrams

If the form includes diagrams, mark the locations of all measurable and non-measurable sites on the diagram.

Off Treatment Notice

Submit the Off Treatment Notice within 14 days of the discontinuation of protocol treatment. (Some protocols have more than one step, each having a separate regimen and requiring its own registration.) Check the Data Submission Schedule – Section 14 - in each protocol for specific guidelines.

Studies activated prior to 2012 may ask for a Protocol Treatment Summary

List the following information about any surgery, radiation therapy, chemotherapy or other treatment specified in the protocol that the patient received.

Treatment Start Date: Record the first date any protocol treatment was given.

Treatment End Date: Record the last day that any protocol treatment was given. For multidrug regimens record the last day any drug in the regimen was given.

If a patient was assigned to observation only, rather than a treatment regimen, the stop date is the last date that the patient was considered to be on protocol. In general, observation patients who are not off study for some other reason are considered on protocol for one year; however, check each protocol for details. When surgery is the protocol therapy, list the date of surgery as the stop date.

Regimen or Procedure or Site(s): Describe the treatment given in the space provided; common drug abbreviations are acceptable and it is not necessary to list individual drugs separately when listing multidrug chemotherapy regimens.

List any surgical procedure or radiation therapy given including the RT sites (brain, chest, etc.). For patients assigned to observation only, mark this section *observation only*.
Protocols in Medidata Rave will have the following questions:

Did the patient receive any protocol treatment (on this registration step)? – Answer 'Yes' if the patient received any protocol therapy***.*** Answering 'No' will allow you to document any instances where a patient is registered but does not receive protocol treatment.

Reason and Date Off Treatment

1 - Treatment completed per protocol: The patient completed the number of courses specified in the protocol. For observation arms, patient completed one year of observation, or otherwise specified time outlined in the protocol. If any other reason applies, do not check this box.

2 - Medically required, due to toxicity: The physician decided to take patient off protocol or a protocol step for a toxicity grade that is listed in the protocol as a reason to discontinue treatment. Or, the physician decides treatment is no longer medically advisable because of a treatment related complication, e.g. IP catheter malfunction, protocol surgery complication.

3 - Patient refused, due to toxicity: The patient refused to continue treatment because of treatment-related side-effects, but the physician would have continued treatment.

4 - Patient refused, other than toxicity: Specify the reason for refusal, such as cost or religious reason.

5 - Progression or relapse: The patient was removed from protocol treatment due to progression or relapse of disease as defined per protocol. Specify the site(s) of progressive disease or relapse.

6 - Death: The patient died while on protocol treatment before a decision to discontinue treatment was made for another reason. Submit a Notice of Death with the Off Treatment Notice.

7 - Other: The reason is something other than those above. Specify the reason, e.g. patient moved away, physician decided to take patient off treatment for a reason other than those allowed by the protocol, in the space provided.

Date Off Treatment: Record the date of the event specified as the *reason off treatment*. The date off treatment is the date of death, the date progression of disease was determined, or the date

the decision was made to discontinue therapy. This date may be different from the one that the patient last received protocol therapy (*stop date* above).

Will the Patient Receive Further Therapy?

No: No further treatment (either on or off protocol) for disease is planned at any institution.

Yes: Additional disease-related treatment is planned. Specify the planned treatment and indicate whether this is a subsequent registration for the same study number.

Unknown: It is unknown at the time of completing the form whether the patient will receive additional disease related treatment. If additional treatment is given, document on follow-up forms.

Date of Last Contact (or Death)

If the patient is alive, code the month, day, and year the patient was last known to be alive. This information can be obtained from direct contact with the patient, physician records, from family members, or other patient caretakers.

Vital Status: Check alive or dead. If the patient has died, a Notice of Death must also be submitted with the Off Treatment Notice. For studies activated after 10/2018, Vital Status fields are removed from all study forms and a new Vital Status form was added to the study (see below for form details).

Follow Up Form

This form should be submitted at least annually (see protocol for specific timing), once the patient is off protocol treatment. The follow up form should also be submitted at post-treatment progression/relapse, diagnosis of <u>new</u> malignancy, or death. Never confuse “Follow Up Forms” with “Follow Up Tumor Assessment forms”. They are separate form types. Some Protocols may require submission of both forms. Always check Protocol Section 14 for study specific forms submission requirements.

Vital Status: Check alive or dead. If the patient has died, a Notice of Death must also be submitted. For studies activated after 10/2018, Vital Status fields will be removed from all study forms. A new Vital Status form will be added to the study (see below for form details).

Date of Last Contact (or Death): If the patient is alive, code the month, day and year the patient was last known to be alive. This information can be obtained from direct contact with the patient, physician records, from family members, or from other caretakers.

Disease Follow-up Status: Check whether or not the patient has been assessed (physical exams and/or tests) for this cancer since the last submission of follow-up information. If yes, provide the month, day and year of the assessment.

Notice of First Relapse or Progression: Check whether or not the patient has relapsed or progressed for the first time since the last submission of follow-up information. If yes, give the month, day and year of the relapse. This date is often a clinical diagnosis and may never be

confirmed microscopically. Even if microscopically confirmed later, this date is the date of the first clinical diagnosis, not the date of the microscopic confirmation.

Sites of Relapse: Record each site of relapse/recurrence, e.g. bone, brain, liver, soft tissue, which was diagnosed on, or within two weeks following the first date that the recurrence was established.

Notice of New Primary: Check whether or not the patient has been diagnosed with a new malignant neoplasm or myelodysplastic syndrome since the last submission of follow-up information. This includes 1) any malignancy of a new histologic type; 2) a malignancy of a previous type which is judged to be a new primary; or 3) a possible diagnosis of a subsequent malignancy (for example, when there is a biopsy of a lesion but it cannot be determined whether it is a new primary tumor or metastatic disease).

Date of New Primary: This is the date the first histological/cytological diagnosis of the malignancy was obtained, even when the determination is made on review of evidence previously read as benign. In the absence of an exact date, the following estimates may be used. Indicate that the date coded is an estimate in the Comments section.

- Date of admission when it is known that the diagnosis was made within one month prior to hospital admission.
- Date of admission when the malignancy was diagnosed during that hospital admission.
- Date of first therapy for the malignancy.

Protocol Treatment: Check whether or not the patient received any non-protocol cancer therapy (prior to progression/relapse) that was not previously reported since the last submission of follow-up information. If yes, give the month, day and year the therapy was initiated as well as the agent name(s) that were given.

Long Term Adverse Events: Check whether or not the patient experienced any severe (grade > or = 3) long term toxicities that was not previously reported since the last submission of follow-up information. This would include any events prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment. Provide the name and grade of the adverse event (as well as attribution and status if applicable to the study).

Study Specific and Supplemental Follow up forms:

Always check Protocol Section 14 to determine if study specific or supplemental follow up forms are required instead of **or** in addition to standard Follow up forms.

Notice of Death

The Notice of Death must be submitted within four weeks of learning that the patient has died.

Study Number: Record the study number of the SWOG protocol to which the patient was most recently registered. For patients registered to more than one SWOG study, the form needs only to be submitted for the study to which the patient was last registered.

Date of Death

Record the month, day, and year on which the patient died. Every attempt should be made to determine the exact date, including requesting a copy of the death certificate if necessary. If attempts to get the exact date fail, default to the 15th if the exact day is unknown, default to June if the exact month is unknown. If conflicting information is obtained regarding the exact date, record the information from the most reliable source e.g., hospital records, or death certificates.

What phase of the trial was the participant in at the time of death

Select baseline, protocol therapy or Follow-up

Causes of Death

Record the following to describe the cause of death.

Any Cancer: This pertains to the cancer for which the patient was registered on study as well as any previous or subsequent malignancies the patient may have had.

1 - No: Patient's cause of death was clearly NOT attributable to cancer. Use if patient was known to be free of cancer at the time of death, or if cancer was under control and death was clearly attributable to causes unrelated to cancer.

2 - Primary cause: Cancer was the primary cause of death. This includes death due to a process caused by the cancer, e.g., renal failure or pneumonia.

3 - Contributory: Cancer was not the primary cause of death but it contributed to the patient's death. For example, disease and toxicity are frequently both contributory to early deaths in hematologic malignancies.

4 - Possible: Disease was present at death and may have contributed to the patient's death but this is not known for certain.

5 - Unknown: Cause of death is totally unknown, or it is unclear whether cancer contributed to death. Unknown should only be used if all other avenues of investigation have been exhausted. If this is truly unknown, then please clarify, in the comments section, what steps were taken to try to answer this. For example, did you try to locate the Death Certificate, looked in the Tumor Registry, have you contacted the Family or the Primary Physician…

If cancer was a primary, contributory or possible cause of death and the patient has had tumor types in addition to that type for which they were registered on study, specify to which type (or types) death is attributed. If the patient died from a type of cancer other than the type required for the most recent registration to a SWOG protocol, explain the status of the study cancer.

Toxicity From Disease Related Treatment: This pertains to toxicities, side-effects, or complications from ANY disease related treatment, not only treatment specified in the protocol.

1 - No: Patient's cause of death was not attributable to treatment related toxicities.

2 - Primary cause: It is clearly documented that toxicity was the primary cause of death.

3 - Contributory: Toxicity was not the primary cause of death but it contributed to the patient's death.

4 - Possible: Treatment may have been related to death, but it cannot be known for certain.

5 - Unknown: Cause of death is totally unknown, or it is unclear whether toxicity may have contributed to death.

If toxicity is a primary, contributory or possible cause of death, specify the toxicity or side-effect, and the treatment that caused the toxicity.

Non-cancer and Non-treatment Related Causes: This pertains to any cause of death other than cancer or toxicities or side-effects from cancer related treatment.

1 - No: Patient's cause of death is attributable to disease or toxicity from treatment, not other causes.

2 - Primary cause: It is clearly documented that death was due to causes other than cancer or toxicity from treatment.

3 - Contributory: Other causes are known to have contributed to the patient's death.

4 - Possible: Other causes may have been related to death, but it cannot be known for certain.

5 - Unknown: Cause of death is totally unknown, or it is unclear whether other causes may have contributed to death.

If other causes are a primary, contributory or possible cause of death, specify the cause.

Sources

Check whether an autopsy was done or not. Knowing that an autopsy was done is sufficient to check *yes* even when a copy of the autopsy report has not been obtained.

Check all sources used to obtain information on the patient’s cause of death.

Vital Status

For studies activated after October 2018, vital status fields have been removed from all SWOG forms and a new Vital Status form will exist at the patient level in Rave. This form should be completed when contact is made with the patient for any reason and should be submitted prior to any other date entry related to that visit to prevent unnecessary error messages.