









Vital Status




Fill out the Vital Status form any time you enter data, **PRIOR to submitting any other data.** Otherwise, you will get System queries on other forms. See protocol section 14 for required timepoints to complete it.

Page: On Tx Vital Status - Vital Status (On Treatment)  




Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit. If this is the first Registration Step for the Study and the patient has not been seen since registration, please enter the Registration Date for Step 1.

Vital status Alive Dead   



Date of last contact ...   

Comments   




If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.




Save this form, but don't submit to SWOG yet.   




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Page: Off Tx Vital Status - Vital Status (Off Treatment)  




Instructions: Please complete this form when contact is made with the patient for any reason. This form should be submitted prior to any other data entry related to that visit.

Vital status Alive Dead   

Date of last contact ...   

Comments   

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

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Baseline Abnormalities Form

(please also refer to the [SWOG CRA Manual for Oncology Research Professionals: General Forms and Guidelines, Chapter 16](#))

Page: Baseline Abnormalities - Baseline

Did the patient have any abnormalities or conditions present PRIOR to protocol treatment?

If Yes, using CTCAE 4.0 Grade definitions, please report them below

If day of Start Date is unknown, please write "UN" in the day field. If month of Start Date is unknown, please select "UNK" from the dropdown menu.

#	Verbatim term	CTCAE(4.0) adverse event term	CTCAE(4.0) grade	Serious	Start date
1	Vertigo	Vertigo	1	No	UN Jun 2014
2	Hot flashes	Hot flashes	1	No	UN UNK 2007
3	Hyperglycemia	Hyperglycemia	1	No	13 May 2019
4	Hypercalcaemia	Hypercalcaemia	1	No	13 May 2019

- 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.
 - While Pain is an acceptable CTCAEv4 term, Pain is also very generic. If this is the appropriate term to use, please specify site/type of pain in the Comments section at the bottom of the form.
- 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.

EXAMPLE Treatment Form for NCORP Studies:

Actual data entry fields may vary per study

Timepoint (derived) Week 52

Reporting Period Start Date (Day 1 of this reporting period.) See general notes below for Reporting Period details ...

Reporting Period End Date (Day 1 of next reporting period. If final reporting period, use date of Week 52 assessment.) ...

Were there any dose modifications or additions/omissions to the planned ICI therapy? A 'Yes' response will populate Treatment Adjustments form

Weight If weight was not collected at study visit, leave this blank and make a note in the Comments explaining kg (xxx.x)

ICI THERAPY FOR THIS REPORTING PERIOD

If any assigned agent was not administered during this reporting period, then leave Date of Administration empty, enter "0" for the actual dose per administration and complete the Treatment Adjustments form. If any assigned agent was withdrawn in a [previous reporting period](#), enter "No" for dose modifications and enter "0" for the planned dose per administration and the actual dose per administration.

#	Treatment Name	Treatment Cycle Number	Date of Administration	Planned Dose Per Administration	Planned Dose Unit	Actual Dose Per Administration	Actual Dose Unit
1	<input type="text"/>	<input type="text"/> (xx)	<input type="text"/> ... <input type="text"/>	<input type="text"/> (xxxx)	<input type="radio"/> mg <input type="radio"/> mg/kg	<input type="text"/> (xxxx)	<input type="radio"/> mg <input type="radio"/> mg/kg

Add a new Log line Inactivate

Did the participant receive any non-ICI adjuvant therapy during this reporting period? A 'Yes' response will populate the non-ICI Treatment form Yes No

Will the participant continue to receive ICI therapy? Yes No

Comments

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General Notes:

- The Reporting Period Start Date for the first study timepoint will generally be the date of registration, unless stated otherwise by the protocol or form instructions.
- The Reporting Period End Date will be the last date that data is collected for that study timepoint, which typically is the date of the study visit for that timepoint.
- The Reporting Period Start Date for subsequent timepoints should match the End Date of the previous timepoint.
 - For example: A participant is registered on 9/20/2023 and their first study visit (Week 4 timepoint) occurs on 10/18/2023
 - In this case, the Week 4 Reporting Period Start Date will be 9/20/2023
 - The Week 4 Reporting Period End Date will be 10/18/2023
 - The Reporting Period Start Date for the next timepoint will be 10/18/23
 - The Reporting Period End Date will be the date of the next study visit, this pattern repeats until the last timepoint
- The Planned Dose and Actual Dose fields have multiple unit options, for weight-based or fixed dosing.
- Additional treatments can be added to the table using the "Add a new Log line" link.

EXAMPLE Adverse Events Form for NCORP Studies:

Actual data entry fields may vary per study

Timepoint (derived) Week 52

Reporting Period Start Date (Day 1 of this reporting period.) See general notes below for Reporting Period details ...

Reporting Period End Date (Day 1 of next reporting period. If final reporting period, use date of Week 52 assessment.) ...

Were adverse events assessed during this time period? Yes No

If no, what was the reason adverse events were not assessed?

If yes, what was the date of the most recent adverse event assessment? If AEs were assessed at any point within the reporting period, please enter date of most recent assessment ...

If yes, did the participant experience any adverse events which are reportable according to the form instructions above during this reporting period? A 'Yes' response will populate the AE: Report form Yes No

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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General Notes:

- The Reporting Period Start Date for the first study timepoint will generally be the date of registration, unless stated otherwise by the protocol or form instructions.
- The Reporting Period End Date will be the last date that data is collected for that study timepoint, which typically is the date of the study visit for that timepoint.
- The Reporting Period Start Date for subsequent timepoints should match the End Date of the previous timepoint.
 - For example: A participant is registered on 9/20/2023 and their first study visit (Week 4 timepoint) occurs on 10/18/2023
 - In this case, the Week 4 Reporting Period Start Date will be 9/20/2023
 - The Week 4 Reporting Period End Date will be 10/18/2023
 - The Reporting Period Start Date for the next timepoint will be 10/18/23
 - The Reporting Period End Date will be the date of the next study visit, this pattern repeats until the last timepoint
- AE reporting requirements may vary per study. Refer to the protocol and form instructions for study specific requirements.

Follow-up Form

DO NOT MAKE ANY ENTRIES ON THE FOLLOW-UP FORM UNTIL YOU HAVE UPDATED THE VITAL STATUS FORM.

This field derives automatically from the most recent Vital Status form. Once you save this form, you CANNOT amend Last Contact Date, so **ALWAYS update Vital Status form before starting a new Follow-up form.**

Page: Follow-up - Follow-up
Instructions: Please submit at each follow-up after completion of protocol treatment and at protocol-specified intervals after relapse or progression.

Date of last contact or death (Date will be derived based on most recent Vital Status submission. If you have had more recent contact with the patient, please submit a new Vital Status form with the new date.)

02 Jun 2021

LATE ADVERSE EVENT

Did the patient experience any reportable* adverse events during this reporting period?
***Severe (grade >=3) adverse event that is possibly, probably or definitely related to protocol treatment, or a Serious Adverse Event (SAE) of any grade/attribution, that has not been previously reported.*

This is only YES if the AE meets the criteria in italics on the left. Please read carefully.

Yes No

DISEASE FOLLOW-UP STATUS

Was disease status (for this cancer) evaluated during this reporting period?

Yes No

If yes, date of last clinical assessment

...

NOTICE OF FIRST RELAPSE OR PROGRESSION

Has the patient developed a first relapse or progression that has not been previously reported?

Yes No

If yes, date of relapse or progression

...

If yes, site(s) of relapse or progression

NON-PROTOCOL TREATMENT

Has the patient received any non-protocol cancer therapy (prior to progression/ relapse) not previously reported?

Yes No

NOTICE OF NEW PRIMARY

Has a new primary cancer or MDS (myelodysplastic syndrome) been diagnosed that has not been previously reported?

Yes No

If yes, date of diagnosis

...

If yes, new primary site

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

EXAMPLE Off Protocol Form for NCORP Studies:

Actual data entry fields may vary per study

Instructions: Submit this form within 15 days after completion (or discontinuation) of protocol participation as outlined in Sections 7.0 and 14.4 of the S2013 Protocol. Date is in DD MON YYYY format.

What was the off protocol date?

(Date of completion, death or decision to withdraw)

 ...

What was the participant's off protocol status?

Comments

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Save this form, but don't submit to SWOG yet.

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General Notes:

- The Off Protocol Notice form should be submitted whenever a participant meets the criteria for removal from protocol participation detailed in the protocol.
 - Treatment changes (discontinuation, new therapy, etc.) or disease changes (progression, relapse, etc.) may or may not require Off Protocol Notice submission. Confirm with the protocol before submitting the Off Protocol Notice form.
- Some studies may also require an Off Treatment/Intervention Notice form be submitted when specific criteria are met
- In the event of a participant death, the Off Protocol Notice may need to be submitted in addition to the Notice of Death form.
- If the Off Protocol Notice is being submitted due to consent withdrawal, make sure to confirm with the participant that they wish to withdraw from all follow-up, including direct and indirect follow-up. If confirmed, please enter a comment noting that participant is withdrawing from all follow-up.

Notice of Death

Page: Notice of Death - Death

Instructions: Answer all questions and explain any blank fields or blank dates in the Comments section.

Date of death ...

Cause of death

Cancer-related causes

Toxicity from disease-related treatment

Non-cancer and non-treatment related causes

Autopsy performed? Yes No Unknown

Source(s) of death information (select all that apply)

Autopsy report

Medical record/death certificate

Physician

Relative or friend

Other

If Other, specify

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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Answering "unknown" to all fields of this form is not a valid response. If this is truly unknown, then in the Comments section of the form, detail what steps were taken to find out the information.

Consent Withdrawal

This form can only be populated by the SWOG Data Coordinators. If the patient has withdrawn all consent, **including** consent for follow-up and survival follow-up, please email the data coordinators via the email address listed on the SWOG Protocol Contact Information Page (near the beginning of the protocol document).

Page: Consent Withdrawal - Consent Withdrawal

**CONSENT WITHDRAWAL**

Complete this section if the participant decides to refuse all further follow-up AND contact for the study.

Obtain clarification if the participant does not explicitly state why they do not want to be contacted. Ask if they would consider indirect contact gleaned from medical record review in lieu of direct follow-up such as a phone call in order to continue reporting survival data. Date is in DD MON YYYY format.

Date of consent withdrawal

 ...

I affirm that this patient has withdrawn their consent for further follow-up on this study.

RESCIND CONSENT WITHDRAWAL

Complete this section if the patient decides to resume follow-up on the study.

Date patient rescinded consent withdrawal

 ...
SOURCE DOCUMENTATION

*Source documentation is **required** to support the consent withdrawal.*

Please ensure all source documents are properly and completely blacked out with black pen or marker only works when the image is photocopied and ways to redact: electronic redacting tools, covering PHI with labels, and shredding. Queries will be generated.

Please also ensure that file names on uploaded documents are redacted and does not have the participant's name in it.

DO NOT enter a date here unless the patient changes their mind and wants to be followed after all. A date here means that we ARE following the patient.

#	Upload file [?]	Comments
1	<input type="button" value="Choose File"/> No file chosen	<input type="text"/>

Add a new Log line Inactivate

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.

Save this form, but don't submit to SWOG yet.

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NOTE:

If the patient withdraws consent after registration, then the institution must determine with the research participant whether:

- 1) The participant no longer wishes to be treated per protocol;
- 2) The participant no longer wishes to be followed per protocol, or
- 3) The participant (both) no longer wishes to be treated nor wishes to be followed per protocol.

The participant may be willing to allow the investigator to continue other research activities (e.g., follow-up assessments, specimen collection, questionnaires, survival status, etc.). The distinction must be documented in the research record and on the Off-Treatment Notice or Follow-Up Form, as appropriate to the participant's indication.

See also: SWOG Best Practices document, accessible from: <https://www.swog.org/clinical-trials/protocol-workbench> and SWOG Policy #30, accessible from: <https://www.swog.org/about/policies-procedures>.

Referral Date: Click or tap to enter a date.

Referring MD: MD Initials

Patient Information and Work-Up Documentation Sheet

Name: Pt name

Clinic #: Pt MRN.

Date of Birth: Click or tap here to enter text.

Protocol: Protocol #

Cancer Type: Cancer type.

CRA: CRA initials

Study Specific Tests:

Required Tests (protocol version date: 11/6/18)	Date Completed	Expiration Date	Protocol Guidelines

Follow Disease By:

CT CXR MRI BONE SCAN PET OTHER

Prior Treatment:

Type of treatment and dates: _____

Date of last Chemotherapy: _____

Washout required? _____

Date of last Radiation Therapy: _____

Washout required? _____

Protocol Specifics:

Surgical Guidelines/Wait time: _____

Treatment Must Start By: _____

Central Pathology Review Needed?: ____

Teach Date: _____ By Whom: _____ Consent/HIPAA Date: _____

Ancillary/CC/CCDR Study Available?: _____ DCP001?: ____

Notified Pharmacy of work-up: ____ Provided Agents(s) on site?: _____

Notified RN Clinician & Financial Services: ____ QOLs Available: _____ Kits Available?: ____

In CTMS: ____

IMPORTANT! CONFIDENTIAL PATIENT INFORMATION!

Name _____ CL# _____ CRA _____ DATE _____

Protocol _____ Arm _____ Current Cycle # _____ MD _____

Reported toxicities for Cycle # _____

*relationship to study drug: 1=not related, 2= unlikely, 3=possible, 4= probable, 5= definite

Toxicity	Grade	*Relationship to Neulasta	Comments
Nausea	0 1 2 3 4	1 2 3 4 5	
Vomiting	0 1 2 3 4	1 2 3 4 5	
Diarrhea	0 1 2 3 4	1 2 3 4 5	
Constipation	0 1 2 3 4	1 2 3 4 5	
Alopecia	0 1 2 3 4	1 2 3 4 5	
Mucositis	0 1 2 3 4	1 2 3 4 5	
Skin	0 1 2 3 4	1 2 3 4 5	
Neuro	0 1 2 3 4	1 2 3 4 5	
Fever/Infection	0 1 2 3 4	1 2 3 4 5	
Fatigue	0 1 2 3 4	1 2 3 4 5	
Dyspnea	0 1 2 3 4	1 2 3 4 5	
Arthralgia	0 1 2 3 4	1 2 3 4 5	
Bone Pain	0 1 2 3 4	1 2 3 4 5	
Myositis	0 1 2 3 4	1 2 3 4 5	
Myalgia	0 1 2 3 4	1 2 3 4 5	
	0 1 2 3 4	1 2 3 4 5	
	0 1 2 3 4	1 2 3 4 5	

Hematology Nadirs:

ANC _____ Date _____ Grade _____ Attribution _____ PS= _____

WBC _____ Date _____ Grade _____ Attribution _____ DZ Status= _____

PLTS _____ Date _____ Grade _____ Attribution _____ Weight= _____

HGB _____ Date _____ Grade _____ Attribution _____

Next Visit: _____

Other notes and dose modification recommendations:

I agree with the above toxicities. _____ Date: _____

(Physician signature)

RETURN TO: CANCER CENTER RESEARCH (CCON)/CRA and Phone number