

Rave EDC Template Manual

Version History

| Document Name | Version | Revision Date |
|--------------------------|---------|---------------|
| Rave EDC Template Manual | 1.0 | 12.09.2021 |
| Rave EDC Template Manual | 2.0 | 12.28.2021 |
| Rave EDC Template Manual | 3.0 | 02.25.2022 |
| Rave EDC Template Manual | 4.0 | 09.22.2022 |
| Rave EDC Template Manual | 5.0 | 03.03.2023 |
| Rave EDC Template Manual | 6.0 | 03.24.2023 |
| Rave EDC Template Manual | 7.0 | 10.06.2023 |
| Rave EDC Template Manual | 8.0 | 02.01.2024 |
| Rave EDC Template Manual | 9.0 | 09.09.2024 |

Note: A summary of the changes for each version can be found at the end of the manual

Introduction

The Rave EDC Template Manual will cover each available CRF and display information on the form, all fields available in that form, and any validations or derived data. Each individual manual has the following sections (if available):

- CRF Purpose
- Notes
 - Extra information that is form specific.
- Screenshot of the CRF
- Field Information
 - Descriptions, Instructions, and Formats.
- Validations
 - Logical checks which can open queries on the CRF.
- Derivations
 - Any fields which are automatically populated.

Picklist

For all fields with a picklist, users can only select values from the provided picklist. No manual entry is allowed.

As of 01/18/2023 Rave Implementation Meeting:

Simple calculations in Rave are approved. The requested calculations must have the below criteria:

1. The calculation is research related.
2. The calculation is based on raw data entered in the database.
3. The details of calculations must be covered in the protocol specification.
4. Have to be approved by OCD.

As of 12/06/2023 CCMG Meeting:

Derivations will not be implemented for calculated fields, but validations can be created to check the calculated data with formula.

The CRFs below should be completed for subjects who sign consent forms but fail screening:

- Enrollment
- Off Study
- Labs should be loaded (if applicable)

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Adverse Events

Purpose

This eCRF is an ongoing form to capture all adverse events experienced by the subject regardless of the course.

An adverse event is any unfavorable or unintended sign, including abnormal laboratory findings, symptom or disease having been absent at baseline, or if present at baseline, appears to worsen, that has a temporal association with a medical treatment or procedure regardless of the relationship of the event to the medical treatment or procedure.

All adverse events will be coded using protocol specific version of NCI Common Terminology Criteria for Adverse Events (CTCAE) version. Every attempt to code the adverse event to a term using the standard terminology will be made before selecting the "other" term in a category.

Record all adverse events experienced by the subject, including laboratory abnormalities, regardless of relationship to the study medication.

An adverse event entry is composed of both the adverse event term plus the grade. Complete a separate row for each adverse event entry to be recorded using the appropriate adverse event term and the appropriate codes for "grade", "attribution(s)", "serious", "action", "therapy", and "outcome" in the respective column for each event.

If an adverse event has not been resolved, leave the Resolved Date blank. The Resolved Date can be filled at a later time when the adverse event is considered resolved. Resolution means a change in grade to a higher or lower grade.

If a subject died on study then the death adverse event onset and resolved dates should be the same.









How to record baseline symptoms that change, either improve or worsen:

If a pre-existing condition resolves, it does not need to be reported as an adverse event since it would have been already recorded on the Baseline Symptoms case report form. Enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form improves, no entry is made on the AE eCRF. See BL eCRF for instructions.










If a pre-existing condition worsens (i.e.: the grade of the baseline symptom increases), that constitutes an adverse event entry which must be reported in full detail.



If a pre-existing condition improves without a resolution, do not enter as an Adverse Event. When it resolves, enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form.


| | | |
|--|---|---|
| AESI  | ... ▼ |  |
| DLT | ... ▼ |  |
| Serious | ... ▼ |  |
| Action | ... ▼ |  |
| Therapy | ... ▼ |  |
| Outcome | ... ▼ |  |
| Expedited Report to IRB? | ... ▼ |  |
| Expedited Report to Sponsor | ... ▼ |  |
| Comments | <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> 0 / 200 |  |

***Please note that the fields below “Serious” are only visible if it is answered “Yes”.**



| | | |
|--|-------|---|
| Serious | Yes ▼ |  |
| Death | ... ▼ |  |
| Hospitalization, Prolonged Hospitalization | ... ▼ |  |
| Life-threatening | ... ▼ |  |
| Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions | ... ▼ |  |
| Congenital anomaly/birth defect | ... ▼ |  |
| Important Medical Event | ... ▼ |  |





Field Descriptions and Instructions



| Field Name | Description / Instructions | Format |
|---------------------------------|--|----------------|
| Course # ^(d) | <p>Indicates the course number that this adverse event started in as derived from the course initiation start date. Late adverse events have no associated Course #. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this adverse event started as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Onset ^(m) | <p>Enter the date of first observation of the adverse event and grade.</p> <p>If a subject died on study then the onset date and the resolve date for the death AE should be the same.</p> | DD-MMM-YYYY |
| Date Resolved | <p>Enter the date of resolution of the adverse event and grade. Leave this field as well as the Outcome field blank if the adverse event is ongoing.</p> <p>Resolution means a change in grade to a higher or lower grade e.g., to the normal grade (grade zero) or the return to the baseline symptom grade.</p> <p>If a subject died on study then the onset date and the resolve date for the death AE should be the same.</p> | DD-MMM-YYYY |
| CTCAE Term (5.0) ^(m) | <p>Using the pick list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term (v5.0).</p> <p>In the absence of a specific adverse event term, choose the "Other" term from the appropriate general category and be sure</p> | Use pick list. |




| Field Name | Description / Instructions | Format |
|---|---|----------------|
| | <p>a meaningful adverse event description is entered in the "adverse event description" field.</p> <p>Dictionary Name - CTCAE5_TERM</p>  <p>CTCAE5_TERM.pdf</p> <p>Note: This pick list does not show all the CTCAE Terms. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched CTCAE Terms. Ex: type 'ypo' to list all the terms that include the lower characters 'ypo' somewhere in the CTCAE Term.</p> <p>Note: Visit CTEP's CTCAE webpage for latest version.</p> | |
| SOC (System Organ Class) ^(d) | <p>Broad classification of adverse events based on anatomy and/or pathophysiology. Within each category there is the adverse event term/description. This is a derived field.</p> <p>Note: This field is derived from the selected CTC Term</p> | Derived field. |
| Adverse Event Description | <p>Enter a succinct clinical description of the adverse event.</p> <p>Note: This field is mandatory, unless the CTCAE term is the same as the description (e.g., nausea, diarrhea).</p> <p>DO NOT enter raw data (i.e.: lab result). Use the term increase or decrease. DO NOT enter the attribution in this field. Use the Attribution field for this purpose.</p> | 100 characters |




| Field Name | Description / Instructions | Format |
|--|--|----------------|
| Grade ^(m) | <p>Grade adverse events using Common Terminology Criteria for Adverse Events (CTCAE) version indicated in the protocol.</p> <p>Note: Note: Some grades are disallowed for some categories in the CTCAE. In the CTCAE tables this will be noted by the use of an em-dash "-". For example, Hair loss/Alopecia can only be graded as a 1 or 2, so grade 3, 4, and 5 do not exist and will be noted in the table with a "-" versus a description.</p> <p>If the protocol does not use either CTC or CTCAE, grade according to the following general criteria:</p> <ul style="list-style-type: none"> • 1: Mild Adverse Event • 2: Moderate Adverse Event • 3: Severe Adverse Event • 4: Life Threatening or Disabling Adverse Event • 5: Death Related to Adverse Event | Use pick list. |
| Attribution to Research ^(m) | <p>Evaluate the adverse event's relationship to the subject's participation in the study, including study-related therapy and procedures. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> • Adverse Event Unrelated • Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p>Note: Attribution to Research must be the same as the highest Attribution to IND, IDE, Commercial, Surgery and Radiation.</p> | Use pick list. |
| Attribution to IND ^(m) | <p>Evaluate the adverse event's relationship to the Investigational Agent. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> • Adverse Event Unrelated | Use pick list. |




| Field Name | Description / Instructions | Format |
|---------------------------|---|----------------|
| | <ul style="list-style-type: none"> Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> | |
| Attribution to IDE | <p>Evaluate the adverse event's relationship to the Investigational Device Exemption. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> Adverse Event Unrelated Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p> Note: This field is optional for some studies.</p> | Use pick list. |
| Attribution to Commercial | <p>Evaluate the adverse event's relationship to the Commercial agent. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> Adverse Event Unrelated Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p> Note: This field is optional for some studies.</p> | Use pick list. |
| Attribution to Radiation | <p>Evaluate the adverse event's relationship to the Radiation therapy. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> Adverse Event Unrelated Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> | Use pick list. |


| Field Name | Description / Instructions | Format |
|---|---|----------------|
| | <p> Note: This field is optional for some studies.</p> | |
| Attribution to Surgery | <p>Evaluate the adverse event's relationship to the Surgery. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> • Adverse Event Unrelated • Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p> Note: This field is optional for some studies.</p> | Use pick list. |
| Attribution to Disease | <p>Evaluate the adverse event's relationship to the disease. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> • Adverse Event Unrelated • Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p> Note: This field is optional for some studies</p> | Use pick list. |
| Attribution to Other (Alternative Etiology) | <p>Evaluate the adverse event's relationship to other causes not listed above. Select one of the following codes to record this evaluation:</p> <ul style="list-style-type: none"> • Adverse Event Unrelated • Adverse Event Related <p>Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below</p> <p> Note: This field is optional for some studies</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------------|--|----------------|
| Other, Specify | Enter an explanation when 'Attribute to Other (Alternative Etiology)' is selected. | 40 characters |
| Is the AE Immune Related? | <p>Indicate if adverse event is immune related by making a selection from the following list:</p> <ul style="list-style-type: none"> • Yes • No • Unknown • Not Applicable • Not Done | Use pick list. |
| Unexpected AE (m) | <p>Indicate if the adverse event is unexpected as defined by the NCI IRB, by entering:</p> <ul style="list-style-type: none"> • NO • YES | Use pick list. |
| AESI | <p>Indicate if the adverse event is of special interest.</p> <ul style="list-style-type: none"> • Yes • No • Unknown | Use pick list. |
| DLT (m) | <p>Indicate if the adverse event is dose limiting, as defined in the protocol, by entering:</p> <ul style="list-style-type: none"> • Yes • No <div style="background-color: #e6f2ff; padding: 10px; margin-top: 10px;"> <p> Note: Refer to the protocol for the definition of a dose limiting toxicity which should include the grade of the events and the duration of the event.</p> <p> Note: Mandatory for Phase I Clinical Trials.</p> </div> | Use pick list. |
| Serious (m) | Indicate if the adverse event was a "serious" event by selecting from the following codes, as per the Code of Federal | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| | <p>Regulations 21 Part 312. If multiple categories are applicable, select the worst.</p> <ul style="list-style-type: none"> • Yes • No | |
| Death | <p>Indicate if the adverse event resulted in death.</p> <ul style="list-style-type: none"> • Yes • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | Use pick list. |
| Hospitalization, Prolonged Hospitalization | <p>Inpatient hospitalization or prolongation of existing hospitalization</p> <ul style="list-style-type: none"> • Yes • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | Use pick list. |
| Life-threatening | <p>An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the subject or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.</p> <ul style="list-style-type: none"> • Yes • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | Use pick list. |
| Persistent or significant incapacity or | <p>Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions</p> <ul style="list-style-type: none"> • Yes | Use pick list |

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| substantial disruption of the ability to conduct normal life functions | <ul style="list-style-type: none"> • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | |
| Congenital anomaly/birth defect | <p>Congenital anomaly/birth defect definition / instructions / description</p> <ul style="list-style-type: none"> • Yes • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | Use pick list |
| Important Medical Event | <p>Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the subject or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.</p> <ul style="list-style-type: none"> • Yes • No <p> Note: This field is hidden if “Serious” is not answered “Yes”.</p> | Use pick list. |
| Action ^(m) | <p>Indicate any changes made to the study regimen in response to the adverse event using the following codes. "Action" refers to the decision to reduce or continue the investigational medication.</p> <ul style="list-style-type: none"> • Withdrawn • Dose reduced • Dose increased • Dose interrupted • Dose not changed • Unknown • Not Applicable | Use pick list. |


| Field Name | Description / Instructions | Format |
|---|--|----------------|
| | <p>If the "Action" for any adverse event is recorded as a change in dosage, the changes in medication administration must be reflected on the Study Medication Administration form.</p> <p> Note: Interrupted also means therapy was delayed.</p> | |
| Therapy ^(m) | <p>Indicate if additional therapy is required to treat the adverse event.</p> <ul style="list-style-type: none"> • None • Symptom (i.e.: required medications to treat event) • Support (i.e.: required medications and/or IV fluids, blood products) • Vigorous (i.e.: required surgery, intubation) <p>A corresponding entry of the therapy given to treat the adverse event must be recorded on the Concomitant Measures/Medication form.</p> | Use pick list. |
| Outcome | <p>Select the final status of the subject when the adverse event is considered "resolved".</p> <ul style="list-style-type: none"> • Recovered/Resolved • Recovering/Resolving • Not Recovered/Not Resolved/Ongoing • Recovered/Resolved with Sequelae • Fatal • Unknown <p> Note: For ongoing adverse events, leave this and the Resolution Date fields empty.</p> <p>Note: For deaths on study, only the event which caused the death should have the outcome coded as "Fatal".</p> <p> The events that were still continuing at the time of the death would still be ongoing. Do not enter a resolved date, and outcome.</p> | Use pick list. |
| Expedited Report to IRB? ^(m) | <p>Indicate if an expedited adverse event report was sent to IRB by entering:</p> <ul style="list-style-type: none"> • Yes | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| | <ul style="list-style-type: none"> No | |
| Expedited Report to Sponsor ^(m) | Indicate if an expedited adverse event report was sent to sponsor by entering: <ul style="list-style-type: none"> Yes No <div style="background-color: #e6f2ff; padding: 5px; margin-top: 10px;">  Note: This field is optional for some studies. </div> | Use pick list. |

Regarding the AE attribution fields:

For protocols that utilize the new system of AE attribution values (2 options only: “Adverse Event Unrelated” and “Adverse Event Related”), the following chart can be used to translate values in source documentation from the older system with 5 options to the new system. If the attribution in the source documentation is unclear the Data Manager should leave the attribution field in C3D/Rave blank until the source documentation is updated and clarified.

| Old System (numbers) | Old System | New System |
|----------------------|----------------|-------------------------|
| 0 | Not Applicable | Adverse Event Unrelated |
| 1 | Unrelated | Adverse Event Unrelated |
| 2 | Unlikely | Adverse Event Unrelated |
| 3 | Possible | Adverse Event Related |
| 4 | Probable | Adverse Event Related |
| 5 | Definite | Adverse Event Related |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|---------------------------------|--|---|
| AE01 | Query will fire if Date Resolved is before Date of Onset. "Date Resolved is before Date of Onset. Please correct." | Correct either the Date of Onset or Date Resolved. |
| AE03 | Two Adverse Event records have identical values for Date of Onset, CTC Term and Grade. "Two Adverse Event records have identical values for Date of Onset, CTC Term and Grade. Please correct." | If duplicate, delete one of the records. If not, manually resolve the discrepancy. |
| AE04, AE05, AE06, AE07 | Two Adverse Event records with the same CTC Term and/or Description have overlapping Date of Onset and Date Resolved ranges. "Two Adverse Event records with the same CTC Term and/or Description have overlapping Date of Onset and Date Resolved ranges. Please correct." | Correct the Onset and Resolution Dates for the Adverse Events in question or review/correct the CTC term/description |
| AE08 | Adverse Event Description missing for some certain CTC terms that require a clinical description. "Adverse Event description is missing. Please correct." | Enter the Adverse Event Description or review/correct the CTC term/description. |
| AE09 | A Baseline Symptom exists with the same CTC term and Grade as the Adverse Event and the Baseline Symptom has not been resolved. "A Baseline Symptom exists with the same CTC term and Grade as the Adverse Event and the Baseline Symptom has not been resolved. Please correct." | Verify the Baseline Symptom resolution date, the Adverse Event onset date, or CTC Term. An Adverse Event with the same grade and CTC Term as the Baseline Symptom is only acceptable when the Baseline Symptom has been resolved and the AE onset date is after the Baseline Symptom resolution date. |

| Code | Description | Resolutions |
|------------------------|--|---|
| AE10 | The CTC Term for the ongoing Adverse Event has a specified lab, but a lab record with lab date = AE onset date and lab grade = AE grade does not exist. "The AE term and grade is not supported by a lab test result. Please correct." | Verify that the Adverse Event is supported by appropriate lab test result. |
| AE11 | Adverse Event is resolved and there is no supporting lab test result. "The AE term was resolved, but a supporting lab with an appropriate grade was not found. Please correct." | Review Adverse Event and related lab test result and their grades. A supporting lab result is one with the same date as the Adverse Event resolution date but with a different grade. |
| Medidata System Checks | Query will fire if the Adverse Event Date of Onset or Date Resolved is in the future. "Future date has been entered. Please correct." | Correct the Onset or Resolution Dates. No future dates should be recorded. |
| AE16 | Query will fire if the Adverse Event Date of Onset is less than the first Course Start Date. "The Adverse Event Date of Onset is before the first Course Start Date in Course Initiation. Please correct." | Correct the Adverse Event Date of Onset to be equal to or after the first Course Start Date. |
| AE17 | The Adverse Event CTC Grade is invalid. "The grade for the CTC AE Term is invalid. Please correct." | Enter a Grade that is permissible for the CTC Term. |
| AE19 | Query will fire if Resolution date has been entered, but Outcome is not 'Recovered/Resolved', 'Recovered/Resolved with Sequelae' or 'Fatal' or vice-versa. "Resolution date has been entered, but Outcome is not 'Recovered/Resolved', 'Recovered/Resolved with Sequelae' or 'Fatal' or vice-versa. Please correct." | Unless an Outcome is 'Recovering/Resolving', 'Not Recovered/Not Resolved/Ongoing' or 'Unknown', Date Resolved must be accompanied by an Outcome, or vice-versa. |

| Code | Description | Resolutions |
|--------|---|---|
| AE20 | Adverse Event is the cause of death but Grade is not Fatal and/or Outcome is not Died and/or Seriousness is not Death. “Adverse Event is the cause of death, but Grade is not "5: Death Related to Adverse Event" and/or Outcome is not "Fatal" and/or Death is not "Yes". Please correct.” | Change the Adverse Event Grade, Outcome, Serious or Death. |
| AE22 | Query will fire if Adverse Event 'Attribute to Other' and 'Other, Specify' are not present together. “Adverse Event 'Attribution to Other (Alternative Etiology)' and 'Other,Specify' are not present together. Please correct.” | Enter 'Other, Specify' if 'Attribute to Other (Alternative Etiology)' is associated. |
| AE23_1 | Query will fire if Adverse Event Attribution to Research is “Related” but none of Attribution to IND, IDE, Commercial, Surgery, and Radiation is “Related”. “Adverse Event Attribution to Research is “Not Related” but one of Attribution to IND, IDE, Commercial, Surgery, and Radiation is “Related”. Please correct.” | Review all Attributions to make sure that Attribution to Research is “Related” if any of Attribution to IND, IDE, Commercial, Surgery, and Radiation is “Related”. |
| AE23_2 | Query will fire if Attribution to Research is 'Related' but none of Attribution to IND, IDE, Commercial, Surgery, and Radiation is 'Related'. “Attribution to Research is 'Related' but none of Attribution to IND, IDE, Commercial, Surgery, and Radiation is 'Related'. Please correct.” | Review all Attributions to make sure that Attribution to Research is “Not Related” if none of Attribution to IND, IDE, Commercial, Surgery, and Radiation is “Related”. |
| AE24 | Query will fire if Serious is entered as 'No', but data is entered for “Death”, “Hospitalization, Prolonged Hospitalization”, “Life-threatening”, “Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions”, “Congenital anomaly/birth defect”, or “Important Medical Event”. “Serious is answered 'No', but one or more of the Serious Grading terms has been entered with data. Please correct. | Review the Serious Grading terms to verify all are empty if Serious is entered with 'No'. |

| Code | Description | Resolutions |
|------|---|---|
| AE25 | Query will fire if Attribution to Research, IND, Disease and Commercial are entered 'Unrelated', but Attribution to Other (Alternative Etiology) and Other, Specify are empty. "Attributions to IND, Commercial, Disease, and Research are entered as 'Unrelated', but "Attribution to Other (Alternative Etiology)" is not 'Related'. Please correct." | Enter data into Attribution to Other (Alternative Etiology) and Other, Specify if Attribution to Research, IND, Disease and Commercial are Unrelated. |

Derivations

| Code | Field Name | Description |
|-------------|---------------|--|
| AE1002_1003 | Course # | Course number is derived based on the course initiation start dates. |
| AE1002_1003 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date. |
| AE1004 | SOC Term | Broad classification of the CTC Adverse Event Term derived from the pick list selection. |

Arm and Cohort Assignment

Purpose

Subject ARM and Cohort information received from PRES.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Arm and Cohort Assignment

Arm and Cohort Assignment, Log Lines

[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line >

Date

Cohort Name

Cohort Description

Arm Name

Arm Description

[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line >

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------|------------------------------------|-----------|
| Date (p) | Date of the Cohort Arm Assignment. | From PRES |
| Cohort Name (p) | Short name of the cohort. | From PRES |

| Field Name | Description / Instructions | Format |
|-----------------------------------|--------------------------------------|-----------|
| Cohort Description ^(p) | Description of the cohort. | From PRES |
| Arm Name ^(p) | Short name of protocol-specific Arm. | From PRES |
| Arm Description ^(p) | Description for subject's Arm. | From PRES |

Legend: ^(d) derived field, ^(m) EDC mandatory, ^(p) uploaded from PRES.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|-------|--|----------------------|
| ARM01 | Query will fire if there are duplicate Date(s) for Arm/Cohort assignment. "Two records have identical values for Date of Arm/Cohort assignment. Please correct." | Review Date in PRES. |

Baseline Medical History

Purpose

Record a brief description of major medical and surgical events during the subject's lifetime, excluding the events related to their cancer therapy.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf


Baseline Medical History -


Date of Examination ⓘ This field is required. Please complete. -

Baseline Medical History, Log Lines All Q

| < | Body System | Finding Results | Medical History If Abnormal | > |
|----|---------------------|-----------------|-----------------------------|---|
| 1 | H/E/E/INT | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 2 | Neck | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 3 | Respiratory | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 4 | Cardiovascular | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 5 | Gastrointestinal | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 6 | Musculoskeletal | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 7 | Dermatologic | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 8 | Hematopoietic/Lymph | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 9 | Endocrine/Metabolic | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 10 | Urinary | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 11 | Genitalia | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 12 | Breasts | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 13 | Pelvis | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 14 | Abdomen | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 15 | Neurologic | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 16 | Psychologic | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |
| 17 | Immune | -- | <input type="text"/> | <input type="checkbox"/> <input type="text"/> |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|------------------------------------|---|----------------|
| Date of Examination ^(m) | Enter the date that the subject was examined and the medical history was documented. Since only one Medical History form is used, if the information has been assembled over a period of time, enter the date of the latest examination. | DD-MMM-YYYY |
| Body System | Predefined Body System. It cannot be changed. | Text |
| Finding Results ^(m) | <p>Indicate whether the finding results for the particular body system were either:</p> <ul style="list-style-type: none"> • Abnormal • Normal • Not Assessed • Not Applicable <p>Comments are required for abnormal finding results.</p> <div style="background-color: #e6f2ff; padding: 10px; border: 1px solid #add8e6;"> <p> Note: Do not select 'Normal' if the body system was not specifically assessed (i.e.: not mentioned in the progress note in the medical record). 'Not Assessed' means a discussion on the body system was not raised or the body system was not assessed.</p> </div> | Use pick list. |
| Medical History if Abnormal | <p>Enter a brief description of major medical and surgical events during the subject's lifetime (i.e.: hypertension under cardiovascular, appendectomy as child under abdomen).</p> <p>Enter the history for the appropriate body system to which the information refers. For "Other" indicate the body or organ system in the history.</p> | 52 characters |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Date of Examination is in the future. “Future date has been entered. Please correct.” | Enter a date that is earlier or equals to the current date. |
| MH02 | Query will fire if Date of Examination is after the first Course Initiation Start Date. “Date of Examination is after the first Course Initiation Start Date. Please correct.” “Date of Examination in Baseline Medical History CRF is after the first Course Initiation Start Date. Please correct.” (appears in Course Initiation CRF) | Review the Date of Examination and/or the first Course Initiation Start Date. |
| MH03 | Query will fire if ‘Finding Result’s is marked abnormal and ‘Medical History if Abnormal’ details were not provided. “‘Finding Result’ is marked abnormal and ‘Medical History if Abnormal’ details were not provided. Please correct.” | Enter the details of the ‘Medical History if Abnormal’ or change the ‘Finding Results’ selection. |
| MH04 | Query will fire if ‘Medical History if Abnormal’ details were specified and ‘Finding Results’ is not marked abnormal. “‘Medical History if Abnormal’ details were specified and ‘Finding Results’ is not marked abnormal. Please correct.” | Change the ‘Finding Results’ to abnormal or remove the provided ‘Medical History if Abnormal’ details. |

Baseline Symptom

Purpose

Record the subject's baseline symptoms **prior to starting treatment**.

Baseline Symptoms are symptoms that are present when the subject starts treatment (e.g., Cycle 1 Day 1 pre-dosing). These are not symptoms that occurred and resolved between the time screening studies/exams/procedures are done and Day 1/pre-treatment. For those symptoms, consider adding to Medical History.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Baseline Symptom


Baseline Symptom, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line


| | | |
|---------------------|---|---------------------------------|
| Onset Date | <input type="text" value="dd"/> <input type="text" value="..."/> <input type="text" value="yyyy"/> <input type="text" value="📅"/> | <input type="text" value="⚙️"/> |
| Date Resolved | <input type="text" value="dd"/> <input type="text" value="..."/> <input type="text" value="yyyy"/> <input type="text" value="📅"/> | <input type="text" value="⚙️"/> |
| CTCAE Term (5.0) | <input type="text" value="..."/> | <input type="text" value="⚙️"/> |
| SOC | | <input type="text" value="⚙️"/> |
| Symptom Description | <input type="text"/> | <input type="text" value="⚙️"/> |
| Grade | <input type="text" value="..."/> | <input type="text" value="⚙️"/> |
| Related to Disease | <input type="text" value="..."/> | <input type="text" value="⚙️"/> |

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------------------|--|----------------|
| Onset Date ^(m) | Enter the date that the symptom was first observed/experienced. | DD-MMM-YYYY |
| Date Resolved | Enter the date the baseline symptom was resolved.(i.e.: no longer exists at any grade). | DD-MMM-YYYY |
| CTCAE Term (5.0) ^(m) | <p>Use the search list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term (v5.0).</p> <p>In the absence of a specific adverse event term, choose the "Other" term from the appropriate general category and be sure a meaningful adverse event description is entered in the "adverse event description" field.</p> <p>Dictionary name – CTCAE5_TERM</p> <div style="text-align: center;">  CTCAE5_TERM.pdf </div> <div style="background-color: #e6f2ff; padding: 10px; margin-top: 10px;"> <p>Note: This pick list does not show all the CTCAE Terms. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched CTCAE Terms. Ex: type 'ypo' to list all the terms that include the lower characters 'ypo' somewhere in the CTCAE Term.</p> <p>Note: Visit CTEP's CTCAE webpage for latest version.</p> </div> | Use pick list. |
| SOC ^(d) | Broad classification of adverse events based on anatomy and/or pathophysiology. Within each category there is the adverse event term/description. This is a derived field. | Derived field. |

| Field Name | Description / Instructions | Format |
|-----------------------------------|--|----------------|
| Symptom Description | <p>Enter a succinct clinical description of the symptom.</p> <p>Note: This field is mandatory for 'Other, Specify...' CTCAE terms. For example: Immune system disorders - Other (Specify,___).</p> <p>It might be also used to further describe symptom such as "Eye pain" by entering "Left eye".</p> | 100 characters |
| Grade ^(m) | <p>Enter the severity of the symptom by using the protocol's specified CTCAE Version. If the symptom is not explicitly mentioned it should be coded in the appropriate "other" category and graded according to the general criteria:</p> <ul style="list-style-type: none"> • 1: Mild Adverse Event • 2: Moderate Adverse Event • 3: Severe Adverse Event • 4: Life Threatening or Disabling Adverse Event • 5: Death Related to Adverse Event | Use pick list. |
| Related to Disease ^(m) | <p>Indicate whether or not the symptom is related to the study disease by selecting one of the following options:</p> <ul style="list-style-type: none"> • Yes • No • Unknown | Use pick list. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Onset Date / Date Resolved is in the future. "Future date has been entered. Please correct." | Enter a date that is equal or earlier than the current date. |
| BS02 | Baseline Symptom CTC/CTCAE Term Grade is not valid. "The grade for the CTCAE Term is invalid. Please correct." | Select a valid Grade from the pick list. |
| BS03 | Query will fire if Onset Date is after the Start Date of the first Course. "Date of Onset is after the Start Date of the first Course. Please correct." "Date of Onset of one or more baseline symptoms in Baseline Symptom CRF is after the Start Date of the first Course. Please correct." (appears in Course Initiation CRF) | Verify that Onset Date is prior or equal to the first course start date. |
| BS09 | Query will fire if Resolved Date is prior to Date of Onset. "Resolved Date is prior to Date of Onset. Please correct." | Resolved Date must be after or equals to the Date of Onset. |
| BS10 | Query will fire if Symptom Description missing for CTCAE Term that requires a description. (Allergy/Immunology - Other (Specify, __)). "Symptom description is missing. Please correct." | Enter a Symptom Description for the corresponding CTCAE Term. |

Derivations

| Code | Field Name | Description |
|--------|------------|--|
| AE1004 | SOC Term | Broad classification of the CTC Adverse Event Term derived from the pick list selection. |

Chimerism

Purpose

Record the transplant date and related pre and post test results.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Chimerism ⚙

Date of Transplant This field is required. Please complete. ⚙

Chimerism, Log Lines

[Back To Complete View](#) < Previous Line Line of 1 Next Line > [Add Another Line](#)

Course # ⚙

Day in Course ⚙

Date of Test ⚙

Time of Test : ⚙

Days Post Transplant ⚙

Specimen ⏪

Result (%) ⚙



Comments ⚙
0 / 250

[Back To Complete View](#) < Previous Line Line of 1 Next Line > [Add Another Line](#)

Do you want to add comments? ⚙

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------------|--|----------------|
| Date of Transplant ^(m) | Date the transplant was performed. | DD-MMM-YYYY |
| Course # ^(d) | <p>Indicates the course number the test is related to based on their date and the Course Initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the test is related to based on their date and the Course Initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Test ^(m) | Date the test was performed. | DD-MMM-YYYY |
| Time of Test | Time the test was performed. | HH(24):MM |
| Days Post Transplant ^(d) | Number of days before or after the transplant that the test was done. It will be a negative number if test was done before the transplant. This is a derived field. | Derived field. |
| Specimen ^(m) | <p>Select a specimen from the pick list.</p> <ul style="list-style-type: none"> • APHERESIS CELLS: Pheresis Cell • BONE MARROW: Bone Marrow • CD14/CD15 MYELOID CELLS: CD14/CD15 Myeloid Cells • CD3 LYMPHOID CELLS: Lymphoid Cells • CD33 MYELOID CELLS: CD33 Myeloid Cells • CELL BLOCK: Cell Blocks | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------------|--|-------------------------|
| | <ul style="list-style-type: none"> • CEREBROSPINAL FLUID (CSF): Cerebrospinal Fluid • PERIPHERAL BLOOD MONONUCLEAR CELLS (PBMC): Peripheral Blood Mononuclear Cell • PLASMA: Plasma • SALIVA: Saliva • SERUM: Serum • TUMOR TISSUE: Tumor Tissue • URINE: Urine • WHOLE BLOOD: Whole Blood | |
| Result (%) ^(m) | Enter test results in percentage. | 3 digits and 2 decimals |
| Comments | Enter comments applicable to the test. | 250 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| CHM01 | Duplicate Specimen, Date of Test and Time of Test. “Duplicate Specimen, Date of Test and Time of Test. Please correct.” | A Specimen must have a unique Date of Test and Time of Test. Review the Specimen and/or the Date of Test and Time of Test. |
| Medidata System Checks | Query will fire if Result (%) is out of range. “Data entered is out of range (<0) / (>100). Please correct.” | Result % must be between 0 and 100%. |

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date of Transplant/Date of Test is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date |

Derivations

| Code | Field Name | Description |
|--------------|----------------------|--|
| CHM1001_1002 | Course # | Course number is derived based on the course initiation start dates and the Date of Test. |
| CHM1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the Date of Test. |
| CHM1003 | Days Post Transplant | Number of days before or after the transplant that the test was done. It will be a negative number if test was done before the transplant. |

Concomitant Measures/Medications

Purpose

Record all concomitant medications, including therapies given to treat adverse events.

If a subject is taking a medication PRN, do not use a separate line for each time the medication is taken, instead report the first and last dates taken.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Concomitant Measures/Medications

Concomitant Measures/Medications, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Course #

Day in Course

Start Date This field is required. Please complete.

Stop Date

Agent Name

Procedure/Measure

Dose

UCM

Schedule

Route

Reason

Comments






0 / 200


Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line






Do you want to add comments?

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| Course # ^(d) | Indicates the course number that this concomitant measure / medication started in as derived from the course initiation start date. | Derived field. |

| Field Name | Description / Instructions | Format |
|------------------------------|--|----------------|
| | <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this concomitant measure / medication started as derived from the course initiation start date.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Start Date ^(m) | <p>Enter the start date of the measure or medication.</p> <p> Note: Partial date is only acceptable for baseline measure or medication.</p> <p>Please enter UN for the "unknown" day value.</p> | DD-MMM-YYYY |
| Stop Date | <p>Enter the stop date of the measure / medication.</p> <p> Note: Partial date is only acceptable for baseline measure or medication.</p> <p>Please enter UN for the "unknown" day value.</p> | DD-MMM-YYYY |
| Agent Name | <p>In the case of agents, state the generic name of the medication administered, or, in the case of combinations such as trimethoprim / sulfamethoxazole, state the brand name (i.e., Bactrim).</p> <p>Dictionary Name - CONCOM_AGENTS_TH</p> <p> CONCOM_AGENTS_T H.pdf</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|--------------------|---|----------------|
| | <p>Note: This pick list does not show all the Agents. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched Agents. Ex: type %ydro% to list all the agents that include the lower characters 'ydro' somewhere in the agent's name.</p> <p>Note: Pre and post medications specified in the protocol and administered as part of the subject's treatment, must be entered in the Study Medication Administration case report form.</p> <p>Note: Do not select an agent name if a procedure has been entered.</p> | |
| Procedure /Measure | <p>If a procedure/measure, state e.g., oxygen administration, pleural tapping, etc.</p> <p>Dictionary Name - CONCOM_PROCEDURES_TH</p>  <p>CONCOM_PROCEDURES_TH.pdf</p> <p>Note: Do not select a procedure if an agent name has been entered.</p> | Use pick list. |
| Dose | <p>Enter the dose of the agent as appropriate.</p> <p>Note: This field is mandatory for agents. If a procedure/measure, leave blank.</p> <p>In the case of combinations such as Bactrim, enter as single dose: Ex: Dose 1, Unit tab, schedule bid.</p> | 100 characters |

| Field Name | Description / Instructions | Format |
|-----------------------|---|----------------|
| | <p>When the schedule is PRN (For example: taking 2 tabs of Percocet PRN every four hours) enter as single dose. Ex: Dose 2, Unit tab, q4hr PRN.</p> | |
| UOM | <p>Select the total daily dose units of measurement.</p> <p>Dictionary Name - UOM_DOSE_TH_2</p>  <p>UOM_DOSE_TH_2.pdf f</p> <p> Note: If a procedure/measure, leave blank.</p> | Use pick list. |
| Schedule | <p>Enter the frequency of medication administration or measure under schedule.</p> | 30 characters |
| Route | <p>Select the route given.</p> <p>Dictionary Name – ACCESS_RTE_NM</p>  <p>ACCESS_RTE_NM.pdf</p> | Use pick list. |
| Reason ^(m) | <p>Select the reason the medication is being administered or why measure done. For example, if Bactrim is being given as a prophylactic, select "pneumocystis prophylaxis".</p> <p>Dictionary Name - CONCOM_REASONS_TH_2</p>  <p>CONCOM_REASONS_TH_2.pdf</p> <p> Note: Do not enter the pharmacological classification of the medication (e.g., antibiotic, analgesic, etc.)</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|-------------------------------|----------------|
| Comments | Enter comments to this field. | 200 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

| Code | Description | Resolutions |
|------|--|---|
| CM01 | Query will fire if Agent and Procedure are missing. “Agent and Procedure are both missing. One of them should be entered. Please correct.” | An Agent or Procedure must be present. |
| CM02 | Query will fire if Both Agent and Procedure are filled. “Both Agent and Procedure are filled. Please correct.” | Agent and Procedure cannot be both selected at the same time. |
| CM03 | Query will fire if Stop Date is before the Start Date. “Stop Date is before the Start Date. Please correct.” | Stop Date must not be earlier than Start Date. |
| CM04 | Query will fire if Agent entered and Dose and/or Units of Measurement are/is missing. “Agent entered and Dose and/or Units of Measurement are/is missing” | If Agent is entered, Dose and Unit of Measurement must be present. |
| CM05 | Query will fire if Dose and/or Unit of Measurement entered and Procedure also entered. “Dose and/or Unit of Measurement entered and Procedure also entered. Please correct.” | If Procedure is entered, Agent, Dose and Unit of Measurement must not be present. |

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Query will fire if Start Date / Stop Date are/is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date. |
| CM10 | Query will fire if Partial Start Date is after the first Course Initiation Date. "Partial Start Date is after the first Course Initiation Date. Please correct." | Partial Start and Stop Dates are only acceptable for baseline measures and/or procedures. |
| CM11 | Query will fire if Partial Stop Date is after the first Course Initiation Date. "Partial Stop Date is after the first Course Initiation Date. Please correct." | Partial Start and Stop Dates are only acceptable for baseline measures and/or procedures. |

Derivations

| Code | Field Name | Description |
|-------------|---------------|--|
| CM1001_1002 | Course # | Course number is derived based on the course initiation start dates and the concomitant measure / medication start date. |
| CM1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the concomitant measure / medication start date. |

Consult

Purpose

Record all information from a consult evaluation.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

1010001 Screening ⚙️

Consult

Consult, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Evaluation Date ⚙️

Consult Evaluation Type ⚙️

NOTE ⚙️

0 / 200

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Do you want to add comments? ⚙️

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|--|----------------|
| Evaluation Date | The date of the consult evaluation. | DD-MMM-YYYY |
| Consult Evaluation Type | Select the type of consult evaluation: <ul style="list-style-type: none"> • ANESTHESIOLOGY • AUDIOLOGY • CARDIOLOGY | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|---|----------------|
| | <ul style="list-style-type: none"> • DENTAL • DERMATOLOGY • ENDOCRINOLOGY • FERTILITY • GYNECOLOGY • NEUROLOGY • NEUROPSYCHOLOGY • NUTRITION • OPHTHALMOLOGY • PAIN AND PALLIATIVE CARE • PSYCHIATRY • PSYCHOLOGY • PULMONARY • RHEUMATOLOGY • SOCIAL WORK • SPEECH/SWALLOW | |
| NOTE | If the consult is not applicable or wasn't done, 'NA' if not applicable or 'Not Done' with a reason should be entered in the "NOTE" section. | 200 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Evaluation Date is a future date. "Future date has been entered. Please correct." | Change the date to a value no later than the current date. |

Course Assessment

Purpose

Record the course assessment information when the course is completed, and the subject is evaluated or taken off treatment.

Course Assessment
⌵

Visit Date⚠ This field is required. Please complete.
⚙

COURSE ASSESSMENT

Start Date of Course
⚙

Dose change from Dose Level entered on Course Initiation CRF
⚙

Course Disposition
⚙

Any Adverse Events in this Course?
⚙

Any concomitant medications taken in this course?
⚙



Do you want to add comments?
⚙


COMMENTS


Save Cancel
☐ Move to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---|--|----------------|
| Visit Date (m) | Enter the date the course started. | DD-MMM-YYYY |
| Start Date of Course ^(d) | Shows the Start Date of Course entered in the Course Initiation case report form. This is a derived field. | Derived field. |
| Dose change from Dose Level entered on Course Initiation CRF ^(m) | Indicate if the subject's treatment was different from that specified by the Dose Level Code for this course as entered on the Course Initiation CRF. If the treatment was different, indicate whether this was planned or unplanned, and record the reason, e.g. dose reduction due to toxicity, on the Comments tab of this CRF. | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| | <p> Note: optional for non-CTEP sponsored studies.</p> <ul style="list-style-type: none"> • Yes, Planned - change in treatment had been decided before the start of the course, e.g., due to toxicity on a previous course. • Yes, Unplanned - change was not intended at the start of the course, e.g., shortening the course (and thus lowering the dose level) due to adverse events or if there was a drug administration error. • No - subject received the treatment specified in the Course Initiation Dose Level • Unknown - only when the actual treatment cannot be determined, e.g., when the subject is uncooperative in reporting self-administration of study medication. | |
| Course Disposition ^(m) | <p>A "completed" course is one that has been conducted in accordance with the protocol with respect to length including the observation period (two day variance allowed). A course is regarded as "discontinued" if it was shorter than specified in the protocol. Select one of the following values:</p> <ul style="list-style-type: none"> • Completed • Discontinued | Use pick list. |
| Any Adverse Events in this Course? ^(m) | <p>Select "Yes" if any adverse event has occurred during this course. This includes adverse events with onset date belonging to a previous course that resolved during this course or that remain ongoing at the conclusion of this course. Select "No" if no adverse events occurred during this course.</p> <p> Note: The event(s) must be recorded on the Adverse Events case report form.</p> | Use pick list. |
| Any concomitant medications taken in this course? ^(m) | <p>Select "Yes" if any concomitant medication was taken during this course. This includes concomitant medications with start date belonging to a previous course that resolved during this course or that remain ongoing at the conclusion of this course. Select "No" or "Unknown" if no concomitant medications were taken during this course.</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|--|--------|
| |  Note: The medication(s) must be recorded on the Concomitant Measures/Medications case report form. | |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment **“This field is required. Please complete.”**

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Visit Date is a future date. “Future date has been entered. Please correct.” | Change the date to a value no later than the current date. |
| CAS09 | Course Assessment marked as having adverse events, but there are no adverse events with an onset date that falls within this course start and end dates. “Course Assessment marked as having adverse events, but there are no adverse events with an onset date that falls within this course's start and end dates. Please correct.” | Change the field "Any Adverse Events in this Course?" to "NO" if no related adverse events exist. Otherwise enter the appropriate adverse events or adjust the appropriate adverse events dates. |

| Code | Description | Resolutions |
|-------|---|--|
| CAS10 | <p>Course Assessment marked as not having adverse events, but there is at least one adverse event with an onset date that falls within this course start and end dates. “Course Assessment marked as having no adverse events, but there are adverse events with an onset date that falls within this course's start and end dates. Please correct.”</p> | <p>Change the field "Any Adverse Events in this Course?" to "YES" if the related adverse events are appropriate. Otherwise remove the adverse events or correct the adverse events dates.</p> |
| CAS11 | <p>Course Assessment marked as having concomitant medications, but there are no concomitant medications with a start date that falls within this course start and end dates. “Course Assessment marked as having concomitant medications, but there are no concomitant medications with a start date that falls within this course's start and end dates. Please correct.”</p> | <p>Change the field "Any concomitant medications taken in this course?" to "No" or "Unknown" if no related adverse events exist. Otherwise enter the appropriate concomitant medications or adjust the appropriate concomitant medication dates.</p> |
| CAS12 | <p>Course Assessment marked as not having any concomitant medications taken, but there is at least one concomitant medication with a start date that falls within this course start and end dates. “Course Assessment marked as having no concomitant medications, but there are concomitant medications with a start date that falls within this course's start and end dates. Please correct.”</p> | <p>Change the field " Any concomitant medications taken in this course?" to "Yes" if the related concomitant medications are appropriate. Otherwise remove the concomitant medication or correct the concomitant medication dates.</p> |

Derivations

| Code | Field Name | Description |
|-------------|----------------------|--|
| CAS1001 | Start Date of Course | The Start Date of Course entered in the Course Initiation case report form. |
| CAS1002 | End Date of Course | The day before the start date of the following course or the off treatment date. |

Course Initiation

Purpose

Record course initiation Start Date, Dose Level and Treatment Institution.

📄 Course Initiation
⌵

Course #
⚙️ ⌵

Start Date of Course

...

📅

⚙️ ⌵

Arm Name
⚙️ ⌵

Arm Description
⚙️ ⌵

Dose Level

...
⌵

⚙️ ⌵

Treatment Institution 📍

...
⌵

⚙️ ⌵

Is this participant evaluable for DLT? (Phase 1 only)

...
⌵

⚙️ ⌵

Do you want to add comments?

...
⌵

⚙️ ⌵

COMMENTS


Save
Cancel

Move to next task 🔍

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------------|---|----------------|
| Visit Date ^(m) | Enter the date the course started. | DD-MMM-YYYY |
| Course # ^(d) | Sequential number of this course of treatment: first course = 1, second course = 2, etc. This is a derived field. | Derived field. |
| Start Date of Course ^(m) | Enter the date on which the course was started. This is the date on which a protocol stipulated medication (or treatment) was first administered. | DD-MMM-YYYY |
| Dose Level ^(m) | Select the appropriate code for the subject's treatment assignment Dose Level as specified. | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| | <p>i Note: This is a study specific picklist.</p> <p>"Dose Level" codes are based on the treatment schedules described in the protocol. Please contact the Informatics team for advice on Dose Level formulation and modification.</p> | |
| Treatment Institution ^(m) | <p>Select the unique CTEP institution code where the subject actually receives this course of treatment.</p> <p>i Note: This is a study specific picklist.</p> <p>i Note: Optional for non-CTEP sponsored studies.</p> | Use pick list. |
| Is this participant evaluable for DLT? (Phase 1 only) ^(m) | <p>Select whether the participant is evaluable for DLT.</p> <ul style="list-style-type: none"> • Yes • No <p>i Note: This field will only be visible for Phase I studies.</p> | Use pick list. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Query will fire if Start Date of Course / Visit Date is in the future. "Future date has been entered. Please correct." | Change the Start Date of Course to a date no later than the current date. |

| Code | Description | Resolutions |
|--------|--|--|
| CINI03 | Course start dates must be unique and in order. “This course's start date is less than or equal to a previous course's start date. Please correct.” | Ensure that no course start dates are repeated and that they appear in the correct chronological order (from the oldest to the more recent). |
| CINI04 | If course initiation number is greater than 1, then prior course should exist first. “Course Initiation prior to this course could not be found. Please correct.” | Ensure the previous course was entered |

Derivations

| Code | Field Name | Description |
|---------------|---------------------------|--|
| CINI1001_1002 | Stop Date | The day before the start date of the following course or the off treatment date. |
| CINI1002 | Course # | Course number derived by the system based on the dates the courses started. |
| CINI1003 | Arm Name, Arm Description | Arm Name and Arm Description derived by the system from the corresponding fields in Arm and Cohort Assignment. |

Diagnostic ECG

Purpose

Record the subject's ECG.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Diagnostic ECG

Diagnostic ECG, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

| | | |
|-----------------|--------------|--|
| Course # | | 0 - |
| Day in Course | | 0 - |
| Date of Exam | dd - - - - - | This field is required. Please complete. 0 - |
| Time | HH : MM | 0 - |
| QRS Interval | | 0 - |
| QT Interval | | 0 - |
| QTc Interval | | 0 - |
| QTcF | | 0 - |
| PR Interval | | 0 - |
| ECG Impression | - - - - - | 0 - |
| Rate | | 0 - |
| Rhythm | - - - - - | 0 - |
| Arrhythmia Type | - - - - - | 0 - |
| P Wave | - - - - - | 0 - |
| QRS Complex | - - - - - | 0 - |

ST Segment - - - - - 0 -

Comments 0 -



Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line


Do you want to add comments? - - - - - 0 -

COMMENTS

Save Cancel

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------|---|----------------|
| Course # ^(d) | <p>Indicates the course number the ECGs are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the cardiac ejection fraction results are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Exam ^(m) | Enter the date the ECG was performed. | DD-MMM-YYYY |
| Time | Enter the time the ECG was performed. | HH(24):MM |
| QRSD Interval | Enter the QRS duration (QRSD) interval in milliseconds. | 8 digits |
| QT Interval | Enter the QT interval in milliseconds. | 3 digits |
| QTC Interval | Enter the QTC interval in milliseconds. | 3 digits |
| QTCF Interval | Enter the QTCF interval in milliseconds. | 4 digits |
| PR Interval | Enter the PR interval in milliseconds. | 3 digits |
| ECG Impression ^(m) | <p>Select one of the following summary findings:</p> <ul style="list-style-type: none"> Abnormal | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------|---|-------------------------|
| | <ul style="list-style-type: none"> • Normal • Borderline | |
| Rate ^(m) | Enter the subject's pulse rate. | 5 digits and 3 decimals |
| Rhythm ^(m) | Select one of the following rhythm findings: <ul style="list-style-type: none"> • Abnormal • Normal | Use pick list. |
| Arrhythmia Type | Select the subject's arrhythmia type. Dictionary name - ECG_FNG_ARRHY_TP  ECG_FNG_ARRHY_TP.pdf | Use pick list. |
| P Wave | Select one of the following P Wave finding: <ul style="list-style-type: none"> • Abnormal • Normal | Use pick list. |
| QRS Complex | Select one of the following QRS Complex finding: <ul style="list-style-type: none"> • Abnormal • Normal | Use pick list. |
| ST Segment | Select one of the following ST Segment finding: <ul style="list-style-type: none"> • Abnormal • Normal | Use pick list. |
| Comments | Enter comments applicable to the ECG. | 250 characters |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Date of Exam is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or prior to the current date. |

Derivations

| Code | Field Name | Description |
|--------------|---------------|--|
| ECG1001_1002 | Course # | Course number is derived based on the course initiation start dates and the Evaluation Date. |
| ECG1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the Evaluation Date. |

Disease Assessment Leukemia

Purpose

Record the Leukemia Disease assessment information when the course is completed, and the subject is evaluated or taken off treatment.

1010001 Course 3
⚙️

Disease Assessment Leukemia

DISEASE ASSESSMENT LEUKEMIA

Date of Response

Response Assessment

Date of Progression

Do you want to add comments?



COMMENTS

Save Cancel
 Move to next task after save


Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|------------------------------------|---|----------------|
| Date of Response | <p>Enter the date of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU. This date will be the same date as the scan, or other method of disease assessment. For NE, record the date the subject's disease was assessed and deemed to be Not Evaluable.</p> <div style="background-color: #e6f2ff; padding: 10px; margin-top: 10px;"> <p> Note: The original date of onset of response should be used for responses that persist through several courses.</p> </div> | DD-MMM-YYYY |
| Response Assessment ^(m) | <p>Select the subject's best disease state as assessed during the course. This determination must be adequately documented in the subject's medical record.</p> <p>NE: Not Evaluable - State the reason in the "Response Note" field.</p> <p>NA: NOT ASSESSED - State the reason in the "Response Note" field.</p> <p>NP: Not Applicable per protocol - Protocol does not require</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|---|--------|
| | <p>a response assessment during the specific course. TE: Too early - Too Early to confirm a response. CRU: Complete Response Unconfirmed – Complete response assessed but not confirmed as per protocol timeframe.</p> <p>Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed:</p> <p>CR: Complete Response - There is a disappearance of all evidence of disease as assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments to demonstrate a disappearance of all evidence of disease.</p> <p>PR or MR: Partial Response or Marginal Response - Response is assessed relative to the <u>baseline at start of treatment</u>, not to previous courses. They must be confirmed <u>by repeat assessments</u>. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.</p> <p>SD: Stable Disease - Tumor growth or shrinkage <u>since the start of treatment</u> is not enough to justify a CR/PR/MR response or a PD progression. Once an actual CR/PR/MR response or PD progression has occurred, an SD assessment is not valid.</p> <p>PD: Progressive Disease - Response relative to the <u>best disease status</u> (smallest tumor measurement) since treatment <u>began</u>. Thus a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a complete response "CR".</p> <p>DU: Disease Unchanged - Subject's disease is unchanged relative to the previous assessment. This code may be used when a CR/PR/MR/PD response is not merited but SD is inappropriate.</p> <p>For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria.</p> <p>MX: Mixed Response RP: Response NR: No Response</p> <p>*RECIST: *Many protocols specify that the following <u>RECIST</u> criteria be used in assessing response. Please use the following selections when assessing response using RECIST criteria only.</p> | |

| Field Name | Description / Instructions | Format |
|------------|--|--------|
| | <p data-bbox="440 321 1170 579">  Note: CTEP's link to an article in the European Journal of Cancer: New response evaluation criteria in solid tumors: Revised RECIST guideline (version 1.1) guideline (version 1.1) </p> <p data-bbox="440 604 1170 1115"> <u>Evaluation of target lesions:</u> CR: Complete Response - Disappearance of all target lesions. PR: Partial Response - At least a 30% decrease in the sum of the LD (longest dimension) of target lesions, taking as reference the baseline sum LD. SD: Stable Disease - Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum LD since the treatment started. PD: Progressive Disease - At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded started on study (this includes the baseline sum if that is the smallest on study) or the appearance of one or more new lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. </p> <p data-bbox="440 1171 1170 1623"> <u>Evaluation of non-target lesions:</u> CR: Complete Response - Disappearance of all non-target lesions and normalization of tumor marker level PD: Progressive Disease - Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Non-CR/Non-PD: Non-CR/Non-PD – Non-Complete Response and Non-Progressive Disease. Persistence of one or more non-target lesion(s) and/or maintenance of tumor marker level above the normal limits. Non-CR/Non-PD is preferred over 'Stable Disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when no lesions can be measured is not advised. </p> <p data-bbox="440 1650 883 1682">Dictionary Name – RESPS_ASSMNT</p> <p data-bbox="440 1707 638 1801">  RESPS_ASSMNT.pdf </p> | |

| Field Name | Description / Instructions | Format |
|---------------------|--|-------------|
| Date of Progression | Enter the date of the evaluation used to determine the subject's disease status of progressive disease. Enter a date of progression if the disease progression occurred after an assessed better response (i.e. PR, CR, SD). | DD-MMM-YYYY |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date of Response or Date of Progression are future dates. "Future date has been entered. Please correct." | Change the date to a value no later than the current date. |
| LAS06 | Response Assessment is "Not Evaluable" or "Not Assessed" and no Response Notes were entered. "Disease Assessment is "Not Evaluable" or "Not Assessed" and no Comments were entered. Please correct." | Enter the Response Notes if Response Assessment is "Not Evaluable" or "Not Assessed". Otherwise change the Response Assessment to a selection other than "Not Evaluable" and "Not Assessed". |
| LAS07 | Date of Response is required when Response Assessment is CR, PR, MR, SD, or DU. "Date of Response is required when Response Assessment is CR, PR, MR, SD, or DU. Please correct." | Enter the Date of Response or Review the Response Assessment. |
| LAS08 | Date of Progression is required when Response Assessment is PD. "Date of Progression is required when Disease Assessment is PD. Please correct." | Enter the Date of Progression or Review the Response Assessment. |

Disease Assessment Neuro

Purpose

Record the Neuro Disease assessment information when the course is completed, and the subject is evaluated or taken off treatment.

▲ 1010006 □ Course 1
📄 Disease Assessment Neuro Inactivate Page ⚙ -

Visit Date 📅 ⚠ This field is required. Please complete. ⚙ -

COURSE ASSESSMENT SUMMARY

Response Type - Leison Size

Response Criteria Type - MacDonald

Is pt NED? ⚙ -

Maximum Corticosteroid Daily Dose at Assessment ⚙ -

Dose UOM ⚙ -

Steroid dose status ⚙ -

Sum of Longest Diameters of all Measurable Lesions (cm) ⚙ -

Sum of TD x PD of all Measurable Lesions (cm2) ⚙ -

Overall Response at this assessment ⚙ -

Verifying Physician
0 / 100 ⚙ -

Verified ⚙ -

Date verified 📅 ⚙ -

COURSE ASSESSMENT

Dose change from Dose Level entered on Course Initiation CRF ⚙ -

Course Disposition ⚙ -

Response Assessment ⚙ -

Date of Response 📅 ⚙ -

Date of Progression 📅 ⚙ -

Do you want to add comments? ⚙ -

COMMENTS

More to next task after save


Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---|---|--------------------------|
| Visit Date ^(m) | Enter the date the course started. | DD-MMM-YYYY |
| Is pt NED? | Question that asks whether there is evidence of disease (NED) at assessment. Choose an option from the list: <ul style="list-style-type: none"> • No • Unknown • Yes | Use pick list. |
| Maximum Corticosteroid Daily Dose at Assessment | Enter the numeric value for the largest daily corticosteroid dose taken by a patient at the time of an assessment. | 8 digits and 2 decimals |
| Dose UOM | Enter Maximum corticosteroid Daily Dose at Assessment "Units of Measurement". Choose an option from the list: | Use pick list. |
| Steroid dose status | Enter the status that represents the steroid therapy dose. Choose an option from the list: <ul style="list-style-type: none"> • NONE • STABLE • Increase • Decrease | Use pick list. |
| Sum of Longest Diameters of all Measurable Lesions (cm) | Enter Numeric value of the sum of the longest diameters of all measurable lesions captured in centimeters (cm). | 6 digits and 2 decimals |
| Sum of TD x PD of all Measurable Lesions (cm ²) | Enter numeric value of total sum of products (transverse diameter multiplied by perpendicular diameter) for all measurable lesions described in square centimeters (cm ²). | 12 digits and 3 decimals |



| Field Name | Description / Instructions | Format |
|-------------------------------------|---|----------------|
| Overall Response at this assessment | <p>Enter Overall Response at this assessment. Choose an option from the list:</p> <ul style="list-style-type: none"> • CR: Complete Response • Early Death: Death Prior to completion of protocol criteria • Incomplete Response/ SD: Incomplete response or Stable Disease • INSUFFICIENT EVALUATION TO DETERMINE RESPONSE STATUS: Insufficient evaluation • NED: Not an approved RECIST value • PD: Progressive Disease • PR: Partial Response • REGR: Not an approved RECIST value • SD: Stable Disease | Use pick list. |
| Verifying Physician | Enter the name of verifying physician. | 100 characters |
| Verified | <p>Choose an option from the list:</p> <ul style="list-style-type: none"> • Confirmed • Needs Revision | Use pick list. |
| Date verified | Enter the Date of verification by Physician | DD-MMM-YYYY |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| Dose change from Dose Level entered on | Indicate if the subject's treatment was different from that specified by the Dose Level for this course as entered on the Course Initiation CRF. If the treatment was different, indicate | Use pick list. |

| Field Name | Description / Instructions | Format |
|--------------------------------------|--|----------------|
| Course Initiation CRF ^(m) | <p>whether this was planned or unplanned, and record the reason, e.g. dose reduction due to toxicity, on the Comments tab of this CRF.</p> <div style="background-color: #e6f2ff; padding: 10px; margin: 10px 0;"> <p> Note: optional for non-CTEP sponsored studies.</p> </div> <ul style="list-style-type: none"> Yes, Planned - change in treatment had been decided before the start of the course, e.g., due to toxicity on a previous course. Yes, Unplanned - change was not intended at the start of the course, e.g., shortening the course (and thus lowering the dose level) due to adverse events or if there was a drug administration error. No - subject received the treatment specified in the Course Initiation Dose Level Unknown - only when the actual treatment cannot be determined, e.g., when the subject is uncooperative in reporting self-administration of study medication. | |
| Course Disposition ^(m) | <p>A "completed" course is one that has been conducted in accordance with the protocol with respect to length including the observation period (two-day variance allowed). A course is regarded as "discontinued" if it was shorter than specified in the protocol. Select one of the following values:</p> <ul style="list-style-type: none"> Completed Discontinued | Use pick list. |
| Response Assessment ^(m) | <p>Select the subject's best disease state as assessed during the course. This determination must be adequately documented in the subject's medical record.</p> <p>NE: Not Evaluable - State the reason in the "Response Note" field.</p> <p>NA: NOT ASSESSED - State the reason in the "Response Note" field.</p> <p>NP: Not Applicable per protocol - Protocol does not require a response assessment during the specific course.</p> <p>TE: Too early - Too Early to confirm a response.</p> <p>CRU: Complete Response Unconfirmed – Complete response assessed but not confirmed as per protocol timeframe.</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|--|--------|
| | <p>Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed:</p> <p>CR: Complete Response - There is a disappearance of all evidence of disease as assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments to demonstrate a disappearance of all evidence of disease.</p> <p>PR or MR: Partial Response or Marginal Response - Response is assessed relative to the <u>baseline at start of treatment</u>, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.</p> <p>SD: Stable Disease - Tumor growth or shrinkage since the <u>start of treatment</u> is not enough to justify a CR/PR/MR response or a PD progression. Once an actual CR/PR/MR response or PD progression has occurred, an SD assessment is not valid.</p> <p>PD: Progressive Disease - Response relative to the <u>best disease status</u> (smallest tumor measurement) since treatment began. Thus a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a complete response "CR".</p> <p>DU: Disease Unchanged - Subject's disease is unchanged relative to the previous assessment. This code may be used when a CR/PR/MR/PD response is not merited but SD is inappropriate.</p> <p>For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria.</p> <p>MX: Mixed response RP: Response NR: No Response</p> <p>*RECIST: *Many protocols specify that the following <u>RECIST</u> criteria be used in assessing response. Please use the following selections when assessing response using RECIST criteria only.</p> | |

| Field Name | Description / Instructions | Format |
|------------|--|--------|
| | <p data-bbox="440 321 1170 579">  Note: CTEP's link to an article in the European Journal of Cancer: New response evaluation criteria in solid tumors: Revised RECIST guideline (version 1.1) guideline (version 1.1) </p> <p data-bbox="440 604 1170 1115"> <u>Evaluation of target lesions:</u> CR: Complete Response - Disappearance of all target lesions. PR: Partial Response - At least a 30% decrease in the sum of the LD (longest dimension) of target lesions, taking as reference the baseline sum LD. SD: Stable Disease - Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum LD since the treatment started. PD: Progressive Disease - At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded started on study (this includes the baseline sum if that is the smallest on study) or the appearance of one or more new lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. </p> <p data-bbox="440 1171 1170 1633"> <u>Evaluation of non-target lesions:</u> CR: Complete Response - Disappearance of all non-target lesions and normalization of tumor marker level PD: Progressive Disease - Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Non-CR/Non-PD: Non-CR/Non-PD – Non-Complete Response and Non-Progressive Disease. Persistence of one or more non-target lesion(s) and/or maintenance of tumor marker level above the normal limits. Non-CR/Non-PD is preferred over 'Stable Disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when no lesions can be measured is not advised. </p> <p data-bbox="440 1675 1170 1707">Dictionary Name – RESPS_ASSMNT</p> <p data-bbox="440 1738 1170 1833">  RESPS_ASSMNT.pdf </p> | |

| Field Name | Description / Instructions | Format |
|---------------------|--|-------------|
| Date of Response | Enter the date of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU. This date will be the same date as the scan, or other method of disease assessment. For NE, record the date the patient's disease was assessed and deemed to be Not Evaluable. | DD-MMM-YYYY |
| Date of Progression | Enter the date of the evaluation used to determine the subject's disease status of progressive disease. Enter a date of progression if the disease progression occurred after an assessed better response (i.e. PR, CR, SD). | DD-MMM-YYYY |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date verified / Date of Response / Date of Progression is a future date. “Future date has been entered. Please correct.” | Change the date to a value no later than the current date. |
| NAS06 | Response Assessment is "Not Evaluable" or "Not Assessed" and no Response Notes were entered. “Disease Assessment is "Not Evaluable" or "Not Assessed" and no Comments were entered. Please correct.” | Enter the Response Notes if Response Assessment is "Not Evaluable" or "Not Assessed". Otherwise change the Response Assessment to a selection other than "Not Evaluable" and "Not Assessed". |

| Code | Description | Resolutions |
|-------|---|--|
| NAS07 | Date of Response is required when Response Assessment is CR, PR, MR, SD, or DU. "Date of Response is required when Response Assessment is CR, PR, MR, SD, or DU. Please correct." | Enter the Date of Response or Review the Response Assessment. |
| NAS08 | Date of Progression is required when Response Assessment is PD. "Date of Progression is required when Disease Assessment is PD. Please correct." | Enter the Date of Progression or Review the Response Assessment. |

Disease Assessment RECIST

Purpose

Record the RECIST Disease Assessment information when the course is completed, and the subject is evaluated or taken off treatment.

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------------|--|-------------|
| Visit Date ^(m) | Enter the date the course started. | DD-MMM-YYYY |
| Date of Response | <p>Enter the date of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU. This date will be the same date as the scan, or other method of disease assessment. For NE, record the date the subject's disease was assessed and deemed to be Not Evaluable.</p> <p>Note: The original date of onset of response should be used for responses that persist through several courses.</p> | DD-MMM-YYYY |

| Field Name | Description / Instructions | Format |
|--|---|------------------------|
| irRC Response | Select the irRC response: <ul style="list-style-type: none"> • irPD: Immune-related progressive disease • irSD: Immune-related Stable Disease • irPR: Immune-related Partial Response • irCR: Immune-related Complete Response • Non-index lesions: Non-index lesions • New, non-measurable lesions (<5x5 mm): New non-measurable lesions (<5x5 mm) • New, non-measurable lesions (>= 5x5 mm): New non-measurable lesions (>= 5x5 mm) • Not Evaluable: Not Assessable/Not Evaluable | Use pick list. |
| Date of Progression | Enter the date of the evaluation used to determine the subject's disease status of progressive disease. Enter a date of progression if the disease progression occurred after an assessed better response (i.e. PR, CR, SD). | DD-MMM-YYYY |
| Sum of Diameters | Enter the sum of the diameters of all the lesions. The calculated sum of the diameters (longest for non-nodal lesions, short axis for nodal lesions) of a tumor composed of atypical neoplastic, often pleomorphic cells that invade other tissues. | 4 digits and 1 decimal |
| Targeted Lesion Baseline Sum | Enter the value of the baseline sum of the diameter of the targeted lesion. | 2 digits and 1 decimal |
| Targeted lesion Best Response Smallest Sum | Enter the value of Smallest Sum of Longest Diameters of all Target Lesions | 2 digits and 1 decimal |
| % Change from Best Response | Enter the Numeric value to represent lesion or site of disease percentage change from a measurement taken during the best response to treatment. | 4 digits and 1 decimal |
| % Change from Baseline | Enter the Numeric value to represent lesion or site of disease percentage change from a baseline measurement | 4 digits and 1 decimal |

| Field Name | Description / Instructions | Format |
|---|--|----------------|
| Targeted Lesions Response | <p>Select the response of targeted lesions from the picklist:</p> <ul style="list-style-type: none"> • CR: Complete Response • NE: Inevaluable or not all evaluated • PD: Progressive Disease • PR: Partial Response • SD: Stable Disease | Use picklist. |
| Non-targeted Lesions Response | <p>Select the response of the non-targeted lesions from the picklist:</p> <ul style="list-style-type: none"> • CR: Complete Response • NE: Inevaluable or nor all evaluated • NON-CR/NON-PD: Non-Complete Response/Non-Progression • PD: Progressive Disease | Use picklist. |
| Was the Appearance of Any New Lesions Documented? | <p>Select 'Yes' or 'No' to record if the appearance of any new lesions was documented.</p> <ul style="list-style-type: none"> • Yes • No | Use picklist. |
| Overall Response | <p>Select the subject's overall response through the course (Text code to represent overall disease response in a target or non-target lesion, using RECIST response criteria):</p> <ul style="list-style-type: none"> • CR: Complete Response • NE: Inevaluable or not all evaluated • PD: Progressive Disease • PR: Partial Response • SD: Stable Disease • NP: Protocol does not require a response assessment during the specific course | Use pick list. |
| Overall Response Duration | <p>Enter the overall response duration of the course. (a maximum length of time over which response is maintained, measured from a date when criteria for complete or partial response are met until a date when recurrent or progressive disease is reported.)</p> | 6 digits |

| Field Name | Description / Instructions | Format |
|-----------------------|--|---------------|
| Best Overall Response | Enter the best overall response during the course. (Text code to represent the best overall disease response recorded from the start of the study treatment until the end of treatment taking into account any requirements for confirmation.) | 13 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Visit Date / Date of Response or Date of Progression are future dates. "Future date has been entered. Please correct." | Change the date to a value no later than the current date. |

Echo/MUGA

Purpose

Record the subject’s cardiac ejection fraction.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Echo/MUGA

Echo/MUGA, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Course #

Day in Course

Evaluation Date ⓘ This field is required. Please complete.

Evaluation Time

Procedure

Pre-Ejection Period

LV Ejection Time

LV Ejection Fraction %



Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Do you want to add comments?

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| Course # ^(d) | Indicates the course number the cardiac ejection fraction results are related to based on their date and time. This is a derived field. | Derived field. |

| Field Name | Description / Instructions | Format |
|---|---|-------------------------|
| | <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the cardiac ejection fraction results are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Evaluation Date ^(m) | Enter the date the procedure was performed. | DD-MMM-YYYY |
| Evaluation Time ^(m) | Enter the time the procedure was performed. | HH(24):MM |
| Procedure ^(m) | <p>Select one of the following procedures from the pick list:</p> <ul style="list-style-type: none"> • Muga • MRI • Echocardiogram • Cardiac Catheterization. • Stress Thallium Test | Use pick list. |
| Pre-Ejection Period | Enter the Pre-Ejection Period. | 8 digits and 3 decimals |
| LV Ejection Time | Enter the Left Ventricular Ejection Time. | 4 digits |
| LV Ejection Fraction (%) ^(m) | Enter the Left Ventricular Fraction percentage. | 3 digits |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Evaluation Date is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or prior to the current date |
| EM02 | Check for duplicate Cardiac evaluation entries – Same Date, Time, and Procedure. “Two Cardiac evaluation entries – Same Date, Time, and Procedure. Please correct.” | Correct the Evaluation Date, Time, and Procedure. |

Derivations

| Code | Field Name | Description |
|-------------|---------------|--|
| EM1001_1002 | Course # | Course number is derived based on the course initiation start dates and the Evaluation Date. |
| EM1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the Evaluation Date. |

Enrollment

Purpose



Record the subject's enrollment information at the time of study entry.


For studies that require de-identified subject data, fields such as Date from which to Start Including Labs, will not be used.

| DISEASE AND CONSENT | |
|---|---|
| Lesion anatomic site description | <input type="text" value=""/> <small>0 / 200</small> |
| Date of Diagnosis | dd -- yyyy |
| Histology | -- |
| Grade of Histology | -- |
| Dose Level | -- |
| Disease Stage at Entry | -- |
| Disease Stage at Diagnosis | -- |
| Gleason Score | |
| T Stage | -- |
| N Stage | -- |
| M Stage | -- |
| Date of Confirmation of Histology | dd -- yyyy |
| Date of Informed Consent Version | dd -- yyyy |
| Date from which to Start Including labs | dd -- yyyy |
| NIH ADVANCE DIRECTIVE & FORM | |
| Collected? | -- |
| Collection Date | dd -- yyyy |
| Comments | <input type="text"/> |


Field Descriptions and Instructions

Enrollment – Disease and Consent

| Field Name | Description / Instructions | Format |
|----------------------------------|--|----------------|
| Lesion anatomic site description | Enter Lesion anatomic site description | 200 characters |
| Date of Diagnosis | Enter the first date of original diagnosis (e.g., when a positive biopsy or surgical result was obtained). Do not give the start date of symptoms as the date of diagnosis. | DD-MMM-YYYY |
| Histology | <p>Select the type of histology, Malignant Neoplasm Diagnosis, found at the time of original diagnosis</p> <p>Dictionary Name - MAL_NEO_DX_HIST_NM</p>  <p>MAL_NEO_DX_HIST_NM.pdf</p> | Use pick list. |
| Grade of Histology | <p>Enter the grade of histology at study entry, if appropriate. Leave it blank otherwise.</p> <p>Make a selection from the list:</p> <ul style="list-style-type: none"> • Unknown • Well • Moderately • Poorly • N/A • Low Grade • High Grade • Undifferentiated • NOS • Not Done <div style="background-color: #e1eef6; padding: 5px; margin-top: 10px;"> <p> Note: Grade of Histology is the Gleason Score for Prostate Subject.</p> </div> | Use pick list. |
| Dose Level ^(m) | Select the appropriate code for the subject's treatment assignment as specified. "Dose level" codes are based on the treatment schedules described in the protocol. Please contact the Informatics team for advice on Dose Level formulation and modification. | Use pick list. |

| Field Name | Description / Instructions | Format |
|---|---|----------------|
| | <p> Note: This is a study specific picklist.</p> | |
| Disease Stage at Entry | <p>Select the stage of the disease at the time of study entry if appropriate. Otherwise, leave it blank.</p> <ul style="list-style-type: none"> • IA • I • IB • II • III • IV • D0 • D1 • D2 • D3 • IIA • IVA • IVB • A • B • C • D • 0 • IIB • IIIA • IIIB • IIIC • IIE • IE • IC • IIC • IVC | Use pick list. |
| Disease Stage at Diagnosis ^(m) | <p>Select the stage of the disease at the time of diagnosis.</p> <ul style="list-style-type: none"> • IA • I • IB • II • III • IV • D0 • D1 • D2 | Use pick list. |

| Field Name | Description / Instructions | Format |
|----------------------|--|----------------|
| | <ul style="list-style-type: none"> • D3 • IIA • IVA • IVB • A • B • C • D • 0 • IIB • IIIA • IIIB • IIIC • IIE • IE • IC • IIC • IVC | |
| Gleason Score (m) | Enter subject's Gleason Score value | 6 characters |
| Disease T Stage | <p>Select the stage of disease based on the primary tumor.</p> <ul style="list-style-type: none"> • T0 • T1 • T2 • T3 • T4 • TX | Use pick list. |
| Disease N Stage | <p>Select the stage of disease based on the nodes present.</p> <ul style="list-style-type: none"> • N0 • N1 • N2 • N3 • NX | Use pick list. |
| Disease M Stage | <p>Select the stage of disease based on the metastases present.</p> <ul style="list-style-type: none"> • M0 • M1 • MX | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|---|-------------|
| Date of Confirmation of Histology | Enter the date when the subject's disease status was confirmed, at the treating institution, prior to study entry (if required by the protocol). | DD-MMM-YYYY |
| Date of Informed Consent Version (m) | Enter the date of the informed consent version of the IRB-approved informed consent form that was signed by the subject at the time of study entry. This will be the date that is displayed on page one of the consent form in the section entitled: "Latest Amendment Approved:" or the date displayed on the "Latest IRB Review" when the amended date is N/A. | DD-MMM-YYYY |
| Date from which to Start Including Labs (m) | This date, the Registering Institution and the Subject ID (Medical Record Number) control the electronic transfer of lab data from the NIH Clinical Center into Rave. This date is usually prior to the subject's informed consent in order to include the lab results to confirm eligibility. <div style="background-color: #e6f2ff; padding: 5px;">  This field is only applicable (mandatory) for subjects with Registering Institutions containing NCI or NIH as part of the Institute abbreviate code (Ex: NCIPOB, NIHCC, etc). </div> | DD-MMM-YYYY |

Field Descriptions and Instructions
Enrollment – NIH Advance Directives Form

| Field Name | Description / Instructions | Format |
|-----------------|--|----------------|
| Collected? | Has the form been collected? <ul style="list-style-type: none"> • No • Unknown • Yes • Not Applicable | Use pick list. |
| Collection Date | Date when form was collected. | DD-MMM-YYYY |

| Field Name | Description / Instructions | Format |
|------------|--------------------------------|----------------|
| Comments | Field for additional comments. | 250 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Date of Confirmation of Histology, Date of Diagnosis, Date of Informed Consent Version or Date from which to Start Including Labs are in the future. “Future date has been entered. Please correct.” | Enter a date that is prior or equals to today's date. |
| ENR09 | Query will fire if Birth Date (in Subject Enrollment CRF) is after the Date from which to include labs. “Date from which to include labs is before Birth Date. Please correct.” | Correct the Date from which to Start Including Labs |
| ENR10 | Query will fire if Birth Date (in Subject Enrollment CRF) is after the Date of Confirmation of Histology. “Date of Confirmation of Histology is before Birth Date. Please correct.” | Correct the Date of Confirmation of Histology |
| ENR11 | Query will fire if Birth Date (in Subject Enrollment CRF) is after the Date of Diagnosis. “Date of Diagnosis is before Birth Date. Please correct.” | Correct the Date of Diagnosis |
| ENR12 | Query will fire if Birth Date (in Subject Enrollment CRF) is after the Informed Consent Version Date. “Informed Consent Version Date is before Birth Date. Please correct.” | Correct the Informed Consent Version Date |

| Code | Description | Resolutions |
|-------|---|---|
| ENR14 | Query will fire if Date of Diagnosis is after Date of Confirmation of Histology (if provided). "Date of Diagnosis is after Date of Confirmation of Histology. Please correct." | Correct Diagnosis Date or Date of Confirmation of Histology. |
| ENR20 | Query will fire on all 3 TNM fields if Enrollment only has part of the TNM Disease Stage information available. "If one of the TNM fields is answered, the rest should be available. Please correct." | If one of the TNM fields is answered, the rest should be available. |

Extent of Disease - Lesions Identification

Purpose

Record all sites of disease, even if they will not be followed for response.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Extent of Disease- Lesions Identification

Extent of Disease- Lesions Identification, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Lesion # This field is required. Please complete.

Anatomic Site

Description of Location

Description of Lesion

Previously Irradiated




Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line


Do you want to add comments?

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--------------|---|----------------|
| Lesion # (m) | Select a unique number for each lesion. Once a lesion number is designated for a specific lesion, that number may not change or be used to denote a different lesion. | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------------|--|----------------|
| | <p> Note: This lesion number must appear at least once on the bottom repeating group.</p> | |
| Anatomic Site (m) | <p>Select the anatomic position where the lesion is located, i.e., Lung, Skull, etc.</p> <p>Dictionary Name – ANAT_SITE_NM</p> <p> ANAT_SITE_NM.pdf</p> | Use pick list. |
| Description of Location (m) | <p>Select a brief description of the lesion location.</p> <p>Dictionary Name - LOC_DESCRPTR_TXT_NM</p> <p> LOC_DESCRPTR_TXT _NM.pdf</p> | Use pick list. |
| Description of Lesion | <p>If applicable, enter a brief description of each lesion, e.g., cystic, well-defined, encapsulated, necrotic appearing center.</p> | 200 characters |
| Previously Irradiated (m) | <p>If the site or lesion has previously been irradiated, select “Yes”, otherwise enter “No” or “Unknown”.</p> <ul style="list-style-type: none"> • Yes • No • Unknown | Use pick list. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|-------|---|--|
| EXT01 | Lesion Number appears more than once on the description section. "Entered Lesion Number is not unique. Please correct." | Extent of Disease Lesion Number should be unique in the description section (top repeating group). |

Extent of Disease - Lesions Measurements

Purpose

Record Measurements of Lesions and details.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Extent of Disease- Lesions Measurements

Extent of Disease: Lesions Measurements, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Lesion # ⓘ This field is required. Please complete.

Course #

Day in Course

Date of Evaluation

How Measured

Measurement-1st Longest

Measurement-2nd Longest

Measurement-3rd Longest

Product

Total Tumor Volume

Exam #

Exam Code

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line



Do you want to add comments?




COMMENT


Save Cancel

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--------------|--|----------------|
| Lesion # (m) | <p>Select a lesion number from the pick list.</p> <p> i Note: This lesion number must appear in the description section (top repeating group). </p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------------------|---|----------------|
| Course # ^(d) | <p>Indicates the course number that this lesion evaluation was done in as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this lesion evaluation was done as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Evaluation ^(m) | Enter the date of the evaluation (i.e.: date of CT scan). Do not enter the date of the report or when the results were received. | DD-MMM-YYYY |
| How Measured ^(m) | <p>Select how the lesion measurement was determined. The same method should be used to measure a specific lesion throughout the study. For example, if the measurements were determined by a chest x-ray, enter CXR.</p> <ul style="list-style-type: none"> • CATSCAN: Computerized Axial Tomography • BONESCAN: Bone scan • BIOPSY: Biopsy • FLOW CYTOMETRY, BLOOD: Flow Cytometry, Blood • FLOW CYTOMETRY, BONE MARROW: Flow Cytometry, Bone Marrow • MRI SCAN: MRI Scan • CXR: CXR • PE: PE • CYTOPATHOLOGY: CYTOPATHOLOGY • FDG-PET SCAN: FDG-PET SCAN • ULTRASOUND : ULTRASOUND • X-RAY: X-RAY • PHOTO: PHOTO • MR PERFUSION: MR PERFUSION • MAGNETIC RESONANCE ANGIOGRAPHY (MRA): MAGNETIC RESONANCE ANGIOGRAPHY (MRA) • FUNCTIONAL MRI: FUNCTIONAL MRI | Use pick list. |

| Field Name | Description / Instructions | Format |
|-------------------------|--|-------------------------|
| | <ul style="list-style-type: none"> • ELECTRON BEAM TOMOGRAPHY EBT: ELECTRON BEAM TOMOGRAPHY EBT • EGD: Esophagogastroduodenoscopy • MSWAT: Modified Severity Weighted Assessment Tool | |
| Measurement-1st Longest | <p>Enter the longest lesion measurement in centimeters.</p> <div style="background-color: #e6f2ff; padding: 10px; border: 1px solid #add8e6;"> <p> Note: for studies that use RECIST criteria, it should always measure the longest diameter of the lesion even if the actual axis is different from the one used to measure the lesion initially.</p> </div> | 6 digits and 2 decimals |
| Measurement-2nd Longest | <p>Enter the second longest lesion measurement in centimeters.</p> <div style="background-color: #e6f2ff; padding: 10px; border: 1px solid #add8e6;"> <p> Note: Not applicable for studies that use RECIST criteria.</p> </div> | 6 digits and 2 decimals |
| Measurement-3rd Longest | <p>Enter the third longest lesion measurement in centimeters.</p> <div style="background-color: #e6f2ff; padding: 10px; border: 1px solid #add8e6;"> <p> Note: Not applicable for studies that use RECIST criteria.</p> </div> | 6 digits and 2 decimals |
| Product | <p>Enter the tumor product which is the multiplication of the First and Second Longest Measurements.</p> | 8 digits and 2 decimals |
| Total Tumor Volume | <p>Enter the total tumor volume which is the multiplication of all three measurements.</p> | 8 digits and 2 decimals |
| Eval # ^(m) | <p>Number each evaluation sequentially for each lesion. Use 0 for the baseline evaluation, 1 for the first evaluation, 2 for the second evaluation, etc.</p> | 2 digits |

| Field Name | Description / Instructions | Format |
|------------|--|----------------|
| | <p> Note: this is the number of the set of scans done after the baseline. For example, if a new lesion was found on the third set of scans that occurred at the end of the course 4, the evaluation number should be 3.</p> | |
| Eval Code | <p>Select the status of non-measurable lesions at the time of each evaluation.</p> <ul style="list-style-type: none"> • N: NEW • R: Resolved • D: Decreasing • I: Increasing • S: Stable • B: Baseline • X: Not Examined | Use pick list. |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

Lesions Measurements

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | <p>Query will fire if Date of Evaluation is in the future. “Future date has been entered. Please correct.”</p> | <p>Change the date to a value no later than the current date.</p> |

| Code | Description | Resolutions |
|---------|---|---|
| EXT02_1 | Lesion Number in the measurement section does not have a corresponding number in the description section (Lesion Identification Page). "Extent of Disease Lesion Number in the Lesions Measurements section is not recorded in the Lesions Identification section. Please correct." | Verify that lesion number in the measurement section is recorded in the description section (Lesion Identification Page). |
| EXT03 | Evaluation Number of a "Non-Measurable" lesion is "0" and Evaluation Code is not "B, and vice-versa. "Extent of Disease Lesion in the Lesions Measurements section has an Evaluation Number of '0' but Evaluation Code is not 'B : Baseline'. Please correct." "Extent of Disease Lesion in the Lesions Measurements section has an Evaluation Code of 'B : Baseline' but Evaluation Number is not '0'. Please correct." | If Evaluation Number of a "Non-Measurable" lesion is "0", Evaluation Code should be "B - Baseline". |
| EXT13 | Query will fire if the lesion has an Evaluation Code of "B - Baseline" and the Evaluation Date is not prior to Start Date of the first course. "The lesion has an Evaluation Code of "B - Baseline" and the Evaluation Date is not prior to Start Date of the first course. Please correct." | Enter an Evaluation Date that is earlier than the Start Date of the first course or correct the Evaluation Code. |
| EXT14 | Query will fire if Evaluation Date for New lesion is prior to the Start Date of first course. "Evaluation Date for New lesion (Eval Code = New) is prior to the Start Date of first course. Please correct." | Enter a date that is equal or after the first course Start Date if Eval Code is selected as New. |
| EXT15 | Query will fire if Evaluation number for New lesion (with Evaluation Code 'N-New') is 0. "Evaluation number (Eval #) for New lesion (with Evaluation Code 'N-New') is 0. Please correct." | Enter a correct sequential number. |

| Code | Description | Resolutions |
|-------|---|------------------------------------|
| EXT16 | New lesion (with Evaluation Code 'N-New') does not have the lowest evaluation number for the corresponding lesion. "Extent of Disease Lesion in the Lesions Measurements section has an Evaluation Code 'N: New', but the Evaluation Number is not the lowest. Please correct." | Enter a correct sequential number. |

Derivations

Lesions Measurements

| Code | Field Name | Description |
|--------------|---------------|--|
| EXT1001_1002 | Course # | Course number is derived based on the course initiation start dates and the extent of disease evaluation date. |
| EXT1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the extent of disease evaluation date. |

Follow-up

Purpose

Record each follow-up contact as identified in the protocol.

There is no need to complete this Case Report Form if the subject died during the treatment portion of the study. Survival CRF still needs to be completed.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

[Follow-up](#)

Follow-up, Log Lines

[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line > [Add Another Line](#)

Date of Last Contact This field is required. Please complete.

Type of Contact

Received Treatment Since Last Contact?

Subject Status

Explain 'Unknown' Subject Status

Response

Response Date


[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line > [Add Another Line](#)



Do you want to add comments?


COMMENTS

[Save](#) [Cancel](#)

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---|---|----------------|
| Date of Last Contact ^(m) | Enter the date the subject was last contacted. If the subject is being considered lost to follow-up (i.e.: unsuccessful contact with the subject / family / health care provider), please indicate the date that no further follow-up will be attempted. | DD-MMM-YYYY |
| Type of Contact ^(m) | Select how the information was obtained: <ul style="list-style-type: none"> • Telephone Contact With Subject • Telephone Contact With Subject's Family • Social Security Death Index (SSDI) • Telephone Contact With Subject's Local Physician • Clinic Appointment • Mail Contact With The Subject • E-Mail Contact With The Subject • Email from family • Email from doctor's office • Other • Mail contact from local MD(s) | Use pick list. |
| Explain 'Other' Type of Contact | Enter an explanation for selecting "Other" for Type of Contact. <div style="background-color: #e6f2ff; padding: 5px; margin-top: 10px;">  Note: This field is invisible unless "Type of Contact" is answered with 'Other'. </div> | 50 characters |
| Received Treatment Since Last Contact? ^(m) | If the subject has received further treatment since the last contact, select <ul style="list-style-type: none"> • No • Yes • Unknown | Use pick list. |
| Subject Status ^(m) | Select one of the options below that indicates the subject's last known status. If the subject has died, enter the date in the Date of Death field. If status is unknown, enter some explanation on the field labeled "Unknown (explain)". <ul style="list-style-type: none"> • 1: Alive With Disease • 2: Alive With No Evidence of Disease • 3: Alive Disease Status Unknown | Use pick list. |

| Field Name | Description / Instructions | Format |
|----------------------------------|---|----------------|
| | <ul style="list-style-type: none"> • 4: Unknown (Explain) • 5: Died | |
| Explain 'Unknown' Subject Status | If Subject Status is unknown, enter some explanation here. Include what attempts were made and how many attempts were made in order to obtain the subject's status (i.e.: no response to 5 messages left). | 24 characters |
| Response ^(m) | <p>Select the subject's best disease state as assessed during the evaluation at current timepoint. This determination must be adequately documented in the subject's medical record.</p> <p>Dictionary Name - RESPS_ASSMNT</p>  <p>RESPS_ASSMNT.pdf</p> | Use pick list. |
| Response Date ^(m) | <p>Enter the date of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU. This date will be the same date as the scan, or other method of disease assessment. For NE, record the date the subject's disease was assessed and deemed to be Not Evaluable.</p> <div style="background-color: #e6f2ff; padding: 10px; border: 1px solid #add8e6;"> <p> Note: The original date of onset of response should be used for responses that persist through several courses.</p> </div> | DD-MMM-YYYY |



 Legend: ^(d) derived field, ^(m) EDC mandatory.





If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date of Last Contact or Response Date is in the future. "Future date has been entered. Please correct." | Enter a date earlier than, or equals to, the current date. |
| FLW06 | Query will fire if Date of Last Contact is not within the Date Off Therapy and Date Off Study. "Date of Last Contact is not within the Date Off Therapy and Date Off Study. Please correct." | Date of Last Contact must fall between the Date Off Therapy and Date Off Study. |
| FLW07 | Duplicate Date of Last Contact. "Duplicate Date of Last Contact. Please correct". | Date of Last Contact must be unique. |
| FLW08 | Query will fire if Subject Status is "Unknown" and explanation is missing. "Subject Status is "Unknown" and explanation is missing. Please correct." | Subject Status "Unknown" requires an explanation. |
| FLW09 | Query will fire if Explain "Unknown" Subject Status was provided, but Subject Status is not "Unknown". "Explain 'Unknown' Subject Status was provided, but Subject Status is not "Unknown". Please correct." | Explain 'Unknown' Subject Status is required if an explanation for "Unknown" Subject Status is provided. |
| FLW10 | Query will fire if Type of Contact is "Other" and Explain 'Other' Type of Contact is not provided. "Type of Contact is "Other", but Explain 'Other' Type of Contact is empty. Please correct." | Enter Explain 'Other' Type of Contact when Type of Contact is "Other". |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------|--|----------------|
| Course # ^(d) | <p>Indicates the course number that this infection episode occurred in as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this infection episode occurred in as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Onset ^(m) | Enter the date the infection episode began. | DD-MMM-YYYY |
| Date Resolved | Enter the date the infection episode resolved. | DD-MMM-YYYY |
| Infection Type ^(m) | <p>Select the infection type. For example: pneumonia, UTI, URI, etc.</p> <ul style="list-style-type: none"> • Bacterial • Fungal • Microbacterial • No Isolated Organism • Parasitic • Pneumonia • Protozoal • Unknown • URI • UTI • Viral • Viral, new infection • Viral, reactivation | Use pick list. |
| Primary Site ^(m) | Select the primary site of the infection. | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------------|---|----------------|
| | Dictionary Name - ANAT_SITE_NM  ANAT_SITE_NM.pdf | |
| Infectious Agent | Select the actual infectious agent, determined from culture or other appropriate test. Dictionary Name - MICROORGANISMS  MICROORGANISMS.pdf | Use pick list. |
| Treatment | Select the treatment (or lack of) given for this infection. This treatment should also be recorded on the Concomitant Measures / Medications case report form. Dictionary Name – ANTIMICROBIALS  ANTIMICROBIALS.pdf | Use pick list. |
| Procedure | Select the procedure (or lack of) done for this infection. This procedure should also be recorded on the Procedures case report form. Dictionary Name - CONCOM_PROCEDURES_TH  CONCOM_PROCEDURES_TH.pdf | Use pick list. |
| Outcome | Select the outcome of this episode: <ul style="list-style-type: none"> • Recovered • Died | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|-------------------------------|----------------|
| Comments | Enter Comments in this field. | 200 characters |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Date of Onset and/or Date Resolved are/is in the future. “ Future date has been entered. Please correct. ” | Enter a date that is equal to or prior to the current date. |
| IFE01 | Query will fire if Date of Onset of the Infection Episode is greater than the Resolve Date. “ Date of Onset of the Infection Episode is greater than the Resolve Date. Please correct. ” | Date of Onset must be prior to Date resolved. |
| IFE05 | Date of Onset, Infection Type, Treatment and Procedure appear more than once. “ Date of Onset, Infection Type, Treatment and Procedure appear more than once. Please correct. ” | An Infection Type, Treatment and Procedure can only be entered once for a particular Date of Onset. |
| IFE06 | Query will fire if Resolved Date provided, but Outcome is missing. “ Resolved Date provided, but Outcome is missing. Please correct. ” | Outcome must be entered if Date Resolved is provided. |
| IFE07 | Query will fire if Date Resolved is missing, but Outcome was provided. “ Date Resolved is missing, but Outcome was provided. Please correct. ” | Date Resolved must be entered if Outcome is provided. |

| Code | Description | Resolutions |
|---------|--|---|
| IFE08_9 | A Concomitant Measure / Medication with an Agent / Procedure matching the Infection Episode Treatment / Procedure with the same Start Date and Date of Onset was not found. "Infection Episode does not have a corresponding record on Concomitant Measures/Medication. Please correct." | An Infection Episode Treatment must have an entry in the Concomitant Measure / Medication case report form with the Start Date the same as the Date of Onset. |

Derivations

| Code | Field Name | Description |
|--------------|---------------|--|
| IFE1001_1002 | Course # | Course number is derived based on the course initiation start dates and the infection episode Date of Onset. |
| IFE1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the infection episode Date of Onset. |

Laboratory

Purpose

Record the subject's lab results.

Subjects on NCI/CCR's intramural studies who have their labs drawn at the Clinical Center will use the Lab Load Interface (LLI) tool to select which labs results to electronically transfer into Rave. The selected results are then loaded onto the appropriate Lab Panel CRFs overnight.

Labs can be populated through lab loader or manually added by using the CRF 'Add Lab Form', they will not be visible by default. 2007 and earlier studies, in general, do not use the LLI tool and labs done in the Clinical Center are automatically loaded directly in Rave.

It takes at least 48 to 72 hours for Clinical Center Labs to become available to Rave.

Outside labs need to be manually entered in Rave.

The following table lists the standard lab panels and Appendix III the tests in each of them. The Rave Study will have only the appropriate labs as specified by the Protocol. Lab CRFs can be manually added for each of these panel folders.

| | | | |
|---------------------|---------------|-------------------------|------------------------|
| • Blood Chemistries | • Serology | • Serum Electrophoresis | • Lymphocyte Phenotype |
| • Hematology | • Other Serum | • Urine Electrophoresis | • HLA |
| • Urinalysis | • Blood Gas | • Coagulation | • Chimerism Lab |
| • Bone Marrow | • Other Urine | • CSF | |



Appendix III - Lab
Panels.pdf

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Blood Chemistries 01/01/2024 12:12 [refresh page]

Reclaim Verification

Lab Date

Lab Time

Course #

Day in Course

Blood Chemistries 01/01/2024 12:12, Log Lines

[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line >

Source of the Lab Data

Lab Test

Lab Value (Char)

UOM

Preferred UOM

Normal Range (e.g. 1.5-5)

Grade





[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line >

Do you want to add comments?

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|--|-------------|
| Lab Date ^(m) | The date the lab sample was collected. This field is populated through lab loader or the CRF 'Add Lab Form'. | DD-MMM-YYYY |
| Lab Time ^(m) | <p>The lab sample collection time in military format (24 hours). This field is populated through lab loader or the CRF 'Add Lab Form'.</p> <p>Ex: 13:56 (for 1:56 PM)</p> <div style="background-color: #e0e0e0; padding: 5px; border: 1px solid #ccc;"> <p>In Rave studies, the lab time will be empty when the CRF is saved with time 00:00. Such time is being saved and simply not being displayed.</p> <p>There is no way to indicate an 'unknown' lab time right now.</p> </div> | HH(24):MM |

| Field Name | Description / Instructions | Format |
|------------------------------|--|-------------------------------|
| Course # ^(d) | <p>Indicates the course number that this lab started, as derived from the course initiation start date.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this lab started, as derived from the course initiation start date.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Source of the Lab Data | <p>Select the source of the lab results.</p> <p>Dictionary name – Lab_Source</p> <p> Lab_Source.pdf</p> | Use pick list. |
| Lab Test | Select the lab test name when entering outside labs manually. | Use panel-specific pick list. |
| Lab Value (Char) | Enter the lab test result value as reported. | 100 characters. |
| UOM | Enter the appropriate lab test value unit of measurement. | 200 characters. |
| Preferred UOM | <p>Enter the preferred unit of measurement for the specified lab test.</p> <p> Lab Units of Measurement.pdf</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------------------------|--|----------------|
| Normal Range (e.g. 1.5-5) | <p>For labs loaded from the MIS/CRIS system, the range is automatically populated.</p> <p>For labs obtained outside the NCI Clinical Center, enter the appropriate normal range.</p> | 30 characters. |
| Grade | <p>Derived from the lab test result value and the lab test ranges from the version of the NCI Common Terminology Criteria for Adverse Events (CTCAE) specified by the Protocol.</p> <ul style="list-style-type: none"> • 1: Mild Adverse Event • 2: Moderate Adverse Event • 3: Severe Adverse Event • 4: Life Threatening or Disabling Adverse Event • 5: Death Related to Adverse Event | 1 character. |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | <p>Query will fire if Lab Date is in the future.</p> <p>"Future date has been entered. Please correct."</p> | <p>Enter a date that is earlier or equals to the current date.</p> |
| LB04 | <p>Query will fire if Lab Value (Char) and UOM do not present together.</p> <p>"Lab Value (Char) and UOM are not present / absent together. Please correct."</p> | <p>Enter a Lab Value or UOM.</p> |

| Code | Description | Resolutions |
|------|--|---|
| LB03 | Two lab tests exist for the same date and time. “Two lab tests exist for the same date and time. Please correct.” | Review both labs and inactivate/correct one of them. |
| LB05 | Query will fire if UOM and Preferred UOM are not equivalent units of measurement. “The entered UOM does not match the Preferred UOM. Please correct.” | Review the UOM and Preferred UOM to ensure they are the same unit of measurement. |




Manually Entered Lab Forms


‘Add New Form’ can be used to manually add lab CRFs. Each new lab CRF that is created will contain the details entered in this form. Data must be entered in all four fields of this form in order to generate a new lab CRF.

Note: If a new lab form is mistakenly added with the wrong Lab Date or Lab Time, you can deactivate that lab form. Additionally, no new Lab CRFs will be added if a CRF already exists with the same panel name, lab date and lab time.

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------|--|--------------------|
| Add lab form? | Choose whether you want to add an additional lab form. <ul style="list-style-type: none"> • Yes • No | Use radio buttons. |

| Field Name | Description / Instructions | Format |
|-----------------------|--|-------------------------------|
| Name of new Lab form: | Select the name of the lab panel that has to be added.  Note: This field is hidden unless “Add lab form?” is answered “Yes”. | Use study-specific pick list. |
| Date of new Lab form: | Enter the date the lab sample was collected.  Note: This field is hidden unless “Add lab form?” is answered “Yes”. | DD-MMM-YYYY |
| Time of new Lab form: | Enter the lab sample collection time in military format (24 hours). Ex: 13:56 (for 1:56 PM)  Note: This field is hidden unless “Add lab form?” is answered “Yes”. | HH(24):MM |
| Notifications | This will display sticky notes if a new form is added, or if a form was not able to be added. | Text |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Off Study

Purpose

Record information concerning the subject's off study date and reason. Complete this form after the subject has been taken off study.


For studies without a protocol specified follow-up period, this form is completed when the subject is taken off therapy. The off study date and reason must be the same as the off therapy case report form date off therapy and reason respectively.

For studies with a protocol specified follow-up period, this form is completed when all follow-up time points and data have been collected as specified in the protocol or if the subject dies within the follow-up period or if follow-up period ends for any other reason. If the off therapy reason prevents the follow-up period from occurring, then the off study date and reason must be the same.

No further data will be collected once this form is completed.

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------|--|-------------|
| Date Off Study (m) | For protocols with a specific follow-up period, enter the date that corresponds to the date when all protocol specific follow-up has been completed. For protocols without a protocol specific follow-up, enter the date that the subject came off therapy, i.e., courses have been completed (including the normal observation period) or discontinued and no further therapy courses are planned. This | DD-MMM-YYYY |

| Field Name | Description / Instructions | Format |
|---------------------------------|--|----------------|
| | <p>date must be the same as the Date Off Therapy entered on the Off Therapy case report form.</p> <p>The date off study will correspond to a progress note in the medical record stating that the subject has been taken off study.</p> | |
| Reason Off Study ^(m) | <p>For protocols without a protocol specific follow-up, use the same 'Reason Off Therapy entered on the Off Therapy case report form.</p> <p>For protocols with a follow-up period, the following off study reasons are also available.</p> <p>Dictionary name - OFF_TX_RSN_THRX_STD_34</p>  <p>OFF_TX_RSN_THRX_STD_34.pdf</p> <ul style="list-style-type: none"> • Completed study • Participant requests to be withdrawn from study • Study cancelled • Death • Screen failure • Permanent loss of capacity to consent • Lost to follow up : Follow-up information could not be obtained because contact with the subject was lost. Every effort to locate subject needs to be considering including contact with family members, referring physicians, sending certificate letter, checking SSDI. • Subject begins new therapy • Subject non compliance with protocol interventions, procedures • Subject no longer eligible before start of conditioning • Unable to generate required number of cells • Progressive Disease • Intercurrent illness/disease that prevents further protocol therapy • Investigator discretion | Use pick list. |
| Date of Disease Progression | If disease progression is selected as the reason the subject came off study, enter the date the disease assessment (i.e.: CT scan) was performed. | DD-MMM-YYYY |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date Off Study and/or Date of Progression cannot be a date in the future. “Future date has been entered. Please correct.” | Enter a date earlier than, or equals to, the current date. |
| OSS01 | Query will fire if Reason Off Study is 'Death' and Date Off Study is not equal to Date of Death on Survival form. “Reason Off Study is 'Death' and Date Off Study is not equal to Date of Death on Survival form. Please correct.” | If subject died during the protocol follow-up period or during therapy, Date Off Study must coincide with Date of Death. |
| OSS21 | Query will fire if Date of Disease Progression cannot be after Date Off Study. “Date of Disease Progression cannot be after Date Off Study. Please correct.” | Enter a Date of Disease Progression that is earlier than or equal to the Date Off Study. |
| OSS22 | Query will fire if “Progressive Disease” selected as Reason Off Study and Date of Disease Progression is missing. “Progressive Disease” selected as Reason Off Study and Date of Disease Progression is missing. Please correct.” | A Progressive Disease selection for Reason Off Study requires a Date of Disease Progression. |
| OSS23 | Query will fire if Date of Disease Progression provided and Reason Off Study is not “Progressive Disease”. “Date of Disease Progression provided and Reason Off Study is not “Progressive Disease”. Please correct.” | Date of Disease Progression must be accompanied by a Reason Off Study of “Disease Progression on Study”. |

| Code | Description | Resolutions |
|-------|--|--|
| OSS24 | <p>Query will fire if Off Therapy Date of Disease Progression is blank, Off Study Date of Disease Progression doesn't fall between the Date Off Therapy and Date Off Study. "Off Therapy Date of Disease Progression is blank, Off Study Date of Disease Progression doesn't fall between the Date Off Therapy and Date Off Study. Please correct."</p> | <p>Date of Disease Progression must be between Date Off Therapy and Date Off Study when progression did not occur during therapy – it occurred during the follow-up period.</p> |
| OSS25 | <p>Query will fire if Reason Off Therapy is 'Progressive Disease - Imaging' or 'Progressive Disease - Clinical symptoms', Reason Off Study is 'Progressive Disease', Date Off Therapy and Date Off Study are the same, and Date of Disease Progression is not the same as the one in the Off Therapy form. "When 'Progressive Disease - Imaging' or 'Progressive Disease - Clinical symptoms' is selected as the Reason for Off Therapy and 'Progressive Disease' is selected as Reason Off Study, then Date of Disease Progression must be the same on both forms. Please correct."</p> | <p>When 'Progressive Disease - Imaging' or 'Progressive Disease - Clinical symptoms' is the Reason for Off Therapy and Reason Off Study is 'Progressive Disease', then Date of Disease Progression must be the same on both forms.</p> |
| OSS27 | <p>Query will fire if Off Study Date is provided but the Off Therapy Date is absent. "Off Study Date is provided but the Off Therapy Date is absent. Please correct."</p> | <p>Enter the Off Therapy Date on Off Therapy form.</p> |

Off Therapy

Purpose

Record information concerning the subject's off therapy date, reason, and best response to therapy.

For studies without a protocol specified follow-up period, also complete the Off Study case report form entering the same Date, Reason and Date of Disease Progression. Also complete the Off Study form with the same information when the Reason Off Therapy prevents the follow-up period from occurring.

Off Therapy

Date Off Therapy

...

Reason Off Therapy

...
x
v

Date of Last Medication Administration

Best Response to Therapy

...
x
v

Date of Best Response

...

Date of Disease Progression

...

Do you want to add comments?

...
v

COMMENTS


<

Save
Cancel

Move to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------------|--|----------------|
| Date Off Therapy (m) | Enter the date when all courses have been completed (including the normal observation period) or discontinued and no further therapy courses are planned. This date will correspond to the clinic visit that would have served as the pre-course visit had the subject continued on therapy. This is the date the subject has been officially taken off therapy. | DD-MMM-YYYY |
| Reason Off Therapy (m) | Select an off therapy reason from one of the following reasons: Dictionary name - OFF_TX_RSN_THRX_STD_20 | Use pick list. |

| Field Name | Description / Instructions | Format |
|---|---|----------------|
| |  <p>OFF_TX_RSN_THRX_ STD_20.pdf</p> <ul style="list-style-type: none"> • Completion of protocol therapy • Progressive disease - imaging • Progressive disease - clinical symptoms • Participant requests to be withdrawn from active therapy • Unacceptable Toxicity as defined by protocol • Investigator discretion • Positive pregnancy test • Requirement for use of prohibitive therapies as defined by protocol • Subject non compliance with protocol interventions, procedures • Intercurrent illness/disease that prevents further protocol therapy • Drug manufacturer no longer providing study agent • Study cancelled • Permanent loss of capacity to consent • Death | |
| Date of Last Medication Administration ^(d) | Indicates date the last medication was administered. This is a derived field. | Derived field. |
| Best Response to Therapy ^(m) | <p>Select the best overall response to therapy while on protocol.</p> <ul style="list-style-type: none"> • CR: Complete response • PR: Partial response • MR: Minimal/Marginal Response • SD: Stable disease • PD: Progressive disease • NE: Not evaluable • NA: Not assessed • NP: Not applicable per protocol • TE: Too early to access, per protocol • CRU: Complete Response Unconfirmed • NON-CR/NON-PD: Non Complete Response and Non Progressive Disease • DU: Disease Unchanged | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------|---|-------------|
| | <p>For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria.</p> <ul style="list-style-type: none"> • MX: Mixed Response • NR: No Response • RP: Response <p>According to RECIST and WHO guidelines this would be the best response assessed from the start of therapy until disease progression.</p> <p>Ordinarily this would be the best of the responses reported on the disease assessment CRFs. For example, do not enter "SD" if the subject was assessed only with progressive disease.</p> <p>Please be sure to enter the best response, not necessarily the response on the last course. For example, if the subject was assessed with a PR followed by a PD, enter the "PR". If response was not assessed at all during the protocol therapy, enter the best response as NA; similarly for NE and NP.</p> <p>RECIST: Unless the protocol includes specific response evaluation criteria, the following RECIST and WHO guidelines should be observed:</p> <p>Responses of PR and MR are assessed relative to the baseline at start of therapy, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.</p> <p>A response of PD is relative to the best disease status (smallest tumor measurement) since therapy began. Thus, a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a CR.</p> | |
| Date of Best Response | Enter the date that a Best Response of Therapy response of CR, PR, or MR was first observed, or that an SD response began. This date must be consistent with the date entered on the Disease Assessment case report form(s) and with evaluations on the Extent of Disease Form. | DD-MMM-YYYY |

| Field Name | Description / Instructions | Format |
|-----------------------------|--|-------------|
| Date of Disease Progression | <p>Enter the date that progression (or relapse) was first observed (i.e.: date of scan).</p> <p>This date is required if the Reason for Off Therapy is for Disease Progression.</p> <p>This date must be consistent with the date of progression entered on the Disease Assessment form(s) and with evaluations on the Extent of Disease Form.</p> <p>Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a subject with no evaluable disease at enrollment (e.g., on an adjuvant therapy study).</p> | DD-MMM-YYYY |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

| Code | Description | Resolutions |
|-------|---|--|
| OTS05 | Query will fire if Best Response to Therapy is not 'PD/NA/NE/NP/TE' and Date of Best Response is missing. “ Best Response to Therapy is not 'PD/NA/NE/NP/TE' and Date of Best Response is missing. Please correct. ” | If anything other than 'PD/NA/NE/NP/TE' is checked for Best Response to Therapy, then Date of Best Response must be entered. |
| OTS07 | Query will fire if Best Response to Therapy is 'Disease Progression' and Date of Progression is missing. “ Best Response to Therapy is PD : Progressive Disease' and Date of Progression is missing. Please correct. ” | If 'Disease Progression' is checked for Best Response to Therapy, then Date of Progression must be entered. |

| Code | Description | Resolutions |
|---|--|---|
| OTS08_28_1, OTS08_28_2, OTS08_28_3, OTS08_28_4 | Date of Progression is not equal to the earliest Date of Progression reported on the Disease Assessment forms. “Date of Disease Progression is not equal to the earliest Date of Progression reported on the Disease Assessment forms. Please correct.” | Date of Progression must be consistent with Date of Progression on Disease Assessment form(s). |
| OTS9_18_2, OTS9_18_3, OTS9_18_4 | Best Response to Therapy is not the same as the best response reported on Disease Assessment forms. “Best Response from Disease Assessment does not match Best Response in Off Therapy Summary. Please correct.” | Best response should be validated against responses on Disease Assessment form(s). |
| Medidata System Checks | Query will fire if Date Off Therapy / Date of Best Response and/or Date of Progression is in the future. “Future date has been entered. Please correct.” | Enter a date earlier than, or equals to, the current date. |
| OTS16 | Query will fire if Reason Off Therapy is 'Death' and Date Off Therapy is not equal to Date of Death on Survival form. “Reason Off Therapy is ' Death' and Date Off Therapy is not equal to Date of Death on Survival form. Please correct.” | If subject died during therapy, Date Off Therapy must the same as the Date of Death on the Survival form. |
| OTS17 | Query will fire if Reason Off Therapy is 'Death' and Date Off Therapy is not equal to Date off Study on Off Study form. “Reason Off Therapy is ' Death' and Date Off Therapy is not equal to Date off Study on Off Study form. Please correct.” “Reason Off Therapy on Off Therapy form is 'Death' and Date Off Therapy on Off Therapy form is not equal to Date off Study on Off Study form. Please correct.” (appears in Off Study CRF) | If subject died during therapy, Date Off Therapy must the same as the Date Off Study on the Off Study form. |

| Code | Description | Resolutions |
|--|---|--|
| OTS9_18_2, OTS9_18_3, OTS9_18_4 | Best Response date on Off Therapy is not same as the Best Response reported on Disease Assessment forms. "Best Response Date from Disease Assessment does not match Best Response Date in Off Therapy Summary. Please correct." | Best response date should be validated against response date on Disease Assessment form. |
| OTS22 | Date of Last Medication is not between latest Start and Stop dates in Study Med Admin. "Date of Last Medication is not between latest Start Date and latest Stop Date on Study Med Admin. Please correct." | Date of Last Medication must be between latest Start Date and latest Stop Date on Study Med Admin. |
| OTS23 | Query will fire if Date Off Therapy is less than the latest Course Start Date. "Date Off Therapy is less than the latest Course Start Date. Please correct." (also appears in Course Initiation CRF) | Enter Date Off Therapy which is equal to or earlier than the last entered Course Start Date. |
| OTS08_28_1, OTS08_28_2, OTS08_28_3, OTS08_28_4, | Date of Disease Progression on Off Therapy is provided but there is no Date of Progression reported on the Disease Assessment forms. "Date of Disease Progression on Off Therapy is provided but there is no Date of Progression reported on the Disease Assessment forms. Please correct." | Make data consistent. |

Derivations

| Code | Field Name | Description |
|---------|--|--|
| OTS1002 | Date of Last Medication Administration | Indicates date the last medication was administered. |

Pathology Markers

Purpose

Record Pathology Microscopic Description information when required by the protocol.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Pathology Markers
-

MICROSCOPIC DESCRIPTION:

Is this subject evaluable for immunostaining (IHC) -

Pathology Markers, Log Lines

[Back To Complete View](#)
[Add Another Line](#)

< Previous Line
Next Line >

Tumor Marker -

Analyzed -

Assay Date -

Marker Test Method -

Intensity Score -

Cell Staining -

Mutation Detected -

Result -

Biomarker Comments -

[Back To Complete View](#)
[Add Another Line](#)

Path Report Description -


Do you want to add comments? -

[COMMENTS](#)

Pathology eCRF – Microscopic Description

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| Is this subject evaluable for immunostaining (IHC) | Select an option from the list: <ul style="list-style-type: none"> • No • Yes | Use pick list. |

| Field Name | Description / Instructions | Format |
|--------------------|--|----------------|
| Tumor Marker | Select Tumor Marker: Dictionary Name – BIOMARKER_NAME  BIOMARKER_NAME.p df | Use pick list. |
| Analyzed | Select an option from the picklist: <ul style="list-style-type: none"> • Yes • No | Use pick list. |
| Assay Date | Enter Assay Date of Analyzed Tumor Marker | DD-MMM-YYYY |
| Marker Test Method | Select a marker test method from the picklist: <ul style="list-style-type: none"> • ELISA • FLUORESCENCE IN SITU HYBRIDIZATION (FISH) • IMMUNOHISTOCHEMISTRY (IHC) | Use pick list. |
| Intensity Score | Select an intensity score from the picklist: <ul style="list-style-type: none"> • 0: No Staining • 1: Weak • 2: Moderate • 3: Strong | Use pick list. |
| Cell Staining (%) | Enter the percentage of cell staining. (Numeric value (percent) to indicate the strength of an immunohistochemistry (IHC) staining result. | 3 digits |
| Mutation Detected | Select an option from the picklist: <ul style="list-style-type: none"> • INDETERMINATE • NO | Use pick list. |

| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| | <ul style="list-style-type: none"> • YES | |
| Result | Select an option from the picklist: <ul style="list-style-type: none"> • NEGATIVE • POSITIVE • UNKNOWN | Use pick list. |
| Biomarker Comments | Enter Text to describe reported results of biomarker testing. | 200 characters |
| Path Report Description | Enter description of pathology report. | 200 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Assay Date is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or prior to the current date |

Pathology Report

Purpose

Record Pathology information when required by the protocol.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Pathology Report

PROPOSAL:

Surgical Pathology#

Surgery Date

Pathology Results Date

Procedure used to Collect Sample

Specify Other Procedure

Body Site of Collection

GROSS DESCRIPTION:

Pathology Report, Log Lines Search field value. '0' or '1' for checkbox fields.

| | Pathology Sample Type | Differentiation | Condition of Margin | |
|---|----------------------------------|----------------------------------|----------------------------------|--|
| 1 | <input type="text" value="..."/> | <input type="text" value="..."/> | <input type="text" value="..."/> | <input type="text" value="📄"/> <input type="text" value="⚙️"/> |















New row(s) 10 per add max. 1 Row(s) 3 Column(s) / 1

Per page

Number of Lymph Nodes Sampled



Number of Positive Lymph Nodes


Findings

| | | |
|--|-------------------------|---|
| Greatest Dimension of Specimen | <input type="text"/> cm |  |
| Second Greatest Dimension of Specimen | <input type="text"/> cm |  |
| Stage of Disease | <input type="text"/> |  |
| Disease T Stage | <input type="text"/> |  |
| Disease N Stage | <input type="text"/> |  |
| Disease M Stage | <input type="text"/> |  |
| Histologic Grade | <input type="text"/> |  |
| HISTOLOGY: | | |
| Peritoneal Lavage Result | <input type="text"/> |  |
| Lymphatic Invasion present | <input type="text"/> |  |
| Vascular Invasion Present | <input type="text"/> |  |
| Microcalcification Present | <input type="text"/> |  |
| Nerosis present | <input type="text"/> |  |
| Notable Benign Changes | <input type="text"/> |  |
| If Yes, Description (Specify) | <input type="text"/> |  |
| <input type="button" value="Save"/> <input type="button" value="Cancel"/> <input type="checkbox"/> Move to next task after save | | |

Pathology eCRF – Proposal


| Field Name | Description / Instructions | Format |
|----------------------------------|--|----------------|
| Surgical Pathology# | Enter the pathology number. | 20 characters |
| Surgery Date | Enter the date of the surgical procedure. | DD-MMM-YYYY |
| Pathology Results Date | Enter the pathology results date. | DD-MMM-YYYY |
| Procedure used to Collect Sample | Select the procedure that was used to collect the sample. Dictionary name - SPEC_COLL_METH_NM | Use pick list. |

| Field Name | Description / Instructions | Format |
|-------------------------|--|----------------|
| |  SPEC_COLL_METH_N M.pdf | |
| Specify Other Procedure | Enter data when “Other” is selected in Procedure Used to Collect Sample field. | 100 characters |
| Body Site of Collection | Select the body site where the sample was collected from. Dictionary name - BODY_SITES_TH  BODY_SITES_TH.pdf | Use pick list. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Pathology eCRF – GROSS DESCRIPTION

| Field Name | Description / Instructions | Format |
|-----------------------|--|----------------|
| Pathology Sample Type | Select the pathology sample type. Dictionary name - SPEC_TP_CCR_1  SPEC_TP_CCR_1.pdf | Use pick list. |
| Differentiation | Select the extent of differentiation from the list: <ul style="list-style-type: none"> • HIGH GRADE: HIGH GRADE • LOW GRADE: LOW GRADE | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|--|-------------------------|
| | <ul style="list-style-type: none"> • MODERATELY: MODERATELY DIFFERENTIATED • N/A: NOT APPLICABLE • POORLY: POORLY DIFFERENTIATED • WELL: WELL DIFFERENTIATED | |
| Condition of Margin | Select a margin condition from the picklist: <ul style="list-style-type: none"> • Less than 1mm (CLOSE) • Dysplasia present • Negative Margin • Positive Margin | Use pick list. |
| Number of Lymph Nodes Sampled | Enter the number of lymph nodes sampled. | 5 digits |
| Number of Positive Lymph Nodes | Enter number of positive nodes. | 5 digits |
| Findings | Enter findings. | 24 characters |
| Greatest Dimension of Specimen (cm) | Enter the Greatest Dimension of Specimen in CM. | 6 digits and 2 decimals |
| Second Greatest Dimension of Specimen (cm) | Enter second greatest dimension of Specimen in CM. | 6 digits and 2 decimals |
| Stage of Disease | Enter Stage of Disease <ul style="list-style-type: none"> • 0 • 1 • IIA • IIB • IIIA • IIIB • IIIC • IV | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------------|--|----------------|
| Disease T Stage | Select the stage of disease <ul style="list-style-type: none"> • T0 • T1 • T2 • T3 • T4 | Use pick list. |
| Disease N Stage | Select the stage of disease <ul style="list-style-type: none"> • N0 • N1 • N2 • N3 | Use pick list. |
| Disease M Stage | Select the stage of disease <ul style="list-style-type: none"> • M0 • M1 • MX | Use pick list. |
| Histologic Grade | Enter the grade of histology. | 10 characters |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Pathology eCRF – Histology

| Field Name | Description / Instructions | Format |
|--------------------------|--|----------------|
| Peritoneal Lavage Result | Select the condition of peritoneal lavage from the picklist: <ul style="list-style-type: none"> • NEGATIVE: Negative Finding • NOT DONE: Not Done • POSITIVE: Positive Finding | Use pick list. |

| Field Name | Description / Instructions | Format |
|-------------------------------|--|----------------|
| Lymphatic Invasion present | Select the condition of lymphatic invasion from the picklist: <ul style="list-style-type: none"> • INDETERMINATE • NO • YES | Use pick list. |
| Vascular Invasion Present | Select the condition of vascular invasion from the picklist: <ul style="list-style-type: none"> • INDETERMINATE • NO • YES | Use pick list. |
| Microcalcification Present | Select the condition of microcalcification from the picklist: <ul style="list-style-type: none"> • INDETERMINATE • NO • YES | Use pick list. |
| Necrosis present | Select the condition of necrosis from the picklist: <ul style="list-style-type: none"> • INDETERMINATE • NO • YES | Use pick list. |
| Notable Benign Changes | Select an option from the picklist: <ul style="list-style-type: none"> • None • Ductal Hyperplasia • ADH | Use pick list. |
| If Yes, Description (Specify) | If notable Benign changes present, use this free text field for comments | 200 characters |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Surgery Date / Pathology Results Date is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or prior to the current date |

Pharmacokinetics

Purpose

Record detailed information about the collection of biological samples for analysis of the presence and quantity of the study agent and/or its metabolites. Since this form is intended to stand alone, some of the fields may duplicate items found in other case report forms.





Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:




Log_lines.pdf

| | | |
|--|---|---|
| Pharmacokinetics | | |
| Visit Date | <input type="text" value="dd"/> <input type="text" value=".."/> <input type="text" value="yyyy"/> | <small>This field is required. Please complete.</small> |
| PHARMACOKINETICS | | |
| Course # | | |
| Day in Course | | |
| Start Date | <input type="text" value="dd"/> <input type="text" value=".."/> <input type="text" value="yyyy"/> | |
| Start Time | <input type="text" value="HH"/> : <input type="text" value="mm"/> | |
| Study Agent | <input type="text" value="..."/> | |
| Specimen Sampled | <input type="text" value="..."/> | |
| Pharmacokinetics, Log Lines | | |
| Back To Complete View < Previous Line Line <input type="text" value="1"/> of 2 Next Line > | | |
| Planned Interval | PRE-DOSE | |
| Sample Collected | <input type="text" value="..."/> | |
| Actual Start Date | <input type="text" value="dd"/> <input type="text" value=".."/> <input type="text" value="yyyy"/> | |
| Actual Start Time | <input type="text" value="HH"/> : <input type="text" value="mm"/> | |
| Time Interval | | |
| Back To Complete View < Previous Line Line <input type="text" value="1"/> of 2 Next Line > | | |
| Do you want to add comments? | <input type="text" value="..."/> | |
| COMMENTS | | |

Field Descriptions and Instructions


| Field Name | Description / Instructions | Format |
|---------------------------------|---|----------------|
| Visit Date ^(m) | <p>Enter the date the form was completed.</p> <p> Note: If the information was obtained at multiple visits, please enter the date the form was completed.</p> | DD-MMM-YYYY |
| Course # ^(d) | <p>Course number derived from the study agent start date and course initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Number of days since the start of the course. Derived from the study agent start date and course initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Start Date ^(m) | Enter the date the study agent administration was started. | DD-MMM-YYYY |
| Start Time ^(m) | Enter the time the study agent administration began. | HH(24):MM |
| Study Agent ^(m) | <p>Enter the name of the study agent (investigational or commercial) which is the subject of the pharmacokinetic study.</p> <p> Note: Only one study agent is allowed per case report form. Separate forms should be used when more than one study agent is being studied.</p> | Use pick list. |
| Specimen Sampled ^(m) | <p>Select the body fluid that is being collected for the biological samples.</p> <ul style="list-style-type: none"> Abdominal Effusion | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------------------|---|----------------|
| | <ul style="list-style-type: none"> • Pheresis Cell • Cerebrospinal Fluid • Pericardial Effusion • Peripheral Blood Mononuclear Cell • Plasma • Pleural Effusion • Saliva • Serum • Tumor Tissue • Whole Blood • SPUTUM | |
| Planned Interval | Planned interval pre-determined per protocol. Study Specific. | Text |
| Sample Collected ^(m) | <p>Indicate whether or not the specimen is collected.</p> <ul style="list-style-type: none"> • No • Unknown • Yes • Not Applicable | Use pick list. |
| Actual Start Date | Enter the specimen collection date. | DD-MMM-YYYY |
| Actual Start Time | Enter the specimen collection time. | HH(24):MM |
| Time Interval ^(d) | Actual interval in minutes from the study agent start time. This is a derived field. | Derived field. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| PHM01 | Query will fire if Start Date is less than the Date of Informed Consent Signed (in Subject Enrollment CRF). "Start Date is less than the Enrollment Date of Informed Consent Signed. Please correct." | Start Date must be on or after the Date of Informed Consent Signed in Subject Enrollment CRF. |
| Medidata System Checks | Query will fire if Visit Date / Start Date / Sample Date is in the future. "Future date has been entered. Please correct." | Enter a date earlier than or equal to the current date. |
| PHM05 | Start Date / Time pair appears more than once – duplicate entry. "Two Pharmacokinetics records have identical values for Actual Start Date and Actual Start Time. Please correct." | Remove the duplicate record or correct the Start Date / Time of one of them. |
| PHM16 | <p>A Study Medication with a Medication/Agent matching the Pharmacokinetic with the same administration Date and Time was not found. "A Study Medication with a Medication/Agent matching the Pharmacokinetic with the same administration Date and Time was not found. Please correct."</p> <div data-bbox="386 1272 1081 1423" style="background-color: #e6f2ff; padding: 5px;"> <p> Note: Study Medications with the following routes are ignored: PO, CIV and Topical.</p> </div> | Verify that the pharmacokinetics study agent administration is recorded on the study medication form. |
| PHM17 | Query will fire if Collected Pharmacokinetics samples does not have corresponding Date and Time. "Collected Pharmacokinetics samples does not have corresponding Date and/or Time. Please correct." | Enter Actual Start Date and Time if 'Sample Collected' is 'YES'. |
| PHM18 | Query will fire if Pharmacokinetics samples are not collected but Date and Time entered. "Pharmacokinetics samples are not collected but Date and Time entered. Please correct." | Actual Start Date and Time should be removed if 'Sample Collected' is NO. |

Derivations

| Code | Field Name | Description |
|--------------|---------------|---|
| PHM1001_1002 | Course # | Course Number is derived from the Study Agent Start Date and the Course Initiation Start Dates. |
| PHM1001_1002 | Day in Course | Day in course is derived from the Study Agent Start Date and the Course Initiation Start Dates |
| PHM1003 | Time Interval | Actual Time Interval is derived from the Actual Date and Time and the Start Date and Time. |

Physical Exam - Cycles


Purpose

Record physical exam results during treatment.

Physical Exam - Cycles

PHYSICAL EXAM - CYCLES

PE Done? No Yes ⚙️


Date of Examination  ⚙️

Day in Course ⚙️


Course # ⚙️


Do you want to add comments? ⚙️


COMMENTS

Move to next task 

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|------------------------------|---|--------------------|
| PE Done? ^(m) | Indicate whether the physical examination was performed: <ul style="list-style-type: none"> • No • Yes | Use radio buttons. |
| Date of Examination | Enter the date the physical examination took place. | DD-MM-YYYY |
| Day in Course ^(d) | Number of days since the beginning of the course, as derived from the course initiation start date and examination date. This is a derived field. <div style="background-color: #e6f2ff; padding: 10px; margin-top: 10px;"> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> </div> | Derived field. |

| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| Course # ^(d) | <p>Indicates the course number the physical exam is related to based on the examination date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|--------------------------------|
| Medidata System Checks | Query will fire if Date of Examination is in the future. "Future date has been entered. Please correct." | Enter an earlier date. |
| PE07 | Query will fire if PE is done but the Date of Examination is not provided. "PE is done but the Date of Examination is not provided. Please correct." | Enter the Date of Examination. |

Derivations

| Code | Field Name | Description |
|-------------|---------------|---|
| PE1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and examination date. |
| PE1001_1002 | Course # | Course number is derived based on the course initiation start dates and the examination date. |

Physical Exam - Screening

Purpose

Record baseline physical exam results.

Physical Exam - Screening

PHYSICAL EXAM - SCREENING

PE Done? No Yes

Date of Examination dd ... yyyy

Do you want to add comments? ...

COMMENTS

Save Cancel Move to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|---|--------------------|
| PE Done? ^(m) | Indicate whether the physical examination was performed: <ul style="list-style-type: none">NoYes | Use radio buttons. |
| Date of Examination | Enter the date the physical examination took place. | DD-MM-YYYY |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.



If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|--------------------------------|
| Medidata System Checks | Query will fire if Date of Examination is in the future. "Future date has been entered. Please correct." | Enter an earlier date. |
| PE07 | Query will open if PE is done but the Date of Examination is not provided. "PE is done but the Date of Examination is not provided. Please correct." | Enter the Date of Examination. |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------------|--|----------------|
| Date of First Dose (m) | Enter the date of the first dose of the radiation therapy. Partial dates are acceptable when the day is not known. Please enter UN for the "unknown" day value. | DD-MMM-YYYY |
| Date of Last Dose | Enter the date of the last dose of the radiation therapy. Partial dates are acceptable when the day is not known. Leave it blank if the therapy is currently being received. Please enter UN for the "unknown" day value. | DD-MMM-YYYY |
| Radiation Type (m) | Select the type of radiation therapy. <ul style="list-style-type: none"> • Adjuvant Rt • Brachytherapy • External Beam Radiation • Neoadjuvant Rt • Other Specify • Palliative Rt • Hyperfractionated • Photon Beam • Radiosurgery • Imrt • Electron Beam • Conformal • Proton Beam • Photodynamic Therapy • Radiofrequency Ablation • Tomotherapy • Whole Brain Radiation Therapy • Stereotactic Radiosurgery • Stereotactic Ablative Radiotherapy • Stereotactic Body Radiation Therapy (SBRT) | Use pick list. |
| Other, Specify | Enter an explanation when 'Other Specify' is selected as a 'Radiation Type', | 100 Characters |
| Radiation extent (m) | Select the extent of the radiation therapy as follows: <ul style="list-style-type: none"> • Extensive Radiation • Limited Radiation | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------|---|----------------|
| | <ul style="list-style-type: none"> Radiation (NOS) | |
| Site ^(m) | <p>Select the site of the radiation therapy.</p> <p>Dictionary name - RT_ANAT_SITE_NM</p>  <p>RT_ANAT_SITE_NM.pdf</p> | Use pick list. |
| Schedule | Select the radiation therapy schedule on which it was given. | 30 characters |
| Total Dose | State the total radiation dose the subject received during the treatment period. Leave this field as well as the Total Dose UOM blank if the radiation therapy is ongoing. | 10 characters |
| Total Dose UOM | <p>Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem).</p> <p>Dictionary name - UOM_DOSE_TH_2</p>  <p>UOM_DOSE_TH_2.pdf</p> | Use pick list. |
| Best Response | <p>Select the best response for the irradiated lesion. It applies to the type of therapy/intervention for which conventional response calls are appropriate. Leave this field blank if the radiation therapy is ongoing.</p> <ul style="list-style-type: none"> CR: Complete Response PR: Partial Response MR: Minimal/Marginal Response SD: Stable Disease PD: Progressive Disease NE: Not Evaluable NA: Not Assessed UK: Unknown | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------------|--|----------------|
| Non-Response Therapy Type | <p>Select the therapy type for which the conventional response calls are not appropriate.</p> <ul style="list-style-type: none"> • AJ: Adjuvant Therapy • PA: Palliative Therapy • NJ: Neoadjuvant Therapy • PR: Prophylaxis • DF: Definitive | Use pick list. |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| PRD01 | Query will fire if Date of First Dose is greater than Date of Last Dose. “Date of First Dose is greater than Date of Last Dose. Please correct.” | Enter a Date of First Dose that is equal to or earlier than the Date of Last Dose. |
| Medidata System Checks | Query will fire if Date of First Dose / Date of Last Dose are in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or earlier than the current date. |
| PRD04 | Query will fire if Both Best Response and Nonresponse Therapy Type are present/absent. “Both Best Response and Nonresponse Therapy Type are present/absent. Please correct.” | One and only one fields should be entered. |

| Code | Description | Resolutions |
|-------|--|---|
| PRD05 | Query will fire if Prior Radiation Type 'Other Specify' and 'Other, Specify' field are not present together. "Prior Radiation Type 'Other Specify' and 'Other, Specify' field are not present together. Please correct." | Enter 'Other Specify' if 'Other Specify' is selected as Prior Radiation Type. |

Prior Surgery Supplement

Purpose

Record details of prior surgery related to the disease being studied by the protocol or when the details would be clinically significant for the evaluation of this study.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Prior Surgery Supplement

Prior Surgery Supplement, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Date of Surgery This field is required. Please complete.

Procedure 0 / 50

Site

Findings


Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line


Do you want to add comments?

[COMMENTS](#)

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------|---|---------------|
| Date of Surgery (m) | Enter the date of the surgical procedure. Partial dates are acceptable when the day is not known. Please enter UN for the “unknown” day value. | DD-MMM-YYYY |
| Procedure (m) | Enter the type of procedure performed to diagnose / to treat the subject's disease. | 50 characters |

| Field Name | Description / Instructions | Format |
|---------------------|---|----------------|
| | Examples include, but not limited to: biopsy, node dissection, cytology, bone marrow biopsy, FNA (fine needle aspiration). | |
| Site ^(m) | <p>Select the anatomical site of the procedure.</p> <p>Dictionary name - BODY_SITES_TH</p>  <p>BODY_SITES_TH.pdf</p> | Use pick list. |
| Findings | Briefly describe the findings of the procedure. | 24 characters |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | <p>Query will fire if Date of Surgery is in the future.</p> <p>“Future date has been entered. Please correct.”</p> | Enter a date that is equal to or earlier than the current date. |

Prior Therapy Supplement

Purpose

Record details of prior therapies related to the disease being studied by the protocol or when the details would be clinically significant for the evaluation of this study as indicated on the Prior Treatment Summary case report form.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Prior Therapy Supplement

Prior Therapy Supplement, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Date of First Dose

Date of Last Dose

Agent Name

Non-Agent Prior Therapy

Schedule

Total Dose

Total Dose UCM

Total Num of Courses Administered

Best Response

NonResponse Therapy Type

Therapy Type




Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line



Do you want to add comments?

COMMENTS

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------------------|--|-------------|
| Date of First Dose ^(m) | Enter the date of the first dose of the prior therapy. Partial dates are acceptable when the day is not known. Please enter UN for the "unknown" day value. | DD-MMM-YYYY |


| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| Date of Last Dose | <p>Enter the date of the last dose of the prior therapy. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received</p> <p>Please enter UN for the “unknown” day value.</p> | DD-MMM-YYYY |
| Agent Name | <p>Select the generic name of the agent that was used.</p> <div data-bbox="430 615 1190 762" style="background-color: #e6f2ff; padding: 5px;"> <p> Note: For standard regimen (multiple agents given as one regimen), enter one record for each agent.</p> </div> <p>Dictionary name - THERAPY_AGENTS_2</p> <div data-bbox="505 848 553 909" style="text-align: center;">  </div> <p>THERAPY_AGENTS_2.pdf</p> | Use pick list. |
| Non-Agent Prior Therapy | <p>Select a non-agent therapy from the list:</p> <ul style="list-style-type: none"> • Phototherapy • Photodynamic Therapy • Tumor Treating Fields Therapy <div data-bbox="430 1230 1117 1346" style="background-color: #e6f2ff; padding: 5px;"> <p> This field will only be available for NCINOB studies.</p> </div> | Use pick list. |
| Schedule | Select the schedule on which the agent (or combination) was given. | 30 characters |
| Total Dose | Enter the total dose of the agent. | 10 characters |
| Total Dose UOM | <p>Enter the total dose units of measurement.</p> <p>Dictionary name – UOM_DOSE_TH_2</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------------------|---|----------------|
| |  UOM_DOSE_TH_2.pdf f | |
| Total Num of Courses Administered | Enter the total number of cycles or courses of the specified drug or therapy agent administered to the subject as of the reported period | 3 digits |
| Best Response | Select the best response encountered: <ul style="list-style-type: none"> • CR: Complete Response • PR: Partial Response • MR: Minimal/Marginal Response • SD: Stable Disease • PD: Progressive Disease • NE: Not Evaluable • NA: Not Assessed • UK: Unknown • NR: No Response • MX: Mixed Response Leave this field blank if the treatment is ongoing. | Use pick list. |
| Non-Response Therapy Type | Select the therapy type for which the conventional response calls are not appropriate. <ul style="list-style-type: none"> • AJ: Adjuvant Therapy • PA: Palliative Therapy • NJ: Neoadjuvant Therapy • PR: Prophylaxis • DF: Definitive | Use pick list. |
| Therapy Type ^(m) | Select the appropriate type of prior therapy: Dictionary name - GENERAL_THERAPY_TH  GENERAL_THERAPY_TH.pdf | Use pick list. |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| PTS01 | Query will fire if Date of First Dose is greater than Date of Last Dose. “Date of First Dose is greater than Date of Last Dose. Please correct.” | Enter a Date of First Dose that is equal to or earlier than the Date of Last Dose. |
| Medidata System Checks | Query will fire if Date of First Dose / Date of Last Dose are in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or earlier than the current date. |
| PTS04 | Query will fire if Both Best Response and Nonresponse Therapy Type are present/absent. “Both Best Response and Nonresponse Therapy Type are present/absent. Please correct.” | One and only one field should be entered. |
| PTS05 | Query will fire if both Agent Name and Non-Agent Prior Therapy are entered. “Both Agent Name and Non-Agent Prior Therapy are filled. Please correct.”  This validation will only be applicable to NCINOB studies. | Only one of Agent Name or Non-Agent Prior Therapy should be entered. |
| PTS06 | Query will fire if Agent Name is entered but Schedule, Total Dose or Total Dose UOM are empty. “Agent Name is entered but Schedule, Total Dose, and/or Total Dose UOM are empty. Please correct.” | Schedule, Total Dose and Total Dose UOM must be entered if and agent is selected from Agent Name. |

Prior Treatment Summary

Purpose

Record whether or not the subject has received any treatments for each of the prior therapy types listed that are related to the disease being studied by the protocol.

Details must be provided for the following on the appropriate Prior Therapy Case Report Form:

1. The last treatment prior to enrollment.
2. Any prior stem cell toxic therapy (e.g. mitomycin C) or cardiotoxic therapy (e.g. doxorubicin or other anthracycline) if relevant to the study agent.
3. Any therapies used to determine "extensive prior therapy" if specified in protocol.
4. Any therapies restricted by the protocol eligibility criteria, either specific drugs or number of prior therapies (e.g. no more than two prior chemotherapy regimens for metastatic disease).
5. Any therapies that are clinically significant for evaluation of the current study.
6. Additionally as required specifically by the protocol.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf



Prior Treatment Summary, Log Lines

All

| | Therapy Type | Any Therapy? | # of Prior Treatments | Date of Last Dose | |
|----|---|--|-----------------------|-------------------|--|
| 1 | Anti-retroviral Therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 2 | Antisense | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 3 | Biphosphonate Therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 4 | Bone Marrow Transplant | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 5 | Chemotherapy (NOS) | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 6 | Chemotherapy multiple agents systemic | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 7 | Chemotherapy single agent systemic | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 8 | Gene Transfer | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 9 | Hematopoietic Stem Cell Transplantation | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 10 | Hormonal Therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 11 | Image Directed Local Therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 12 | Immunotherapy local | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 13 | Immunotherapy multiple agents systemic | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 14 | Immunotherapy single agents systemic | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 15 | No prior therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 16 | Oncolytic Virotherapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 17 | Prior Therapy (NOS) | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 18 | Radiation therapy definitive | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 19 | Radiation therapy palliative | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 20 | Radiopharmaceutical | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 21 | Radiosensitizing Agent | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 22 | Small molecule inhibitor targeted therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 23 | Surgery debulking | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 24 | Surgery definitive | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 25 | Systemic Therapy | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |
| 26 | Vaccine | <input type="radio"/> Yes <input type="radio"/> No | <input type="text"/> | dd -- yyyy | <input type="button" value="🗨️"/> <input type="button" value="🔍"/> |


26 Row(s) 4 Column(s) 1 / 1 Per page 10 25 50 100


Do you want to add comments?

COMMENTS

Move to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------------|---|--------------------|
| Therapy Type | <p>Name of the type of therapy.</p> <p> Note: "Limited Radiation" is therapy using ionizing radiation to a limited (<50%) portion of the body, while "Extensive Radiation" exposes a significant portion of the body (>50%), e.g. cardiospinal, pelvic, or total-body.</p> | Text |
| Any Therapy? ^(m) | <p>Indicate whether or not the subject has received any prior treatment for the type of therapy listed.</p> <ul style="list-style-type: none"> • Yes • No | Use radio buttons. |
| # of Prior Treatments | Enter the number of prior regime types of therapies received. | 2 digits |
| Date of Last Dose | <p>Enter the date of the last dose of the most recent prior treatment regimen for each therapy type. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received.</p> <p>For combination therapies, record the date of the last dose of medication for the combination.</p> | DD-MMM-YYYY |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| PTX02 | Query will fire if Date of Last Dose is specified for a therapy type but the respective "Any Therapy?" is not checked 'Yes'. "Date of Last Dose is entered but the respective "Any Therapy?" is not checked 'Yes'. Please correct." | Verify Date of Last Dose and/or "Any Therapy?". |
| Medidata System Checks | Query will fire if Date of Last Dose is in the future. "Future date has been entered. Please correct." | Enter a Date of Last Dose that is equal to or earlier than the current date. |
| PTX04 | Query will fire if Number of Prior Regimens is negative or not a number. "Number of Prior Regimens is negative or not a number. Please correct." | Enter a number between 0 and 99 when applicable. |
| PTX05 | Query will fire if Any Therapy is "Yes" and number of regimens is not provided for Chemotherapy-related Therapy Types. "Any Therapy is "Yes" and Number of Prior Regimens is not provided. Please correct." | Enter the number of Prior Regimens for Chemotherapy-related Therapy Types. |

Procedure

Purpose

Record the results of the procedures that are performed as part of the protocol. All laboratory results are to be recorded on the appropriate lab CRF. All procedures that are done as a result of an adverse event are to be recorded on the Concomitant Measures CRF.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Procedure

Procedure, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Course # [icon] [icon]

Day in Course [icon] [icon]

Date [icon] [icon] [icon] [icon] This field is required. Please complete. [icon]

Time [icon] [icon] [icon]

Procedure [icon] [icon]

Body Site [icon] [icon]




Abnormal Result? [icon]

Findings [icon]

0 / 200

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------|---|----------------|
| Course # ^(d) | <p>Indicates the course number the procedure is related to based on their date and time. This is a derived field.</p> <p>Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |

| Field Name | Description / Instructions | Format |
|----------------------|---|----------------|
| Day in Course (d) | <p>Indicates the day since the beginning of course the procedure is related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date (m) | Enter the date that the procedure was done, not the date it was interpreted by the radiologist or investigator. | DD-MMM-YYYY |
| Time | Enter the time the procedure was done. | HH(24):MM |
| Procedure (m) | <p>Select the procedure from the pick list.</p> <p>Dictionary Name - NCI_PROCEDURES</p> <p> NCI_PROCEDURES.p df</p> | Use pick list. |
| Body Site (m) | <p>Select the body site from the pick list. In the case of tests such as CATSCAN, MRI, and X-RAY record the applicable body site. For CAT Scan and MRI use thorax, abdomen, pelvis, or brain.</p> <p>Dictionary Name - BODY_SITES_TH</p> <p> BODY_SITES_TH.pdf</p> | Use pick list. |
| Abnormal Result? (m) | <p>Select whether the finding results for the particular procedure / body site were either:</p> <ul style="list-style-type: none"> • Abnormal • Normal | Use pick list. |
| Findings | If abnormal, enter as summary of the abnormal findings. | 200 characters |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."



Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Procedure date is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date. |
| LBLL02 | Query will fire if Findings were entered and Abnormal is not "Abnormal". "Findings were entered and Abnormal Result is not "Abnormal". Please correct." | "Abnormal" must be selected if Findings were entered. |
| LBLL03 | Query will fire if Abnormal is "Abnormal" and no brief description was entered in the Findings. "Abnormal Result is "Abnormal" and no brief description was entered in the Findings. Please correct." | Abnormal Findings must have a brief description. |

Derivations


| Code | Field Name | Description |
|-------------|---------------|---|
| LL1001_1002 | Course # | Course number is derived based on the course initiation start dates and the procedure date. |
| LL1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the procedure date. |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---|--|----------------|
| Test Date ^(m) | Date the test was performed. | DD-MMM-YYYY |
| Test Time | Time the test was performed. | HH(24):MM |
| Course # ^(d) | <p>Indicates the course number the test is related to based on their date and the Course Initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the test is related to based on their date and the Course Initiation start dates. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Vital Capacity (VC) (VC_RESYS) | Enter the Vital Capacity test for the patient in Liters. | 50 characters. |
| Expiratory Volume (EXP_VOL_RESYS) | Enter the Expiratory Volume test for the patient in Liters. | 50 characters. |
| Forced Vital Capacity (Maximum) (MAX_C_RESYS) | Enter the Forced Vital Capacity test for the patient in Liters. | 50 characters. |
| Volume Residual (VOL_RES_RESYS) | Enter the Volume Residual test for the patient in Liters. | 50 characters. |

| Field Name | Description / Instructions | Format |
|---|--|-----------------|
| Functional Residual Capacity (FUNCT_RES_C_RESYS) | Enter the Functional Residual Capacity test for the patient in Liters. | 250 characters. |
| Diffusion Capacity (DIFFUS_CAP_RESYS) | Enter the Diffusion Capacity test for the patient in milliliters per minute. | 50 characters. |
| Diffusing Capacity, Predicted (DIFF_CAP_PRED_RESYS) | Enter the Diffusion Capacity (Predicted) percentage for the patient. | 50 characters. |
| Maximum Forced Expiratory Flow (MAX_FXP_FLOW_RESYS) | Enter the Maximum Forced Expiratory Flow test for the patient in Liters per minute. | 50 characters. |
| Forced Expiratory Volume (FEV1_RESYS) | Enter the Forced Expiratory Volume test for the patient in Liters. | 50 characters. |
| Forced Expiratory Volume, Predicted (FEV1_PRED_RESYS) | Enter the Forced Expiratory Volume, Predicted percentage for the patient. | 50 characters. |
| Forced Vital Capacity (FVC) (FVC_RESYS) | Enter the Forced Vital Capacity test for the patient.in liters. | 50 characters. |
| Forced Vital Capacity (FVC), Predicted (FVC_PRED_RESYS) | Enter the Forced Vital Capacity (FVC), Predicted, Predicted percentage for the patient. | 50 characters. |
| Diffusing Capacity to Alveolar Ventilation Ratio (DL_VA_RTO_RESYS) | Enter the Diffusing Capacity to Alveolar Ventilation Ratio test for the patient in milliliters per minute. | 50 characters. |

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| Diffusing Capacity to Alveolar Ventilation Ratio (DL_VA_RTO_PRED_RESYS) | Enter the Diffusing Capacity to Alveolar Ventilation Ratio percentage for the patient. | 50 characters. |
| Volume expelled during midportion of expiration (FEF25_75_RESYS) | Enter the Volume expelled during midportion of expiration for the patient in liters per second. | 50 characters. |
| Volume expelled during midportion of expiration, Predicted (FEF25_75_PRED_RESYS) | Enter the Volume expelled during midportion of expiration, Predicted percentage for the patient. | 50 characters. |
| Total Lung Capacity (CAP_TTL_RESYS) | Enter the Total Lung Capacity percentage for the patient in Liters. | 50 characters. |
| Total Lung Capacity, Predicted (CAP_TTL_PRED_RESYS) | Enter the Total Lung Capacity, Predicted percentage for the patient in liters per second. | 50 characters. |
| FEV1 to FVC Ratio (FEV1_FVC_RTO_RESYS) | Enter the FEV1 to FVC Ratio percentage for the patient. | 50 characters. |
| Residual Volume to Total Lung Capacity Ratio | Enter the Residual Volume to Total Lung Capacity Ratio percentage for the patient in Liters | 50 characters. |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Test Date is a future date. "Future date has been entered. Please correct." | Change the date to a value no later than the current date. |

Derivations

| Code | Field Name | Description |
|-------------|---------------|---|
| LAB_PFT1003 | Course # | Course number is derived based on the course initiation start dates and the Date of Test. |
| LAB_PFT1004 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the Date of Test. |

Questionnaire

Purpose

Use this form to record information about the subject's questionnaire if applicable.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Questionnaire ⌵

Questionnaire, Log Lines All ▾ Search field value '0' or '1' for checkbox fields. 🔍

| < | Questionnaire Name | Data Collected | Date of Assessment | Reason if No (Data Not Collected) | > |
|---|----------------------|----------------|--------------------|-----------------------------------|---------|
| 1 | Questionnaire Form 1 | ... ▾ | | | 🖨️ ⚙️ ▾ |
| 2 | Questionnaire Form 2 | ... ▾ | | | 🖨️ ⚙️ ▾ |

2 Row(s) ⏪ < 1 / 1 > ⏩ Per page 10 25 50 100

4 Column(s)



Do you want to add comments? ... ▾ ⚙️ ▾


COMMENTS

Save Cancel Move to next task and leave

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------------------|--|--------------------------|
| Questionnaire Name ^(m) | Name of Questionnaire form to be collected, predetermined per study. This field cannot be changed. | Study specific picklist. |
| Data Collected | Use this field to record information about subject's questionnaire completion. | Use pick list. |

| Field Name | Description / Instructions | Format |
|-----------------------------------|--|----------------|
| | <ul style="list-style-type: none"> • Yes • No | |
| Date of Assessment ^(m) | <p>Enter the planned date of assessment.</p> <p> Note: This field is invisible unless “Data Collected” is answered with ‘Yes’.</p> | DD-MMM-YYYY |
| Reason if No (Data Not Collected) | <p>Enter description of reason if the questionnaire was not collected.</p> <p> Note: This field is invisible unless “Data Collected” is answered with ‘No’.</p> | 200 characters |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment **“This field is required. Please complete.”**

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Date of Assessment is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or earlier than the current date. |
| QST01 | Query will fire if Data Collected is entered as “No” and Reason if No is blank. “Data Collected is entered as “No”, but ‘Reason if No (Data Not Collected)’ is blank. Please correct.” | Correct the “Data Collected” response or enter data in “Reason if No”. |

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Date of Assessment is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or earlier than the current date. |
| QST02 | Query will fire if Data Collected is entered as "Yes" and Reason if No is provided. "Data Collected is entered as "Yes", but 'Reason if No (Data Not Collected)' is not empty. Please correct." | Remove entered data from "Reason if No" or correct "Data Collected" to 'Yes'. |

Radiation Treatment

Purpose

Record details of radiation therapy when specified by the protocol.


Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:





Log_lines.pdf

| Radiation Treatment | | |
|--|---|----------------------------------|
| Radiation Treatment, Log Lines | | |
| Back To Complete View | | Add Another Line |
| < Previous Line Line 1 of 1 Next Line > | | |
| Day in Course | | |
| Start Date | <input type="text" value="dd"/> <input type="text" value="yy"/> <input type="text" value="yyyy"/> | |
| This field is required. Please complete. | | |
| Stop Date | <input type="text" value="dd"/> <input type="text" value="yy"/> <input type="text" value="yyyy"/> | |
| Radiation Type | <input type="text" value="..."/> | |
| Other, Specify | <input type="text" value=""/> | |
| Radiation Field | <input type="text" value="..."/> | |
| Dose | <input type="text" value=""/> | |
| Dose UOM | <input type="text" value="..."/> | |
| Missed Dose | <input type="text" value="..."/> | |
| Number of Doses Missed | <input type="text" value=""/> | |
| Dose per Fraction | <input type="text" value=""/> | |
| Total # of Fractions | <input type="text" value=""/> | |
| Elapsed Days | <input type="text" value=""/> | |
| Back To Complete View | | Add Another Line |
| < Previous Line Line 1 of 1 Next Line > | | |
| Do you want to add comments? | <input type="text" value="..."/> | |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------|--|----------------|
| Day in Course ^(d) | <p>Indicates the day since the beginning of course initiation. Derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Start Date ^(m) | Enter the start date of the radiation therapy. | DD-MMM-YYYY |
| Stop Date ^(m) | Enter the date of the last dose of the radiation therapy. | DD-MMM-YYYY |
| Radiation Type ^(m) | <p>Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant".</p> <ul style="list-style-type: none"> • Adjuvant Rt • Brachytherapy • External Beam Radiation • Neoadjuvant Rt • Other Specify • Palliative Rt • Hyperfractionated • Photon Beam • Radiosurgery • Imrt • Electron Beam • Conformal • Proton Beam • Photodynamic Therapy • Radiofrequency Ablation • Tomotherapy • Whole Brain Radiation Therapy • Stereotactic Radiosurgery • Stereotactic Ablative Radiotherapy • Stereotactic Body Radiation Therapy (SBRT) | Use pick list. |
| Other, Specify | Enter an explanation when 'Other, Specify' is selected as a 'Radiation Type'. | 100 characters |

| Field Name | Description / Instructions | Format |
|----------------------------|---|----------------|
| Radiation Field | Select the site of the radiation therapy. Dictionary name - RT_ANAT_SITE_NM  RT_ANAT_SITE_NM.pdf | Use pick list. |
| Dose ^(m) | State the total radiation dose the subject received during the treatment period. | 10 characters |
| Dose UOM ^(m) | Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem). Dictionary name - UOM_DOSE_TH_2  UOM_DOSE_TH_2.pdf | Use pick list. |
| Missed Dose ^(m) | Select an option from the picklist: <ul style="list-style-type: none"> • No • Unknown • Yes, planned • Yes, unplanned • Yes, both planned and unplanned • Yes • Data not available | Use pick list. |
| Number of Doses Missed | Enter the total number of missed doses. | 4 digits |
| Dose per Fraction | Enter the fractionated dose of radiation therapy administered to a treatment field or site according to protocol. | 5 digits |

| Field Name | Description / Instructions | Format |
|----------------------|--|-----------|
| Total # of Fractions | Enter the number of dose-portions or fractions of radiation therapy actually administered. | 4 digits |
| Elapsed Days | Enter the actual number of days radiation therapy was administered. | 10 digits |

✔ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Query will fire if Start Date / Stop Date is in the future. “Future date has been entered. Please correct.” | Enter a date that is equal to or earlier than the current date. |
| RAD03 | Query will fire if Start Date is greater than Stop Date. “Start Date is greater than Stop Date. Please correct.” | Correct the Start Date or Stop Date. |
| RD04 | Query will fire if Radiation Type 'Other Specify' and 'Other, Specify' field are not present together. “Radiation Type 'Other Specify' and 'Other, Specify' field are not present together. Please correct.” | Enter 'Other Specify' if 'Other Specify' is selected as Radiation Type. |

Derivations

| Code | Field Name | Description |
|--------------|---------------|---|
| RAD1001_1002 | Day in Course | Derived from the respective course initiation start date. |

RANO Disease Assessment

Purpose

Record the RANO Disease Assessment information when the course is completed, and the subject is evaluated or taken off treatment.

RANO Disease Assessment

RANO DISEASE ASSESSMENT SUMMARY

Response Type - lesion Size

Response Criteria Type - RANO

Is pt NED?

Steroid dose status

Sum of TD + PD of all Measurable Lesions (mm²)

Verifying Physician

Verified

Date verified

RANO DISEASE ASSESSMENT

RANO Response Date

RANO Criteria for Response

IRANO Response Date

IRANO Criteria for response

RANO Progression date

IRANO Date of actual progression


[Save](#) [Cancel](#) Show to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------|--|----------------|
| Is pt NED? | <p>Question that asks whether there is evidence of disease (NED) at assessment. Choose an option from the list:</p> <ul style="list-style-type: none"> • No • Unknown • Yes | Use pick list. |
| Steroid dose status | <p>Enter the status that represents the steroid therapy dose. Choose an option from the list:</p> <ul style="list-style-type: none"> • NONE • STABLE • Increase • Decrease | Use pick list. |

| Field Name | Description / Instructions | Format |
|---|---|-------------------------|
| Sum of TD x PD of all Measurable Lesions (cm ²) | Enter numeric value of total sum of products (transverse diameter multiplied by perpendicular diameter) for all measurable lesions described in square centimeters (cm ²). | 8 digits and 0 decimals |
| Verifying Physician | Enter the name of verifying physician | 100 characters |
| Verified | Choose an option from the list: <ul style="list-style-type: none"> • Confirmed • Needs Revision | Use pick list. |
| Date verified | Enter the Date of verification by Physician | DD-MMM-YYYY |
| RANO Response Date | Enter the date of Response measured by RANO Criteria | DD-MMM-YYYY |
| RANO Criteria for Response | Select a RANO response criteria from the list: <ul style="list-style-type: none"> • AJ: Adjuvant Therapy • CPD: Clinical Progression • CR: Complete Response • CRU: Complete Response Unconfirmed • DU: Disease Unchanged • IMR: Immunoresponse • IPD: Immunoprogession • MR: Minimal/Marginal response • MX: Mixed response • NA: NOT ASSESSED • NE: Not Evaluable • NON-CR/NON-PD: Non-CR/Non-PD • NP: NOT APPLICABLE PER PROTOCOL • NPB: No Palliative Benefit • NR: NO RESPONSE • PA: Palliative Therapy • PB: Palliative Benefit • PD: Progressive Disease • PPD: Pseudoprogession • PR: Partial Response • PSR: Pseudoresponse • RD: Responsive Disease | Use pick list. |

| Field Name | Description / Instructions | Format |
|----------------------------------|---|----------------|
| | <ul style="list-style-type: none"> • RP: Response • RPD: Radiographic Progressive Disease • SD: Stable Disease • SPD: Surgical progression • TE: Too early • UK: Unknown | |
| iRANO Response Date | Enter the date of Response measured by iRANO Criteria | DD-MMM-YYYY |
| iRANO Criteria for Response | Select an iRANO response criteria from the list: <ul style="list-style-type: none"> • Complete Remission • Minor Response • Partial Remission • Progressive Disease • Stable Disease | Use pick list. |
| RANO Progression date | Enter the Date of disease progression response status based on RANO criteria. | DD-MMM-YYYY |
| iRANO Date of actual progression | Enter the Date of disease progression response status based on iRANO criteria. | DD-MMM-YYYY |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Date verified / RANO Response Date / iRANO Response Date / RANO Progression Date or iRANO Date of actual progression is a future date. "Future date has been entered. Please correct." | Change the date to a value no later than the current date. |
| RAS06 | RANO Criteria for Response is "Not Evaluable" or "Not Assessed" and no comments were entered. "RANO Criteria for Response is "Not Evaluable" or "Not Assessed" and no Comments were entered. Please correct." | Enter comment if RANO Criteria for Response is "Not Evaluable" or "Not Assessed". Otherwise change the RANO Criteria for Response to a selection other than "Not Evaluable" and "Not Assessed". |
| RAS07 | Query will fire when Disease Assessment in CR, PR, MR, SD or DU and Date of Response is not provided. "Date of Response is required when RANO Criteria for Response is CR, PR, MR, SD, or DU. Please correct." | Enter the Date of Response or review the RANO Criteria for Response. |
| RAS08 | Query will fire when Disease Assessment is PD but Date of Progression isn't provided. "Date of Progression is required when RANO Criteria for Response is PD. Please correct." | Enter the Date of Progression or review the RANO Criteria for Response. |

RECIST Extent of Disease - Lesion Identification

Purpose

Record all sites of disease that meet the RECIST criteria.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

RECIST Extent of Disease - Lesion Identification

RECIST Extent of Disease - Lesion Identification, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

| | | | |
|-----------------------------|-----|-----|-----|
| Lesion # | ... | ... | ... |
| Site | ... | ... | ... |
| Description of Location | ... | ... | ... |
| Lesion Description | | | ... |
| Previously Irradiated? | ... | ... | ... |
| Target / Non-Target | ... | ... | ... |
| Measurable / Non-Measurable | ... | ... | ... |
| Measurable Lesion Type | ... | ... | ... |
| Non-Measurable Lesion Type | ... | ... | ... |




Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Do you want to add comments? ...

COMMENTS

Save Cancel

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--|---|----------------|
| Lesion # | <p>Select a unique number for each lesion. Once a lesion number is designated for a specific lesion, that number may not change or be used to denote a different lesion.</p> <p> Note: This lesion number must appear at least once on the bottom repeating group.</p> | Use pick list. |
| Site | <p>Select the position where the lesion is located, i.e., Lung, Skull, etc.</p> <p>Dictionary Name – ANAT_SITE_NM</p> <p> ANAT_SITE_NM.pdf</p> | Use pick list. |
| Description of Location ^(m) | <p>Select a brief description of the lesion location.</p> <p>Dictionary Name - LOC_DESCRPTR_TXT_NM</p> <p> LOC_DESCRPTR_TXT _NM.pdf</p> | Use pick list. |
| Lesion Description | <p>If applicable, enter a brief description of each lesion, e.g., cystic, well-defined, encapsulated, necrotic appearing center.</p> | 200 characters |
| Previously Irradiated? ^(m) | <p>If the site or lesion has previously been irradiated.</p> <ul style="list-style-type: none"> • Yes • No • Unknown | Use pick list. |
| Target / Non-Target ^(m) | <p>Select the Target / Non-Target from the picklist:</p> <ul style="list-style-type: none"> • NON-TARGET: Non-Target Lesion Identification • TARGET: Target Lesion Identification | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| | <p>Note: Only applicable for studies that use RECIST criteria. It applies to the first time the lesion is detected. It should not be changed based on the subsequent evaluations.</p> | |
| Measurable / Non-Measurable ^(m) | Enter "MEASURABLE", for measurable, "NON-MEASURABLE" for non-measurable, as defined in the protocol. | Use pick list. |
| Measurable Lesion Type | <p>Select the type of measurable lesion from the picklist:</p> <ul style="list-style-type: none"> • BONE LESIONS • CYSTIC LESIONS • MALIGNANT LYMPH NODE • METASTATIC LESION • PREVIOUSLY TREATED LESIONS • PRIMARY TUMOR | Use pick list. |
| Non-Measurable Lesion Type | <p>Select the type of non-measurable lesion from the picklist:</p> <ul style="list-style-type: none"> • ABDOMINAL ORGANOMEGALY • ASCITES • PRIMARY TUMOR • PREVIOUSLY TREATED LESIONS • CYSTIC LESIONS • BONE LESIONS • METASTATIC LESION • ABDOMINAL MASSES • INFLAMMATORY BREAST DISEASE • PLEURAL OR PERICARDIAL EFFUSION • LEPTOMENINGEAL DISEASE • MALIGNANT LYMPH NODE • LYMPHANGITIC INVOLVEMENT OF SKIN OR LUNG | Use pick list. |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

RECIST Lesions Measurements

| Code | Description | Resolutions |
|-------|---|---|
| EXT01 | Lesion Number in the measurement section does not have a corresponding number in the description section (Lesion Identification Page). "Entered Lesion Number is not unique. Please correct." | Verify that lesion number in the measurement section is recorded in the description section (Lesion Identification Page). |

RECIST Extent of Disease - Lesion Measurement

Purpose

Record Measurements of the Lesions that meet the RECIST criteria.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

RECIST Extent of Disease - Lesion Measurement


RECIST Extent of Disease - Lesion Measurement, Log Lines



[Back To Complete View](#) < Previous Line Line of 1 Next Line > [Add Another Line](#)

| | | |
|----------------------|---|----------------------------------|
| Time Point | <input type="text" value="..."/> | <input type="button" value="⚙"/> |
| Lesion # | <input type="text" value="..."/> | <input type="button" value="⚙"/> |
| Course # | <input type="text"/> | <input type="button" value="⚙"/> |
| Day in Course | <input type="text"/> | <input type="button" value="⚙"/> |
| Date of Imaging | <input type="text" value="dd"/> <input type="text" value="..."/> <input type="text" value="yyyy"/> <input type="button" value="📅"/> | <input type="button" value="⚙"/> |
| Date Measur. Taken | <input type="text" value="dd"/> <input type="text" value="..."/> <input type="text" value="yyyy"/> <input type="button" value="📅"/> | <input type="button" value="⚙"/> |
| Method of Assessment | <input type="text" value="..."/> | <input type="button" value="⚙"/> |
| Short Axis | <input type="text"/> | <input type="button" value="⚙"/> |
| Long Axis | <input type="text"/> | <input type="button" value="⚙"/> |
| Eval # | <input type="text"/> | <input type="button" value="⚙"/> |
| Eval Code | <input type="text" value="..."/> | <input type="button" value="⚙"/> |
| Comments | <input type="text"/> | <input type="button" value="⚙"/> |


0 / 250

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|------------------------------|--|----------------|
| Time Point | <p>Select a time point from the given picklist.</p> <p>Dictionary name - ASSESS_PD_TIME</p>  <p>ASSESS_PD_TIME.pdf</p> | Use pick list. |
| Lesion # | <p>Select a lesion number from the pick list.</p> <p>Note: This lesion number must appear in the description section (top repeating group).</p> | Use pick list. |
| Course # ^(d) | <p>Indicates the course number that this lesion evaluation was done in as derived from the course initiation start date. This is a derived field.</p> <p>Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course that this lesion evaluation was done as derived from the course initiation start date. This is a derived field.</p> <p>Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Imaging | Enter the date the imaging was taken. | DD-MMM-YYYY |
| Date Measurement Taken | Enter the date the measurement was taken. | DD-MMM-YYYY |

| Field Name | Description / Instructions | Format |
|-------------------------------------|---|------------------------|
| Method of Assessment ^(m) | <p>Select how the lesion measurement was assessed. The same method should be used to measure a specific lesion throughout the study. For example, if the measurements were determined by a chest x-ray, enter CXR.</p> <ul style="list-style-type: none"> • CALIPER: Caliper • CHEST X-RAY: Chest Radiography • CLINICAL EXAM: Physical Examination Clinical • COLOR PHOTOGRAPHY INCLUDING RULER: Color photography including ruler • CT: Computed Tomography • CYTOLOGY: Cytology • ENDOSCOPY: Endoscopy • HISTOLOGY: Histology • MRI: Magnetic Resonance Imaging • PET: Positron Emission Tomography • PET/CT: Positron Emission Tomography • TUMOR MARKER: Biomarker • ULTRASOUND: Ultrasonography | Use pick list. |
| Short Axis | <p>Enter the longest lesion diameter measurement in centimeters.</p> <div style="background-color: #e6f2ff; padding: 5px; border: 1px solid #add8e6;"> <p> Note: studies that use RECIST criteria, it should always measure the longest diameter of the lesion even if the actual axis is different from the one used to measure the lesion initially.</p> </div> | 5 digits and 1 decimal |
| Long Axis ^(m) | Enter the longest lesion measurement in centimeters. | 5 digits and 1 decimal |
| Eval # | <p>Number each evaluation sequentially for each lesion. Use 0 for the baseline evaluation, 1 for the first evaluation, 2 for the second evaluation, etc.</p> <div style="background-color: #e6f2ff; padding: 5px; border: 1px solid #add8e6;"> <p> Note: this is the number of the set of scans done after the baseline. For example, if a new lesion was found on the third set of scans that occurred at the end of the course 4, the evaluation number should be 3.</p> </div> | 2 digits |

| Field Name | Description / Instructions | Format |
|------------|---|----------------|
| Eval Code | <p>Select the status of non-measurable lesions at the time of each evaluation.</p> <ul style="list-style-type: none"> • N: NEW • R: Resolved • D: Decreasing • I: Increasing • S: Stable • B: Baseline • X: Not Examined | Use pick list. |
| Comments | Enter comments applicable to the disease. | 250 characters |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

Lesion Measurement

| Code | Description | Resolutions |
|-------|---|--|
| EXT02 | <p>Lesion Number in the measurement section does not have a corresponding number in the description section (Lesion Identification Page). “Extent of Disease Lesion Number in the Lesions Measurements section is not recorded in the Lesions Identification section. Please correct.”</p> | <p>Verify that lesion number in the measurement section is recorded in the description section (Lesion Identification Page).</p> |

| Code | Description | Resolutions |
|------------------------|---|---|
| EXT03 | <p>Evaluation Number of a "Non-Measurable" lesion is "0" and Evaluation Code is not "B", and vice-versa. "Extent of Disease Lesion in Lesions Measurements has an Evaluation Code of 'B : Baseline' but Evaluation Number is not '0'. Please correct."</p> <p>"Extent of Disease Lesion in Lesions Measurements has an Evaluation Number of '0' but Evaluation Code is not 'B : Baseline'. Please correct."</p> | <p>If Evaluation Number of a "Non-Measurable" lesion is "0", Evaluation Code should be "B: Baseline".</p> |
| EXT09 | <p>Lesion is marked as "Non-Measurable" and Evaluation Code was not provided. "Extent of Disease Lesion is marked Non-Measurable in Lesions Identification but the Evaluation Code is not recorded in the Lesions Measurements. Please correct."</p> | <p>Lesion is marked as "Non-Measurable" should have an Evaluation Code.</p> |
| EXT12 | <p>Lesion is marked as "Measurable" and longest measurement does not exist. "Lesion is marked as "Measurable" but longest measurement is not entered. Please correct."</p> | <p>Enter the lesion's longest measurement.</p> |
| Medidata System Checks | <p>Query will fire if Date of Imaging / Date of Measur. Taken is in the future. "Future date has been entered. Please correct."</p> | <p>Enter a date that is equal to or prior to the current date.</p> |
| EXT13 | <p>Query will fire if the lesion has an Evaluation Code of "B - Baseline" and the Date of Imaging is not prior to Start Date of the first course. "The lesion has an Evaluation Code of "B - Baseline" and the Date of Imaging is not prior to Start Date of the first course. Please correct."</p> | <p>Correct the lesion's Date of Imaging or the Evaluation Code.</p> |
| EXT14 | <p>Query will fire if Date of Imaging for New lesion (Eval Code = New) is prior to the Start Date of first course. "Date of Imaging for New lesion (Eval Code = New) is prior to the Start Date of first course. Please correct."</p> | <p>Enter a date that is equal or after the first course Start Date.</p> |

| Code | Description | Resolutions |
|-------|--|------------------------------------|
| EXT15 | Query will fire if Evaluation number for New lesion (with Evaluation Code 'N: New') is 0. "Evaluation number(Eval #) for New lesion (with Evaluation Code 'N-New') is 0. Please correct." | Enter a correct sequential number. |
| EXT16 | New lesion (with Evaluation Code 'N: New') does not have the lowest evaluation number for the corresponding lesion. "Extent of Disease Lesion in the Lesions Measurements section has an Evaluation Code 'N: New', but the Evaluation Number is not the lowest. Please correct." | Enter a correct sequential number. |

Derivations

RECIST Lesion Measurement

| Code | Field Name | Description |
|---------------|---------------|--|
| REXT1001_1002 | Course # | Course number is derived based on the course initiation start dates and the extent of disease evaluation date. |
| REXT1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the extent of disease evaluation date. |

Research Sample Collection

Purpose

Record the subject's sample collection.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

1010001 Ongoing

Research Sample Collection

Research Sample Collection, Log Lines

All Search field value. '0' or '1' for checkbox fields.

| | Research collection tubes | Collected? | Sample Collection Date | Comments | |
|---|---------------------------|------------|------------------------|----------------------|---|
| 1 | BLOOD FOR FACS | ... | dd ... yyyy | <input type="text"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 2 | BLOOD FOR TUMOR MARKERS | ... | dd ... yyyy | <input type="text"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 3 | CITRATE TUBE FOR PCR | ... | dd ... yyyy | <input type="text"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 4 | BONE MARROW ASPIRATE | ... | dd ... yyyy | <input type="text"/> | <input type="checkbox"/> <input type="checkbox"/> |
| 5 | BONE MARROW BIOPSY | ... | dd ... yyyy | <input type="text"/> | <input type="checkbox"/> <input type="checkbox"/> |

5 Row(s) 4 Column(s)


Do you want to add comments?

COMMENTS

Save Cancel Move to next task after save

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---------------------------|--|--------------------------|
| Research collection tubes | Name of sample to be collected, predetermined per study. This field cannot be changed. | Study specific picklist. |
| Collected? | <p>Indicate whether the research samples are collected:</p> <ul style="list-style-type: none"> • No • Unknown • Yes • Not Applicable | Use picklist. |
| Sample Collection Date | Enter the date of sample collection. | DD-MMM-YYYY |
| Comments | Enter comments applicable to the sample collection. | 200 characters |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Validations

| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Sample Collection Date is in the future. “ Future date has been entered. Please correct. ” | Enter a date that is equal to or prior to the current date |

| Code | Description | Resolutions |
|-------|---|---|
| RSC01 | Query will fire if "Collected" is 'Yes' but the Sample Collection Date is not provided. "Collected?' is 'Yes' but Sample Collection Date is not entered. Please correct." | Sample Collection Date must be provided when "Collected?" is set to 'Yes'. |
| RSC02 | Query will fire if Sample Collection Date is specified but the respective "Collected?" is not checked 'Yes. "Collected?' is not equal to 'Yes' but Sample Collection Date is entered. Please correct." | Sample Collection Date should be removed when "Collected?" is not set to 'Yes'. |


Study Med Admin

Purpose

Record study medication administration and missed doses of study medication administration. Use a separate line for each medication and for each non-consecutive dose administration. Examples:

Oral daily agent:

Enter the start date of the cycle and then enter the date of last dose in the stop date field of the cycle.

 Note: start and stop times are not necessary for oral agents.

If the daily dosing is interrupted, enter the stop date, and on another line enter the start date if resumed during the same cycle.

Agent administers on Days 1-5 weekly every 28 days

Enter four lines, one for each consecutive weekly dosing.

If the daily dosing is interrupted, enter the stop date, and on another line enter the start date if resumed during the same cycle.

Agent administer on Days 1, 3, 5 every 21 days

Three line entries are required.

Continuous IV administration >24 hours

Enter start date and time of the infusion and when the infusion is completed (e.g., after 72 hours), enter the stop date and time.

Two IV agents are administered, one on Day 1 and the other on Days 1 and 15

Enter the two agents on separate lines for Day 1 and then on the third line, enter the Day 15 administration of the second drug.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Study Med Admin

Study Med Admin, Log Lines

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Administered, Yes/No? This field is required. Please complete.

Day in Course

Start Date

Start Time

Stop Date

Stop Time

Medication

Route

LOT#

Duration

Duration UOM

Back To Complete View < Previous Line Line 1 of 1 Next Line > Add Another Line

Do you want to add comments?

COMMENTS

*Please note that the fields below are only visible when “Administered, Yes/No?” is answered “Yes”.

Actual Total Dose

Actual Dose UOM

*Please note that the fields below are only visible when “Administered, Yes/No?” is answered “No”.

Reason for Missed Dose




Explain 'Other' Reason Missed






Total Missed Dose Amount



UOM

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------|---|----------------|
| Administered, Yes/No? | <p>Select an option indicating whether study drugs were administered.</p> <ul style="list-style-type: none"> • Yes • No • Not Applicable | Use pick list. |

| Field Name | Description / Instructions | Format |
|---------------------------------------|--|----------------|
| Day in Course ^(d) | <p>Indicates the day since the beginning of course initiation. Derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Start Date ^(m) | Enter the date the medication was administered. | DD-MMM-YYYY |
| Start Time | For IV infusions only: Enter the start time of the infusion. | HH(24):MM |
| Stop Date | Enter the date the medication was discontinued. | DD-MMM-YYYY |
| Stop Time | For IV infusions only: Enter the stop time of the infusion. | HH(24):MM |
| Medication ^(m) | <p>Select a medication from the list (study dependent).</p> <p> Note: The medication pick list incorporates all study medications, including pre and post medications specified in the protocol as part of the treatment. These medications should be documented in this case report form and NOT in the Concomitant Measures / Medications form.</p> | Use pick list. |
| Reason for Missed Dose ^(m) | <p>Select the reason the medication was missed.</p> <ul style="list-style-type: none"> • MEDICATION ERROR • SUBJECT COMPLIANCE • TOXICITY • OTHER, SPECIFY <p> Note: This field will be visible when "Administered, Yes/No?" is answered "No".</p> | Use pick list. |

| Field Name | Description / Instructions | Format |
|---|---|-------------------------|
| Explain 'Other' Reason Missed | <p>Enter an explanation for selecting “Other” for Reason for Missed Dose.</p> <p> Note: This field will be visible when “Administered, Yes/No?” is answered “No”.</p> | 100 characters |
| Total Missed Dose Amount ^(m) | <p>Enter the actual amount of medication missed for the date entered above.</p> <p> Note: In the case of medications (such as vaccines and viral particles) where the dose is expressed with scientific exponential units using powers of 10, record (for example) 10⁷ as 1 and select 10E7 as the Missed Amount UOM.</p> <p> Note: This field will be visible when “Administered, Yes/No?” is answered “No”.</p> | 6 characters |
| UOM ^(m) | <p>Select the Missed Dose Amount unit of measurement.</p> <p>Dictionary name - UOM_DOSE_TH_2</p> <p> UOM_DOSE_TH_2.pdf</p> <p> Note: This field will be visible when “Administered, Yes/No?” is answered “No”.</p> | Use pick list. |
| Actual Total Dose ^(m) | <p>Enter the total actual dose given for the medication name entered above for the time period encompassed by the duration. See Actual UOM below for the units of measure of the actual dose.</p> | 5 digits and 3 decimals |

| Field Name | Description / Instructions | Format |
|------------------------|---|--------------------------|
| | <p>Note: In the case of medications (such as vaccines and viral particles) where the dose is expressed with scientific exponential units using powers of 10, record (for example) 106 as 1X10E6.</p> <p>Note: This field will be visible when “Administered, Yes/No?” is answered “Yes”.</p> | |
| Actual Dose UOM (m) | <p>Select the Actual Dose Level unit of measurement.</p> <p>Dictionary name - UOM_DOSE_TH_2</p>  <p>UOM_DOSE_TH_2.pdf</p> <p>f</p> <p>Note: This field will be visible when “Administered, Yes/No?” is answered “Yes”.</p> | Use pick list. |
| Route (m) | <p>Select the route from the list.</p> <p>Dictionary name - ACCESS_RTE_NM</p>  <p>ACCESS_RTE_NM.pdf</p> | Use pick list. |
| LOT# | Enter the Lot Number for the medication supply. | 14 characters |
| Duration (m) | Enter the duration calculated from the start date/time and stop date/time. | 10 digits and 5 decimals |
| Duration UOM (m) | Select the units of measurement so that the duration can be derived. | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------|---|--------|
| | <ul style="list-style-type: none"> • DY: Days • HR: Hours • MN: Minutes • WK: Weeks • MO: Months • SEC: Seconds | |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked “(m) EDC mandatory” is empty the query will fire comment “This field is required. Please complete.”

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Query will fire if Start Date / Stop Date are/is in the future. “Future date has been entered. Please correct.” | Enter a date earlier than or equals to the current date. |
| SD04 | Query will fire if Stop Date/Time is prior to Start Date/Time. “Stop Date/Time is prior to Start Date/Time. Please correct.” | Correct the Start Date/Time or Stop Date/Time. |
| SD05 | Duplicate Medication records exist. “This Study Medication with Start Date/Time and Stop Date/Time has been entered more than once. Please correct.” | A unique entry for Medication, Start Date/Time and Stop Date/Time is required. |
| SD06, SD07, SD08, SD09 | Overlapping start and stop dates/times for the same medication. “Overlapping start and stop dates/times for the same medication. Please correct.” | Review the medications in question and their respective start and stop dates/times. |
| SD10 | Query will fire if Start Time or Stop Time is missing. “Start Time or Stop Time is missing. Please correct.” | Both Start and Stop Time must be either present or absent. |

| Code | Description | Resolutions |
|------|---|--|
| SD16 | Query will fire if Reason for Missed Dose 'Other, Specify' and 'Explain 'Other' Reason Missed' field are not present together. "Reason for Missed Dose 'Other, Specify' and Explain 'Other' Reason Missed' field are not present together. Please correct." | Enter 'Explain 'Other' Reason Missed' if 'Other, Specify' is selected as Reason for Missed Dose. |
| SD17 | Query will fire if Administered, Yes/No is answered "Yes" but Actual Total Dose and/or Actual Dose UOM are not specified. "Administered, Yes/No?" is answered "Yes", but 'Actual Total Dose' and/or 'Actual Dose UOM' are empty. Please correct." | Actual Total Dose and Total Dose UOM must be provided when the Administered, Yes/No is set to "Yes". |

Derivations

| Code | Field Name | Description |
|--------|---------------|---|
| SD1001 | Day in Course | Derived from the respective course initiation start date. |

Subject Enrollment

Purpose

Subject enrollment information received from PRES.

Subject Enrollment


| | |
|-----------------------------------|--------------------------|
| Subject ID | 1010005 |
| Is the subject eligible? | <input type="checkbox"/> |
| Sex | --- |
| Gender | --- |
| Date of Birth | --- -- |
| Age at Entry | --- |
| Subject's Initials | --- |
| Race | --- |
| Ethnicity | --- |
| Disease Term | --- |
| Registering Institute | --- |
| Registering Institute Description | --- |
| Date Informed Consent Signed | --- -- |

[Save](#) [Cancel](#)

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|---|---|-----------|
| Subject ID ^(p) | The ID of the subject for this study. | From PRES |
| Is the subject eligible? ^(p) | A yes/no indicator that asks the investigator to stipulate whether the subject is eligible for inclusion on this protocol | From PRES |
| Sex ^(p) | Subject's sex. | From PRES |
| Gender ^(p) | Subject's gender. | From PRES |
| Date of Birth ^(p) | Subject's date of birth. | From PRES |

| Field Name | Description / Instructions | Format |
|--|---|-----------|
| Age at Entry ^(p) | Age is derived from the subject's birth date at enrollment and it remains the same throughout the study. | From PRES |
| Subject's Initials ^(p) | Subject's initials. Usually 3 characters – first, middle and last name initials. | From PRES |
| Race ^(p) | Subject's race. | From PRES |
| Ethnicity ^(p) | Subject's Ethnicity. | From PRES |
| Disease Term ^(p) | Disease Term ("MedDRA") as listed on the CTEP Web site . | From PRES |
| Registering Institute ^(p) | Unique CTEP Institute Code where the subject was originally registered on study (e.g., institution where the subject signed the informed consent form). | From PRES |
| Registering Institute Description ^(p) | Full name of the Registering Institute. | From PRES |
| Date Informed Consent Signed ^(p) | The date informed consent was signed. | From PRES |

 Legend: ^(d) derived field, ^(m) EDC mandatory, ^(p) uploaded from PRES.

If field marked “(m) EDC mandatory” is empty the query will fire comment “**This field is required. Please complete.**”

Field Picklists and Values

| Field | Picklist Values |
|-----------|--|
| Sex | <ul style="list-style-type: none">• Male• Female• Ambiguous• Unknown |
| Gender | <ul style="list-style-type: none">• Decline to answer-D• Female-F• Male-M• Neither exclusively male or female-N• Other-O• Transgender Female-MtF• Transgender Male-FtM |
| Race | <ul style="list-style-type: none">• American Indian or Alaska Native• Asian• Black or African American• White• Unknown• Native Hawaiian or Other Pacific Islander• Other |
| Ethnicity | <ul style="list-style-type: none">• Hispanic or Latino• Not Hispanic or Latino• Unknown |

Surgery

Purpose

Record details of surgery performed as part of the treatment when required by the protocol.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Surgery

Surgery, Log Lines

[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line > [Add Another Line](#)

Day in Course ⚙️

Date of Surgery 📅 ⚠️ This field is required. Please complete. ⚙️

Procedure 0 / 100 ⚙️

Findings ⚙️

Residual Disease ⚙️

Were Margin Clear? ⚙️

Margin Comments 0 / 250 ⚙️

Total Lymph Nodes Involved ⚙️

Total Lymph Nodes Evaluated ⚙️


[Back To Complete View](#) < Previous Line Line 1 of 1 Next Line > [Add Another Line](#)

Do you want to add comments? ⚙️

[COMMENTS](#)

[Save](#) [Cancel](#)

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--------------------------------|---|----------------|
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the cardiac ejection fraction results are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Surgery ^(m) | Enter the date of the surgical procedure. | DD-MMM-YYYY |
| Procedure ^(m) | <p>Enter the type of procedure performed to diagnose / to treat the subject's disease.</p> <p>Examples include, but not limited to biopsy, node dissection, cytology, bone marrow biopsy, FNA (fine needle aspiration).</p> | 100 characters |
| Findings | Briefly describe the findings of the procedure. | 24 characters |
| Residual Disease | Briefly describe the extent of the residual disease, if any, at the conclusion of the operation. (i.e.: microscopic, macroscopic). | 30 characters |
| Were Margin Clear? | <p>Select the results of tissue margin examination.</p> <ul style="list-style-type: none"> • Less than 1mm (CLOSE) • Dysplasia present • Negative Margin • Positive Margin | Use pick list. |
| Margin Comments | Enter the comment for margin examination. | 250 characters |
| Total Lymph Nodes Involved | Enter the number of lymph nodes involved with disease as determined by pathologic examination. | 5 digits |

| Field Name | Description / Instructions | Format |
|-----------------------------|--|----------|
| Total Lymph Nodes Evaluated | Enter the total number of lymph nodes removed and pathologically assessed for disease. | 5 digits |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|---|
| Medidata System Checks | Query will fire if Date of Surgery is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or earlier than the current date. |

Derivations

| Code | Field Name | Description |
|---------|---------------|---|
| SUG1002 | Day in Course | Derived from the respective course initiation start date. |

Survival

Purpose

Use this form to record information about the patient's death and autopsy results if applicable.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

Survival

Date of Death

Cause of Death (Presumed)

Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify 0 / 200

Was Autopsy Done?

Cause of Death (Autopsy-determined)

Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify 0 / 200

PI Reported Primary Cause Leading to Death 0 / 255

Survival, Log Lines

Sites of Disease at Autopsy

| | | |
|---|----------------------------------|--|
| 1 | <input type="text" value="..."/> | |
|---|----------------------------------|--|

1 New row(s) 1 Row(s) 10 per add max 1 Column(s) / 1

Per page


Do you want to add comments?

COMMENTS

Move to next task

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| Date of Death ^(m) | Enter the date the patient has died. | DD-MMM-YYYY |
| Cause of Death (Presumed) ^(m) | <p>If the patient died without intervening therapy specific to the disease for which the patient was put on study, this section should be completed.</p> <p>Categorize the cause as due to:</p> <ul style="list-style-type: none"> • Malignant Disease • Toxicity from Protocol Treatment • Infection • Other (Explain) • CoMorbid Event, Specify <p>If "Other (Explain)" or "CoMorbid Event, Specify" is checked, enter a succinct description of the presumed cause of death on the field "Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify".</p> | Use pick list. |
| Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify | Enter a succinct description if option "Other (Explain)" or "CoMorbid Event, Specify" is selected as presumed cause of death. For example: Concurrent illness/MI". | 200 characters |
| Was Autopsy Done? | <p>Select an option indicating whether an autopsy was performed.</p> <ul style="list-style-type: none"> • Yes (Autopsy done.) • No (Autopsy not done.) • Unknown (Do not know if an autopsy was done.) | Use pick list. |
| Autopsy Results Available? ^(m) | <p>Select an option indicating whether the results of an autopsy are available.</p> <ul style="list-style-type: none"> • Yes (Autopsy results available.) • No (Autopsy results not yet available.) | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|--|----------------|
| Cause of Death (Autopsy-determined) | <p>If an autopsy was performed and a cause of death was determined at autopsy, it should be categorized according to:</p> <ul style="list-style-type: none"> • Malignant Disease • Toxicity from Protocol Treatment • Infection • Other (Explain) • CoMorbid Event, Specify <p>Only one category should be checked. If "Other (Explain)" or "CoMorbid Event, Specify" is checked, enter a succinct description of the autopsy finding cause of death on the field "Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify".</p> | Use pick list. |
| Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify | If option "Other (Explain)" or "CoMorbid Event, Specify" is selected as autopsy-determined cause of death, enter a succinct description, i.e., MI. | 200 characters |
| PI Reported Primary Cause Leading to Death | Enter description for primary cause of death. | 255 characters |
| Sites of Disease at Autopsy | <p>Select the major sites of malignant disease involvement found at the autopsy, i.e., heart, brain, lungs, etc.</p> <p>Dictionary name – BODY_SITES_TH</p>  <p>BODY_SITES_TH.pdf</p> | Use pick list. |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations


| Code | Description | Resolutions |
|------------------------|--|--|
| Medidata System Checks | Query will fire if Date of Death is in the future. "Future date has been entered. Please correct." | Enter a Date of Death that is earlier than or equal to the current date. |
| SUR02 | Query will fire if Autopsy Results Available is set to "Yes", but Cause of Death (Autopsy Finding) is not specified. "Autopsy Results Available is set to "Yes", but Cause of Death (Autopsy Finding) is not specified. Please correct." | Cause of Death (Autopsy Finding) must be provided when the Autopsy Results Available is set to "Yes". |
| SUR03 | Query will fire if Autopsy Results Available is not set to "Yes" and some, or all, of the other autopsy fields have been entered. "Autopsy Results Available is not "Yes", Cause of Death or Explain 'Other' is specified. Please correct." | Verify Autopsy Results Available and the other autopsy fields. |
| SUR04 | Query will fire if 'Cause of Death (Autopsy-determined) is "Other (Explain)" or "CoMorbid Event, Specify" and 'Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify' is not specified. "Cause of Death (Autopsy-determined) is "Other (Explain)" or "CoMorbid Event, Specify" and "Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify" is not specified. Please correct." | Verify 'Cause of Death (Autopsy-determined)' and 'Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify' fields. |
| SUR05 | Query will fire if an explanation is provided in 'Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify', but 'Cause of Death (Autopsy-determined) is not "Other (Explain)" or "CoMorbid Event, Specify". "Explanation provided in "Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify", but Cause of Death (Autopsy-determined) is not "Other (Explain)" or "CoMorbid Event, Specify". Please correct." | 'Cause of Death (Autopsy-determined)' must be 'Other (Explain)' or 'CoMorbid Event, Specify' when an explanation is provided in the ' Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify' field. |

| Code | Description | Resolutions |
|-------|---|--|
| SUR06 | <p>Query will fire if 'Cause of Death (Presumed)' is "Other (Explain)" or "CoMorbid Event, Specify" and 'Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify' is missing. "Cause of Death (Presumed) is "Other (Explain)" or "CoMorbid Event, Specify" and "Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify" is missing. Please correct."</p> | <p>An 'Other (Explain)' or 'CoMorbid Event, Specify' "Cause of Death (Presumed)" requires an explanation in the "Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify" field.</p> |
| SUR07 | <p>Query will fire if an explanation is provided in 'Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify', but 'Cause of Death (Presumed)' is not "Other (Explain)" or "CoMorbid Event, Specify". "Explanation provided in "Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify", but Cause of Death (Presumed) is not "Other (Explain)" or "CoMorbid Event, Specify". Please correct."</p> | <p>"Cause of Death (Presumed)" must be 'Other' or 'CoMorbid Event, Specify' when an explanation is provided in the "Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify" field.</p> |
| SUR08 | <p>Query will fire if Date of Death is greater than 30 days past Off Study Date. "Date of Death is greater than 30 days past Off Study Date. Please make sure the Date of Death and Off Study Date are apart by 30 days or less. Please correct."</p> | <p>Survival eCRF is not applicable as patient is off study.</p> |

Urinary Excretion

Purpose

Record detailed information about the collection of urine samples for analysis of the presence and quantity of the study medication and/or its metabolites.

 Note: This CRF will be put on the cycle section.

Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



Log_lines.pdf

1010005 Course 1 Inactivate Page

Urinary Excretion

Visit Date: dd / ... / yyyy

Course Number:

Day in Course:

Study Agent: ...

Start Date of Dosing: dd / ... / yyyy

Start Time of First Injection: HH : mm




Stop Date of Dosing: dd / ... / yyyy



Stop Time of First Injection: HH : mm

Urinary Excretion, Log Lines All Search field value '0' or '1' for checkbox fields.

| < | Planned Interval | Sample Collected? | Start Date | Start Time | Stop Date | Stop Time | Urine Volume | > |
|---|---------------------------|-------------------|-----------------|------------|-----------------|-----------|--------------|---|
| 1 | 0-24 HRS AFTER INJECTION | ... | dd / ... / yyyy | HH : mm | dd / ... / yyyy | HH : mm | ml | |
| 2 | 24-48 HRS AFTER INJECTION | ... | dd / ... / yyyy | HH : mm | dd / ... / yyyy | HH : mm | ml | |
| 3 | 48-72 HRS AFTER INJECTION | ... | dd / ... / yyyy | HH : mm | dd / ... / yyyy | HH : mm | ml | |
| 4 | 80-80 HRS AFTER INJECTION | ... | dd / ... / yyyy | HH : mm | dd / ... / yyyy | HH : mm | ml | |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-----------------------------------|---|----------------|
| Visit Date | The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Dosing field. | DD-MMM-YYYY |
| Course Number (d) | <p>Indicates the course number that this urinary excretion sample is related to as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course (d) | <p>Indicates the day since the beginning of course that this urinary excretion sample is related to as derived from the course initiation start date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Study Agent (m) | <p>Enter the name of the study agent (investigational or commercial) which is the subject of the urinary excretion study.</p> <p> Note: Only one study agent is allowed per case report form. Separate forms should be used when more than one study agent is being studied.</p> | Use pick list. |
| Start Date of Dosing (m) | Enter the date the study agent was administered. | DD-MMM-YYYY |
| Start Time of First Injection (m) | Enter the time of the first injection of the study agent, or if appropriate, for taking the study agent via any "non-IV" route of administration (for example, enter the time that the agent is administered orally or rectally). | HH(24):MM |

| Field Name | Description / Instructions | Format |
|----------------------------------|---|----------------|
| Stop Date of Dosing | <p>Enter the date the study agent administration was stopped.</p> <p> Note: This field will be used for infusional therapies only.</p> | DD-MMM-YYYY |
| Stop Time of First Injection | <p>Enter the stop time of the first injection of the study agent, or if appropriate, for taking the study agent via any "non-IV" route of administration (for example, enter the time that the agent is administered orally or rectally).</p> <p> Note: This field will be used for infusional therapies only.</p> | HH(24):MM |
| Planned Interval | Planned interval pre-determined per protocol. | Text |
| Sample Collected? ^(m) | <p>Indicate whether or not the specimen is collected.</p> <ul style="list-style-type: none"> • No • Unknown • Yes - then the Start Date, Time and Urine Volume should be entered • Not Applicable | Use pick list. |
| Start Date | Enter the collection start date. | DD-MMM-YYYY |
| Start Time | Enter the collection start time even if the assay results are not available. | HH(24):MM |
| Stop Date | Enter the collection end date. | DD-MMM-YYYY |
| Stop Time | Enter the collection end time even if the assay results are not available. | HH(24):MM |
| Urine Volume (ml) | Enter the urine volume collected in milliliters. | 4 digits |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|--|---|
| Medidata System Checks | Query will fire if Urinary excretion date(s) (Visit Date / Start Date / Stop Date / Start Date of Dosing / Stop Date of Dosing) is/are in the future. "Future date has been entered. Please correct." | Enter dates that are equal to or prior to the current date. |
| UE06 | Query will fire if Collection End Date/Time is prior to the collection Start Date/Time. "Collection End Date/Time is prior to the collection Start Date/Time. Please correct." | Collection End Date/Time must be after the collection Start Date/Time. |
| UE08 | Query will fire if Start Date / Time and Stop Date / Time pair appears more than once – duplicate entry. "Two Urinary Excretion records have identical values for Start Date, Start Time and Stop Date, Stop Time. Please correct." | Remove the duplicate record or correct the Start Date / Time and Stop Date / Time of one of them. |
| UE16 | Query will fire if Collected Urinary Excretion sample does not have corresponding Start Date, Time and Urine volume. "Collected Urinary Excretion sample does not have corresponding Start Date / Time or Urine volume. Please correct." | Enter Start Date, Time and Urine Volume if 'Sample Collected' is 'Yes'. |

Derivations

| Code | Field Name | Description |
|-------------|-------------------|---|
| UE1001_1002 | Course Number | Course number is derived based on the course initiation start dates and the infection episode onset date. |
| UE1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the infection episode onset date. |

Vital Signs

Purpose

Record the subject's Vital Signs while on study. Please note that if Vital Signs are taken as a part of protocol specific Physical Exam, record those Vital Signs on the Physical Exam eCRF.




Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:







Log_lines.pdf

| Vital Signs | | |
|---|---|----------------------------------|
| Vital Signs, Log Lines | | |
| Back To Complete View | | Add Another Line |
| < Previous Line Line 1 of 1 Next Line > | | |
| Course # | <input type="text"/> | |
| Day in Course | <input type="text"/> | |
| Date of Vitals | <input type="text" value="dd"/> - <input type="text" value="mm"/> - <input type="text" value="yyyy"/> | |
| Time | <input type="text" value="HH"/> : <input type="text" value="mm"/> | |
| Notes | <div style="border: 1px solid gray; height: 30px; width: 100%;"></div> <small>0 / 200</small> | |
| Performance Status (Karnofsky) | <input type="text" value="..."/> | |
| Status (Zubrot) | <input type="text" value="..."/> | |
| Performance Status (Lansky) | <input type="text" value="..."/> | |
| Body Weight | <input type="text"/> kg | |
| Height | <input type="text"/> cm | |
| BSA | <input type="text"/> | |
| Temperature | <input type="text"/> C | |
| Pulse | <input type="text"/> | |
| Systolic Blood Pressure | <input type="text"/> | |
| Diastolic Blood Pressure | <input type="text"/> | |
| Respiration Rate | <input type="text"/> | |
| Pulse Oximetry | <input type="text"/> | |

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|--------------------------------|---|----------------|
| Course # ^(d) | <p>Indicates the course number the vital signs are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Indicates the day since the beginning of course the vital signs are related to based on their date and time. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Vitals ^(m) | Enter the date the vital signs were taken. | DD-MMM-YYYY |
| Time | Enter the time the vital signs were taken. | HH(24):MM |
| Notes | <p>If necessary, enter some brief notes.</p> <p> Note: This information is not sent to the reporting agency.</p> | 200 characters |
| Performance Status (Karnofsky) | <p>Select a value from the Karnofsky performance status scale.</p> <ul style="list-style-type: none"> • 0: Dead • 10: Imminent Death • 20: Very sick; supportive treatment and/or hospitalization required • 30: Severely disabled; hospitalization required but death not imminent • 40: Disabled; requiring special care and assistance • 50: Considerable assistance and frequent medical care required; some self-care possible • 60: Able to care for most needs, but requires occasional assistance • 70: Able to care for self, but unable to work or carry on other normal activities | Use pick list. |

| Field Name | Description / Instructions | Format |
|------------------------------------|---|-------------------------|
| | <ul style="list-style-type: none"> • 80: Normal activity but requiring effort. Signs and symptoms of disease more prominent • 90: Able to carry on normal activity but with minor signs of illness present • 100: Normal with no complaints or evidence of disease | |
| Status (ECOG) | <p>Select a value from the Zubrod/ECOG performance status scale.</p> <ul style="list-style-type: none"> • 0: Asymptomatic • 1: Symptomatic, Fully Ambulatory • 2: Symptomatic, In Bed Less Than 50% Of Day • 3: Symptomatic, In Bed More Than 50% Of The Day, But Not Bedridden • 4: Bedridden | Use pick list. |
| Performance Status (Lansky) | <p>Select a value from the Lansky performance status scale.</p> <ul style="list-style-type: none"> • 0: unresponsive • 10: No play; does not get out of bed • 20: Often sleeping; play entirely limited to very passive activities • 30: In bed; needs assistance even for quiet play • 40: Mostly in bed; participates in quiet activities • 50: Gets dressed but lies around much of the day; no active play; able to participate in all quiet play • 60: Up and around; but minimal active play; keeps busy with quieter activities • 70: Both greater restriction of and less time spent in play activity • 80: Active; but tires more quickly • 90: Minor restrictions in physically strenuous activity • 100: Fully active, normal | Use pick list. |
| Body Weight (kg) ^(m) | <p>Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors.</p> <div style="text-align: center;">  <p>Appendix I - Conversion Tables.pdf</p> </div> | 3 digits and 2 decimals |

| Field Name | Description / Instructions | Format |
|----------------------------|---|-------------------------|
| Height (cm) ^(m) | <p>Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 3 digits and 2 decimals |
| BSA ^(m) | <p>Enter the subject's body surface area in m² (to two decimal places) if needed for the calculation of study medication dose level. A nomogram for children's and adult's body surface area calculation can be found in Appendix I.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 5 digits and 3 decimals |
| Temperature (C) | <p>Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 3 digits and 1 decimal |
| Pulse | Enter the subject's pulse rate. | 5 digits and 3 decimals |
| Systolic Blood Pressure | Enter the subject's systolic blood pressure. | 8 digits and 3 decimals |
| Diastolic Blood Pressure | Enter the subject's diastolic blood pressure. | 8 digits and 3 decimals |
| Respiration Rate | Enter the subject's respiration rate. | 5 digits and 3 decimals |

| Field Name | Description / Instructions | Format |
|----------------|---|-------------------------|
| Pulse Oximetry | Enter the subject's pulse oximetry reading. | 3 digits and 2 decimals |

Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|-------|---|--|
| VIT01 | Query will fire if Systolic Blood Pressure is less than Diastolic Blood Pressure. "Systolic Blood Pressure is less than or equal to Diastolic Blood Pressure. Please correct." | Systolic Blood Pressure must be greater than Diastolic Blood Pressure. |
| VIT02 | Two Vital Signs entries have the same Date and Time. "Vital Signs entry has a duplicate entry with the same date/time. Please correct." | Correct the date and/or time. |
| VIT03 | Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula. "BSA is not within 10% accuracy of the calculated BSA using the MIS formula. Please correct." | Correct the BSA. The MIS BSA formula is: $BSA (m^2) = Height(cm)^{0.725} \times Weight(kg)^{0.425} / 139.315$ |
| VIT04 | Entered BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. "BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. Please correct." | Correct the BSA. The Mosteller BSA formula is: $BSA (m^2) = (\frac{Height(cm) \times Weight(kg)}{3600})^{1/2}$ |

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Date of Vitals is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date. |
| Medidata System Checks | Query will fire if Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic and/or Diastolic Blood Pressure are/is less than zero. "Data entered is out of range (< 0). Please correct." | Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic Blood Pressure and Diastolic Blood Pressure must be greater than zero. |
| Medidata System Checks | Query will fire if Pulse Oximetry is out of range. "Data entered is out of range (> 100). Please correct." | Pulse Oximetry must be an integer number between 0 and 100. |
| Medidata System Checks | Query will fire if Height is out of range. "Data entered is out of range (> 200)/(<120). Please correct." | Height must be an integer number between 120 and 200. |

Derivations

| Code | Field Name | Description |
|--------------|---------------|---|
| VIT1001_1002 | Course # | Course number is derived based on the course initiation start dates and the vital signs date. |
| VIT1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the vital signs date. |

Vital Signs - Cycles

Purpose

Record vital signs during treatment.

Vital Signs - Cycles



VITAL SIGNS - CYCLES



| | | |
|---------------------------------------|---|--|
| Course # | | |
| Day in Course | | |
| Date of Vitals | dd - - yyyy | |
| Time | HH - mm | |
| Notes | <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> <small>0 / 200</small> | |
| Karnofsky | ... | |
| ECOG | ... | |
| Lansky | ... | |
| Weight (kg) | <input type="text"/> kg | |
| Height (cm) | <input type="text"/> cm | |
| Body Surface Area (m ²) | <input type="text"/> m ² | |
| Temperature (celsius) | <input type="text"/> C | |
| Pulse (beats per minute) | <input type="text"/> bpm | |
| Systolic BP (millimeters of mercury) | <input type="text"/> mmHg | |
| Diastolic BP (millimeters of mercury) | <input type="text"/> mmHg | |
| Respiratory Rate (breaths per minute) | <input type="text"/> BPM | |
| Pulse Ox (percent) | <input type="text"/> % | |
| Do you want to add comments? | ... | |






COMMENTS

Move to next task

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------|---|----------------|
| Course # ^(d) | <p>Sequential number of this course of treatment: first course = 1, second course = 2, etc. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Day in Course ^(d) | <p>Number of days since the beginning of the course is derived from the course initiation start date and examination date. This is a derived field.</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | Derived field. |
| Date of Vitals ^(m) | Enter the date the vital signs were taken. | DD-MMM-YYYY |
| Time | Enter the time the vital signs were taken. | HH(24):MM |
| Notes | If necessary, enter some brief notes. | 200 characters |
| Karnofsky | <p>Select a value from the Karnofsky performance status scale.</p> <ul style="list-style-type: none"> • 0: Dead • 10: Imminent Death • 20: Very sick; supportive treatment and/or hospitalization required • 30: Severely disabled; hospitalization required but death not imminent • 40: Disabled; requiring special care and assistance • 50: Considerable assistance and frequent medical care required; some self-care possible • 60: Able to care for most needs, but requires occasional assistance • 70: Able to care for self, but unable to work or carry on other normal activities • 80: Normal activity but requiring effort. Signs and symptoms of disease more prominent | Use pick list. |

| Field Name | Description / Instructions | Format |
|----------------------------|---|-------------------------|
| | <ul style="list-style-type: none"> 90: Able to carry on normal activity but with minor signs of illness present 100: Normal with no complaints or evidence of disease | |
| ECOG | <p>Select a value from the Zubrod/ECOG performance status scale.</p> <ul style="list-style-type: none"> 0: Asymptomatic 1: Symptomatic, Fully Ambulatory 2: Symptomatic, In Bed Less Than 50% Of Day 3: Symptomatic, In Bed More Than 50% Of The Day, But Not Bedridden 4: Bedridden | Use pick list. |
| Lansky | <p>Select a value from the Lansky performance status scale.</p> <ul style="list-style-type: none"> 0: unresponsive 10: No play; does not get out of bed 20: Often sleeping; play entirely limited to very passive activities 30: In bed; needs assistance even for quiet play 40: Mostly in bed; participates in quiet activities 50: Gets dressed but lies around much of the day; no active play; able to participate in all quiet play 60: Up and around; but minimal active play; keeps busy with quieter activities 70: Both greater restriction of and less time spent in play activity 80: Active; but tires more quickly 90: Minor restrictions in physically strenuous activity 100: Fully active, normal | Use pick list. |
| Weight (kg) ^(m) | <p>Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors.</p> <div style="text-align: center;">  <p>Appendix I - Conversion Tables.pdf</p> </div> <div style="background-color: #e0f0ff; padding: 5px; margin-top: 10px;"> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> </div> | 5 digits and 2 decimals |

| Field Name | Description / Instructions | Format |
|--|--|-------------------------|
| Height (cm) ^(m) | <p>Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors.</p> <p> Appendix I - Conversion Tables.pdf</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | 6 digits and 1 decimal |
| Body Surface Area (m ²) ^(m) | <p>Enter the subject's body surface area in m² (to two decimal places) if needed for the calculation of study medication dose level. A nomogram for children's and adult's body surface area calculation can be found in Appendix I.</p> <p> Appendix I - Conversion Tables.pdf</p> <p> Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.</p> | 5 digits and 3 decimals |
| Temperature (celsius) | <p>Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors.</p> <p> Appendix I - Conversion Tables.pdf</p> | 3 digits and 1 decimal |
| Pulse (beats per minute) | Enter the subject's pulse rate. | 5 digits and 3 decimals |
| Systolic BP (millimeters of mercury) | Enter the subject's systolic blood pressure. | 8 digits and 3 decimals |

| Field Name | Description / Instructions | Format |
|--|---|-------------------------|
| Diastolic BP (millimeters of mercury) | Enter the subject's diastolic blood pressure. | 8 digits and 3 decimals |
| Respiratory Rate (breaths per minute) | Enter the subject's respiration rate. | 5 digits and 3 decimals |
| Pulse Ox (percent) | Enter the subject's pulse oximetry reading. | 5 digits and 2 decimals |

✓ Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|-------|---|--|
| VIT01 | Query will fire if Systolic Blood Pressure is less than Diastolic Blood Pressure. "Systolic Blood Pressure is less than or equal to Diastolic Blood Pressure. Please correct." | Systolic Blood Pressure must be greater than Diastolic Blood Pressure. |
| VIT03 | Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula. "BSA is not within 10% accuracy of the calculated BSA using the MIS formula. Please correct." | Correct the BSA. The MIS BSA formula is: BSA (m ²) = Height(cm) ^{0.725} x Weight(kg) ^{0.425} / 139.315 |

| Code | Description | Resolutions |
|------------------------|--|--|
| VIT04 | Entered BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. "BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. Please correct." | Correct the BSA. The Mosteller BSA formula is: BSA (m ²) = (CCRClinicalIT2: Height(cm) x Weight(kg) / 3600) ^½ |
| Medidata System Checks | Query will fire if Vitals Date is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date. |
| Medidata System Checks | Query will fire if Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic and/or Diastolic Blood Pressure are/is less than zero. "Height / Weight / BSA / Temperature / Pulse/ Respiration Rate / Systolic / Diastolic Blood Pressure are/is less than zero. Please correct." | Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic Blood Pressure and Diastolic Blood Pressure must be greater than zero. |
| Medidata System Checks | Query will fire if Pulse Oximetry is out of range. "Data entered is out of range (>100)/(<0). Please correct." | Pulse Oximetry must be an integer number between 0 and 100. |
| Medidata System Checks | Query will fire if Height is out of range. "Data entered is out of range (>200)/(<120). Please correct." | Height must be an integer number between 120 and 200. |
| VIT15 | Vitals (on cycle sections) have Date of Vitals outside the range of the cycle start and stop date. "Date of Vitals is outside the range of this course's Start and Stop dates. Please correct." | Enter an appropriate date. Note: this does not apply for all protocols. |


Derivations

| Code | Field Name | Description |
|-----------------|---------------|---|
| PE_VIT1001_1002 | Course # | Course number is derived based on the course initiation start dates and the vital signs date. |
| PE_VIT1001_1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the vital signs date. |























Vital Signs - Screening

Purpose


Record baseline vital signs results.

 Vital Signs - Screening []

VITAL SIGNS - SCREENING PE




| | | |
|---------------------------------------|--|---|
| Date of Vitals | <input type="text" value="dd"/> <input type="text" value="..."/> <input type="text" value="yyyy"/>  |  |
| Time | <input type="text" value="HH"/> : <input type="text" value="mm"/> |  |
| Notes | <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div> <p>0 / 200</p> |  |
| Karnofsky | <input type="text" value="..."/>  |  |
| ECOG | <input type="text" value="..."/>  |  |
| Lansky | <input type="text" value="..."/>  |  |
| Weight (kg) | <input type="text"/> kg |  |
| Height (cm) | <input type="text"/> cm |   |
| Body Surface Area (m ²) | <input type="text"/> m ² |  |
| Temperature (celsius) | <input type="text"/> C |  |
| Pulse (beats per minute) | <input type="text"/> bpm |  |
| Systolic BP (millimeters of mercury) | <input type="text"/> mmHg |  |
| Diastolic BP (millimeters of mercury) | <input type="text"/> mmHg |  |
| Respiratory Rate (breaths per minute) | <input type="text"/> BPM |  |
| Pulse Ox (percent) | <input type="text"/> % |  |
| Do you want to add comments? | <input type="text" value="..."/>  |  |


COMMENTS


Move to next task 

Field Descriptions and Instructions

| Field Name | Description / Instructions | Format |
|-------------------------------|--|----------------|
| Date of Vitals ^(m) | Enter the date the vital signs were taken. | DD-MM-YYYY |
| Time | Enter the time the vital signs were taken. | HH(24):MM |
| Notes | If necessary, enter some brief notes. | 200 characters |
| Karnofsky | <p>Select a value from the Karnofsky performance status scale.</p> <ul style="list-style-type: none"> • 0: Dead • 10: Imminent Death • 20: Very sick; supportive treatment and/or hospitalization required • 30: Severely disabled; hospitalization required but death not imminent • 40: Disabled; requiring special care and assistance • 50: Considerable assistance and frequent medical care required; some self-care possible • 60: Able to care for most needs, but requires occasional assistance • 70: Able to care for self, but unable to work or carry on other normal activities • 80: Normal activity but requiring effort. Signs and symptoms of disease more prominent • 90: Able to carry on normal activity but with minor signs of illness present • 100: Normal with no complaints or evidence of disease | Use pick list. |
| ECOG | <p>Select a value from the Zubrod/ECOG performance status scale.</p> <ul style="list-style-type: none"> • 0: Asymptomatic • 1: Symptomatic, Fully Ambulatory • 2: Symptomatic, In Bed Less Than 50% Of Day • 3: Symptomatic, In Bed More Than 50% Of The Day, But Not Bedridden • 4: Bedridden | Use pick list. |
| Lansky | <p>Select a value from the Lansky performance status scale.</p> <ul style="list-style-type: none"> • 0: unresponsive • 10: No play; does not get out of bed | Use pick list. |

| Field Name | Description / Instructions | Format |
|--|--|-------------------------|
| | <ul style="list-style-type: none"> • 20: Often sleeping; play entirely limited to very passive activities • 30: In bed; needs assistance even for quiet play • 40: Mostly in bed; participates in quiet activities • 50: Gets dressed but lies around much of the day; no active play; able to participate in all quiet play • 60: Up and around; but minimal active play; keeps busy with quieter activities • 70: Both greater restriction of and less time spent in play activity • 80: Active; but tires more quickly • 90: Minor restrictions in physically strenuous activity • 100: Fully active, normal | |
| Weight (kg) ^(m) | <p>Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 5 digits and 2 decimals |
| Height (cm) ^(m) | <p>Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 5 digits and 2 decimals |
| Body Surface Area (m ²) ^(m) | <p>Enter the subject's body surface area in m² (to two decimal places) if needed for the calculation of study medication dose level. A nomogram for children's and adult's body surface area calculation can be found in Appendix I.</p>  <p>Appendix I - Conversion Tables.pdf</p> | 5 digits and 3 decimals |
| Temperature (celsius) | <p>Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors.</p> | 3 digits and 1 decimal |

| Field Name | Description / Instructions | Format |
|---------------------------------------|--|-------------------------|
| |  Appendix I - Conversion Tables.pdf | |
| Pulse (beats per minute) | Enter the subject's pulse rate. | 5 digits and 3 decimals |
| Systolic BP (millimeters of mercury) | Enter the subject's systolic blood pressure. | 8 digits and 3 decimals |
| Diastolic BP (millimeters of mercury) | Enter the subject's diastolic blood pressure. | 8 digits and 3 decimals |
| Respiratory Rate (breaths per minute) | Enter the subject's respiration rate. | 5 digits and 3 decimals |
| Pulse Ox (percent) | Enter the subject's pulse oximetry reading. | 3 digits and 2 decimals |

 Legend: ^(d) derived field, ^(m) EDC mandatory.

If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

Validations

| Code | Description | Resolutions |
|------------------------|---|--|
| Medidata System Checks | Query will fire if Date of Vitals is in the future. "Future date has been entered. Please correct." | Enter a date that is equal to or prior to the current date. |
| VIT01 | Query will fire if Systolic Blood Pressure is less than Diastolic Blood Pressure. "Systolic Blood Pressure is less than or equal to Diastolic Blood Pressure. Please correct." | Systolic Blood Pressure must be greater than Diastolic Blood Pressure. |
| VIT03 | Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula. "BSA is not within 10% accuracy of the calculated BSA using the MIS formula. Please correct." | Correct the BSA. The MIS BSA formula is: $BSA (m^2) = Height(cm)^{0.725} \times Weight(kg)^{0.425} / 139.315$ |
| VIT04 | Entered BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. "BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula. Please correct." | Correct the BSA. The Mosteller BSA formula is: $BSA (m^2) = (\frac{CCRClinicalIT2: Height(cm) \times Weight(kg)}{3600})^{1/2}$ |
| Medidata System Checks | Query will fire if Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic and/or Diastolic Blood Pressure are/is less than zero. "Height / Weight / BSA / Temperature / Pulse / Respiration Rate / Systolic / Diastolic Blood Pressure are/is less than zero. Please correct." | Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic Blood Pressure and Diastolic Blood Pressure must be greater than zero. |
| Medidata System Checks | Query will fire if Pulse Oximetry is out of range. "Data entered is out of range (>100)/(<0). Please correct." | Pulse Oximetry must be an integer number between 0 and 100. |
| Medidata System Checks | Query will fire if Height is out of range. "Data entered is out of range (>200)/(<120). Please correct." | Height must be an integer number between 120 and 200. |

Version Change Summary

Version 2.0 Changes

| CRF | Changes in v2.0 |
|---------------------------|---|
| Adverse Events | <ul style="list-style-type: none"> Updated AE/SOC with CTCAE Term (v5.0) – added “(v5.0)” in field description Changed dictionary name and attached new link in CTCAE Term (5.0) (“CTCAE5_SOC” has been replaced with “CTCAE5_TERM”) Removed previous CTCAE Term row Updated validation AE17 Removed derivation AE1001 Updated screenshot |
| Arm and Cohort Assignment | <ul style="list-style-type: none"> Changed formats to reflect that all fields are being imported from PRES Added validation ARM01 Replaced “patient” with “subject” in Arm Description Updated screenshot |
| Baseline Symptom | <ul style="list-style-type: none"> Updated AE/SOC with CTCAE Term (v5.0) – added “(v5.0)” in field description Changed dictionary name and attached new link in CTCAE Term (5.0) (“CTCAE5_SOC” has been replaced with “CTCAE5_TERM”) Removed previous CTCAE Term row Removed derivation AE1001 Updated BS02 validation Related to Disease field - Updated from “Use radio buttons” to “Use pick list” Updated screenshot |
| Course Initiation | <ul style="list-style-type: none"> Removed Visit Date Added Arm Name and Arm Description fields Added derivation CINI1003 Updated screenshot |

Version 3.0 Changes

| CRF | Changes in v3.0 |
|----------------------------------|--|
| Adverse Events | <ul style="list-style-type: none"> Added AE attribution conversion table Updated AE attribution field descriptions to include a note (in blue) Removed “*” and “Under Development” from AE10 and AE11 in Validations Added query text to AE10 and AE11 entries Updated derivation codes |
| Baseline Symptom | <ul style="list-style-type: none"> Updated query text for edit check BS03 Updated validation entry for edit check BS02 |
| Baseline Medical History | <ul style="list-style-type: none"> Updated query text for edit check MH02 |
| Chimerism | <ul style="list-style-type: none"> Updated derivation codes Updated future date validation entry in Validations |
| Concomitant Measures/Medications | <ul style="list-style-type: none"> Updated derivation codes |
| Diagnostic ECG | <ul style="list-style-type: none"> Updated derivation codes |

| | |
|---|--|
| Disease Assessment Leukemia | <ul style="list-style-type: none"> Removed edit check LAS05 entry from Validations |
| Disease Assessment Neuro | <ul style="list-style-type: none"> Removed edit check NAS05 entry from Validations |
| Echo/MUGA | <ul style="list-style-type: none"> Updated derivation codes |
| Extent of Disease - Lesion Measurements | <ul style="list-style-type: none"> Updated derivation codes Updated query text for edit check EXT03 |
| Infection Episode | <ul style="list-style-type: none"> Updated derivation codes |
| Labs | <ul style="list-style-type: none"> Updated derivation codes |
| Pharmacokinetics | <ul style="list-style-type: none"> Updated derivation codes |
| Physical Exam - Screening | <ul style="list-style-type: none"> Removed 'BSA > 9' edit check in Validations Removed Vitals Date future date check entry in Validations |
| Physical Exam - Cycles | <ul style="list-style-type: none"> Updated derivation codes |
| Procedure | <ul style="list-style-type: none"> Updated derivation codes |
| Radiation Treatment | <ul style="list-style-type: none"> Updated future date check entry in Validations |
| RANO Disease Assessment | <ul style="list-style-type: none"> Removed edit check RAS05 entry from Validations |
| RECIST Extent of Disease - Lesion Measurement | <ul style="list-style-type: none"> Updated derivation codes Removed "Under Development" from Validations |
| Study Med Admin | <ul style="list-style-type: none"> Added the field "Route" to Fields and Descriptions section Updated screenshot |
| Study Med Missed | <ul style="list-style-type: none"> Added entries for validations SD05.1 and SD06/07/08/09.1 |
| Urinary Excretion | <ul style="list-style-type: none"> Updated derivation codes |
| Vital Signs | <ul style="list-style-type: none"> Updated derivation codes |

Version 4.0 Changes

| CRF | Changes in v4.0 |
|-------------------------------|---|
| Adverse Events | <ul style="list-style-type: none"> Updated AE23_1 description Updated "start date" to "onset date" in Date of Onset description Added "If a subject died on study then the onset date and the resolve date for the death AE should be the same." to Date Resolved description |
| Arm and Cohort Assignment | <ul style="list-style-type: none"> Changed "Date" field description from "Date of the Form" to "Date of the Cohort Arm Assignment" |
| Enrollment | <ul style="list-style-type: none"> Updated picklist values in Disease Stage at Entry |
| Labs | <ul style="list-style-type: none"> Removed LB01, LB1005 Removed Range Indicator, Value (Numeric) and Value in Preferred UOM Changed field order to reflect the latest template layout Updated screenshot Added Preferred UOM derivation ("Lab UOM") to derivation list |
| Off Treatment | <ul style="list-style-type: none"> Added OTS23 |
| Research Sample Collection | <ul style="list-style-type: none"> Added RSC01 Added RSC02 |
| Subject Enrollment | <ul style="list-style-type: none"> Added Sex field to field list Updated screenshot |

Version 5.0 Changes

| CRF | Changes in v5.0 |
|----------------------------|---|
| Adverse Events | <ul style="list-style-type: none"> • Updated screenshot • Updated “Serious” description • Updated “Attribution to Other” to “Attribution to Other (Alternative Etiology)” • Added new fields: “Death”, “Hospitalization, Prolonged Hospitalization”, “Life-threatening”, “Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions”, “Congenital anomaly/birth defect”, “Important Medical Event” • Updated “Action” description • Updated “Outcome” description • Updated AE20 validation query text • Added validations: AE24, AE25 |
| Arm and Cohort Assignment | <ul style="list-style-type: none"> • Added PRES integration to Legend |
| Enrollment | <ul style="list-style-type: none"> • Added ‘TX’ in “T Stage” picklist • Added ‘NX’ in “N Stage” picklist |
| Labs | <ul style="list-style-type: none"> • Preferred UOM format changed to pick list • Added LAB05 to Validations list • Updated screenshot |
| Pulmonary Function Test | <ul style="list-style-type: none"> • Added new CRF to manual |
| Questionnaire | <ul style="list-style-type: none"> • Added new CRF to manual |
| Research Sample Collection | <ul style="list-style-type: none"> • Updated “Research collection tubes” format |
| Subject Enrollment | <ul style="list-style-type: none"> • Added PRES integration to Legend • Added Field Picklists and Values table |
| Survival | <ul style="list-style-type: none"> • Added new field “Was Autopsy Done?” • Updated field name “Cause of Death (Autopsy Findings)” to “Cause of Death (Autopsy-determined)” • Added new field “PI Reported Primary Cause Leading to Death” • Updated picklist in “Autopsy Results Available?” • Updated screenshot |

Version 6.0 Changes

| CRF | Changes in v6.0 |
|---|---|
| Adverse Events | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ • Updated AE19 Resolution |
| Chimerism | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Concomitant/Measures MedicationsS | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Diagnostic ECG | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Echo/MUGA | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Extent of Disease – Lesion Measurements | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Infection Episode | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ |
| Labs | <ul style="list-style-type: none"> • Added Note in ‘Course #’ and ‘Day in Course’ • Removed Lab UOM derivation from Derivations table • Changed ‘Grade’ format from derived field to “1 character” |

| | |
|------------------------------|--|
| | <ul style="list-style-type: none"> • Changed 'Lab Test' format from derived field to "Use pick list" • Added embedded dictionary link in 'Preferred UOM' |
| Pharmacokinetics | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| Physical Exam - Cycles | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| Procedure | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| PFT | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| Radiation Treatment | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| RECIST Extent of Measurement | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| Study Med Admin | <ul style="list-style-type: none"> • Added combined Study Med Admin and Study Med Missed form manual |
| Study Med Missed | <ul style="list-style-type: none"> • Removed CRF from the manual |
| Surgery | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| Survival | <ul style="list-style-type: none"> • Updated SUR04/05/06/07 validation queries |
| Urinary Excretion | <ul style="list-style-type: none"> • Added Note in 'Course Number' and 'Day in Course' |
| Vitals Signs | <ul style="list-style-type: none"> • Added Note in 'Course #' and 'Day in Course' |
| General | <ul style="list-style-type: none"> • Added Introduction page |

Version 7.0 Changes

| CRF | Changes in v7.0 |
|----------------------------|---|
| Adverse Events | <ul style="list-style-type: none"> • Updated AE20 query text and resolution |
| Course Assessment | <ul style="list-style-type: none"> • Added new question 'Any concomitant medications taken in this course?' • Added edit checks CAS11 and CAS12 • Updated screenshot |
| Course Initiation | <ul style="list-style-type: none"> • Added new question 'Is this participant evaluable for DLT? (Phase 1 only)' • Updated screenshot |
| Disease Assessment RECIST | <ul style="list-style-type: none"> • Updated picklists for 'Targeted Lesions Response', 'Non-targeted Lesions Response' and 'Overall Response' |
| Follow-up | <ul style="list-style-type: none"> • Added new question 'Explain 'Other' Type of Contact' • Added new edit check FLW10 |
| Labs | <ul style="list-style-type: none"> • Added Lab panels list • Updated 'Lab Test' and 'Preferred UOM' formats • Updated screenshot |
| Off Treatment | <ul style="list-style-type: none"> • Updated OTS08_28 and OTS9_18 query texts |
| Pharmacokinetics | <ul style="list-style-type: none"> • Updated PHM01 validation logic and query text |
| Physical Exam - Screening | <ul style="list-style-type: none"> • Split into two separate forms: 'Physical Exam - Screening' and 'Vital Signs - Screening' • Removed 'Zubrod' from 'ECOG/Zubrod' • Updated screenshot |
| Physical Exam - Cycles | <ul style="list-style-type: none"> • Split into two separate forms: 'Physical Exam - Cycles' and 'Vital Signs - Cycles' • Removed 'Zubrod' from 'ECOG/Zubrod' • Updated screenshot |
| Questionnaire | <ul style="list-style-type: none"> • Added a note for 'Date of Assessment' |
| Research Sample Collection | <ul style="list-style-type: none"> • Updated RSC02 validation logic and query text |
| Vital Signs | <ul style="list-style-type: none"> • Removed 'Zubrod' from 'Status (ECOG/Zubrod)' |

Version 8.0 Changes

| CRF | Changes in v8.0 |
|--|--|
| Adverse Events | <ul style="list-style-type: none"> Updated AE19 description |
| Baseline Medical History | <ul style="list-style-type: none"> Updated screenshot |
| Consult | <ul style="list-style-type: none"> Removed 'OTHER' from the 'Consult Evaluation Type' picklist |
| Enrollment | <ul style="list-style-type: none"> Removed values (associated with other/specify) from the embedded 'Histology' picklist |
| Extent of Disease - Lesion Identification | <ul style="list-style-type: none"> Removed values (associated with other/specify) from the embedded 'Description of Location' and 'Anatomic Site' picklists |
| Infection Episode | <ul style="list-style-type: none"> Removed values (associated with other/specify) from the embedded 'Primary Site' and 'Infectious Agent' picklists |
| Introduction | <ul style="list-style-type: none"> Added new meeting items to the Introduction page |
| Labs | <ul style="list-style-type: none"> Added new lab fields Updated screenshot Updated LB03 validation description and resolution Added new 'Add Lab Form' CRF |
| Pathology Markers | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Tumor Marker' picklist Removed 'OTHER, SPECIFY' from the 'Marker Test Method' picklist |
| Pathology Report | <ul style="list-style-type: none"> Removed 'Other' from the 'Notable Benign Changes' picklist Removed a value (associated with other/specify) from the embedded 'Body Site of Collection' picklist |
| Physical Exam - Cycles | <ul style="list-style-type: none"> Added 'Course #' as a field and a derivation Updated screenshot |
| Prior Radiation Supplement | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Site' picklist |
| Prior Surgery Supplement | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Site' picklist |
| Prior Treatment Summary | <ul style="list-style-type: none"> Changed the description for '# of Prior Regimens' Updated PTX05 validation description and resolution |
| Procedure | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Body Site' picklist |
| Radiation Treatment | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Radiation Field' picklist |
| RECIST Extent of Disease - Lesion Identification | <ul style="list-style-type: none"> Removed values (associated with other/specify) from the embedded 'Site' and 'Description of Location' picklists |
| RECIST Extent of Disease - Lesion Measurement | <ul style="list-style-type: none"> Removed values (associated with other/specify) from the embedded 'Time Point' picklist |
| Survival | <ul style="list-style-type: none"> Removed a value (associated with other/specify) from the embedded 'Sites of Disease at Autopsy' picklist |

Version 9.0 Changes

| CRF | Changes in v9.0 |
|------------------------------|---|
| Disease Assessment RECIST | <ul style="list-style-type: none"> Updated screenshot Removed the field 'Response Assessment' Removed edit checks DAS06, DAS07 and DAS08 |

| | |
|--------------------------|--|
| Follow-up | <ul style="list-style-type: none"> Updated FLW06 Description and Resolution to replace 'Treatment' with 'Therapy' |
| Introduction | <ul style="list-style-type: none"> Added new item at the bottom of the Introductions page |
| Prior Therapy Supplement | <ul style="list-style-type: none"> Updated screenshot Added the field 'Non-Agent Prior Therapy' Added the edit checks PTS05 and PTS06 Removed mandatory flag from 'Agent Name' |
| Off Study | <ul style="list-style-type: none"> Updated screenshot Updated the Purpose section to account for the title change of the 'Off Treatment' CRF to 'Off Therapy', and the removal of "Other (Explain)" fields Updated occurrences of "treatment" to "therapy" Updated the picklist for 'Reason Off Study' Removed the field 'Explain 'Other' Reason' Removed validations OSS03, OSS18, OSS19 and OSS20 Updated the Descriptions and Resolutions for OSS01, OSS22, OSS23, OSS24, OSS25 and OSS27 |
| Off Therapy | <ul style="list-style-type: none"> Updated screenshot Updated CRF name from 'Off Treatment' to 'Off Therapy' Removed the field 'Explain 'Other' Reason Off Treatment' Updated the field name 'Date Off Treatment' to 'Date Off Therapy' Updated the field name 'Reason Off Treatment' to 'Reason Off Therapy' Updated the field name 'Best Response to Treatment' to 'Best Response to Therapy' Updated the picklist for 'Reason Off Therapy' Updated occurrences of "treatment" to "therapy" Removed validations OTS19, OTS20 and OTS21 Updated query texts for OTS05, OTS07, OTS08_28, OTS09_18, OTS16, OTS17 and OTS23 Removed occurrences of the code OTS09_18_1 |
| Survival | <ul style="list-style-type: none"> Updated screenshot Updated the Field Name 'Explain 'Other' Cause of Death (Presumed)' to 'Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify' Updated the Field Name 'Explain 'Other' Cause of Death (Autopsy)' to 'Explain 'Other' Cause of Death (Autopsy-determined) or CoMorbid Event, Specify' Updated the Descriptions of 'Cause of Death (Autops-determined)', 'Cause of Death (Presumed)', 'Explain 'Other' Cause of Death (Presumed)' or CoMorbid Event, Specify' and 'Explain 'Other' Cause of Death (Presumed) or CoMorbid Event, Specify' Updated the Formats of 'Cause of Death (Presumed)' and 'Cause of Death (Autopsy-determined)' Updated Descriptions and Resolutions for SUR04, SUR05, SUR06 and SUR07 |