

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	04.19.2024

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
 - o Extra information that is form specific.
- Screenshot of the CRF
- Field Information
 - Descriptions, Instructions, and Formats.
- Validations
 - o 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)

Table of Contents

Adverse Events	1
Arm and Cohort Assignment	18
Baseline Medical History	20
Baseline Symptom	23
Chimerism	28
Concomitant Measures/Medications	32
Consult	38
Course Assessment	40
Course Initiation	45
Diagnostic ECG	48
Disease Assessment Leukemia	52
Disease Assessment Neuro	56
Disease Assessment RECIST	64
Echo/MUGA	68
Enrollment	71
Extent of Disease - Lesions Identification	78
Extent of Disease - Lesions Measurements	81
Follow-up	87
Infection Episode	91
Labs	
Manually Entered Lab Forms	
Off Study	
Off Therapy	
Pathology Markers	
Pathology Report	
Pharmacokinetics	
Physical Exam - Cycles	
Physical Exam - Screening	
Prior Radiation Supplement	
Prior Surgery Supplement	
Prior Therapy Supplement	
Prior Treatment Summary	
Procedure	
Pulmonary Function Tests	149
Questionnaire	154

Radiation Treatment	157
RANO Disease Assessment	161
RECIST Extent of Disease - Lesion Identification	165
RECIST Extent of Disease - Lesion Measurement	169
Research Sample Collection	175
Study Med Admin	178
Subject Enrollment	185
Surgery	188
Survival	191
Urinary Excretion	196
Vital Signs	201
Vital Signs – Cycles	207
Vital Signs – Screening	214
Version Change Summary	219

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.

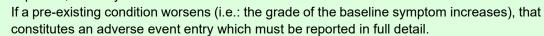
An adverse event entry is composed of both the adverse event term plus the grade. Complete a separate row for each adverse event entry to be recorded using the appropriate adverse event term and the appropriate codes for "grade", "attribution(s)", "serious", "action", "therapy", and "outcome" in the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

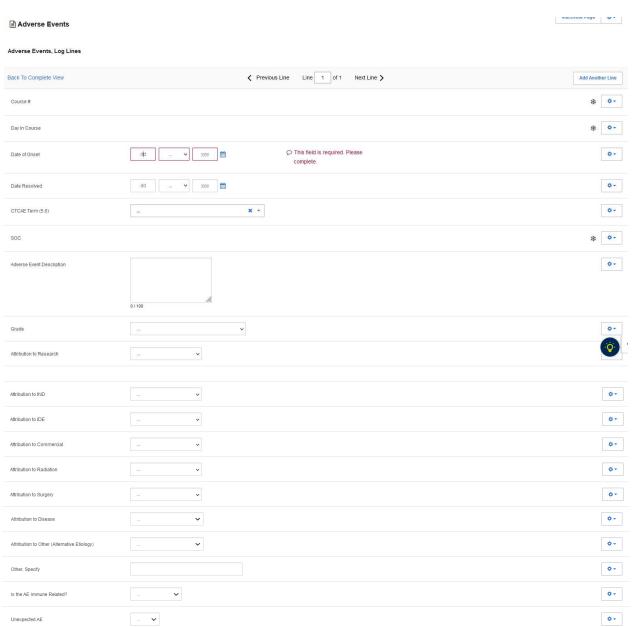
If a pre-existing condition resolves, it does not need to be reported as an adverse event since it would have been already recorded on the Baseline Symptoms case report form. Enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form improves, no entry is made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



If a pre-existing condition 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.

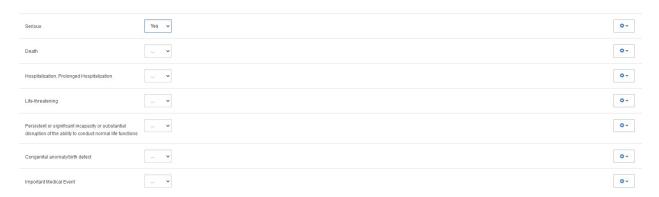
Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:







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



Field Descriptions and Instructions

Field Name	Description / Instructions	Format
Course # (d)	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.	Derived field.
Godieo n	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	J Silved III dia
Day in Course (d)	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.	Derived field.
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
	Enter the date of first observation of the adverse event and grade.	
Date of Onset (m)	If a subject died on study then the onset date and the resolve date for the death AE should be the same.	DD-MMM-YYYY
	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.	
Date Resolved	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.	DD-MMM-YYYY
	If a subject died on study then the onset date and the resolve date for the death AE should be the same.	
CTCAE Term (5.0) ^(m)	Using the pick list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term (v5.0).	Lloo piek liet
	In the absence of a specific adverse event term, choose the "Other" term from the appropriate general category and be sure	Use pick list.

Field Name	Description / Instructions	Format
	a meaningful adverse event description is entered in the "adverse event description" field. Dictionary Name - CTCAE5_TERM CTCAE5_TERM.pdf	
	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.	
	Note: Visit CTEP's CTCAE webpage for latest version.	
SOC (System	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.
Organ Class) ^(d)	Note: This field is derived from the selected CTC Term	Derived lield.
	Enter a succinct clinical description of the adverse event.	
Adverse Event Description	Note: This field is mandatory, unless the CTCAE term is the same as the description (e.g., nausea, diarrhea).	100 characters
	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.	

Field Name	Description / Instructions	Format
Grade (m)	Grade adverse events using Common Terminology Criteria for Adverse Events (CTCAE) version indicated in the protocol.	
	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 "-" verses a description.	Use pick list.
	If the protocol does not use either CTC or CTCAE, grade according to the following general criteria:	
	 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 	
	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:	
	Adverse Event UnrelatedAdverse Event Related	
Attribution to Research ^(m)	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: Attribution to Research must be the same as the highest Attribution to IND, IDE, Commercial, Surgery and Radiation.	
Attribution to IND	Evaluate the adverse event's relationship to the Investigational Agent. Select one of the following codes to record this evaluation:	Use pick list.
	Adverse Event Unrelated	

Field Name	Description / Instructions	Format
	Adverse Event Related	
	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	
	Evaluate the adverse event's relationship to the Investigational Device Exemption. Select one of the following codes to record this evaluation:	
	Adverse Event UnrelatedAdverse Event Related	
Attribution to IDE	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: This field is optional for some studies.	
	Evaluate the adverse event's relationship to the Commercial agent. Select one of the following codes to record this evaluation:	
	Adverse Event UnrelatedAdverse Event Related	
Attribution to Commercial	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: This field is optional for some studies.	
	Evaluate the adverse event's relationship to the Radiation therapy. Select one of the following codes to record this evaluation:	
Attribution to Radiation	Adverse Event UnrelatedAdverse Event Related	Use pick list.
	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	

Field Name	Description / Instructions	Format
	Note: This field is optional for some studies.	
	Evaluate the adverse event's relationship to the Surgery. Select one of the following codes to record this evaluation:	
	Adverse Event UnrelatedAdverse Event Related	
Attribution to Surgery	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: This field is optional for some studies.	
	Evaluate the adverse event's relationship to the disease. Select one of the following codes to record this evaluation:	
	Adverse Event UnrelatedAdverse Event Related	
Attribution to Disease	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: This field is optional for some studies	
	Evaluate the adverse event's relationship to other causes not listed above. Select one of the following codes to record this evaluation:	
Attribution to	Adverse Event UnrelatedAdverse Event Related	
Other (Alternative Etiology)	Note: In instances where protocols utilize the older 1-5 scale of attribution, please see the guidance and conversion scale below	Use pick list.
	Note: This field is optional for some studies	

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?	Indicate if adverse event is immune related by making a selection from the following list: • Yes • No • Unknown • Not Applicable • Not Done	Use pick list.
Unexpected AE	Indicate if the adverse event is unexpected as defined by the NCI IRB, by entering: • NO • YES	Use pick list.
AESI	Indicate if the adverse event is of special interest. • Yes • No • Unknown	Use pick list.
DLT (m)	Indicate if the adverse event is dose limiting, as defined in the protocol, by entering: • Yes • No 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. • Note: Mandatory for Phase I Clinical Trials.	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
	Regulations 21 Part 312. If multiple categories are applicable, select the worst.	
	Yes No	
	Indicate if the adverse event resulted in death.	
Death	Yes No	Use pick list.
Death	Note: This field is hidden if "Serious" is not answered "Yes".	OSC PION HOL.
	Inpatient hospitalization or prolongation of existing hospitalization	
Hospitalization, Prolonged Hospitalization	• Yes • No	Use pick list.
	Note: This field is hidden if "Serious" is not answered "Yes".	
Life-threatening	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. • Yes • No	Use pick list.
	Note: This field is hidden if "Serious" is not answered "Yes".	
Persistent or significant incapacity or	Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions • Yes	Use pick list

Field Name	Description / Instructions	Format
substantial disruption of the ability to conduct normal life functions	• No Note: This field is hidden if "Serious" is not answered "Yes".	
Congenital anomaly/birth defect	Congenital anomaly/birth defect definition / instructions / description • Yes • No Note: This field is hidden if "Serious" is not answered "Yes".	Use pick list
Important Medical Event	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. • Yes • No Note: This field is hidden if "Serious" is not answered "Yes".	Use pick list.
Action (m)	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. • Withdrawn • Dose reduced • Dose increased • Dose interrupted • Dose not changed • Unknown • Not Applicable	Use pick list.

Field Name	Description / Instructions	Format
	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.	
	Note: Interrupted also means therapy was delayed.	
	Indicate if additional therapy is required to treat the adverse event.	
Therapy ^(m)	 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) 	Use pick list.
	A corresponding entry of the therapy given to treat the adverse event must be recorded on the Concomitant Measures/Medication form.	
	Select the final status of the subject when the adverse event is considered "resolved".	
	 Recovered/Resolved Recovering/Resolving Not Recovered/Not Resolved/Ongoing Recovered/Resolved with Sequelae Fatal Unknown 	
Outcome	Note: For ongoing adverse events, leave this and the Resolution Date fields empty.	Use pick list.
	Note: For deaths on study, only the event which caused the death should have the outcome coded as "Fatal". The events that were still continuing at the time of the death would still be ongoing. Do not enter a resolved date, and outcome.	
Expedited Report to IRB? (m)	Indicate if an expedited adverse event report was sent to IRB by entering: • Yes	Use pick list.

Field Name	Description / Instructions	Format
	• No	
Expedited Report to Sponsor (m)	Indicate if an expedited adverse event report was sent to sponsor by entering: • Yes • No	Use pick list.
	Note: This field is optional for some studies.	

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."

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 CTCAE 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.

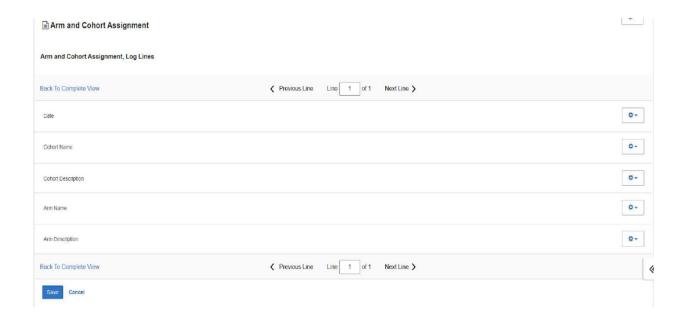
Arm and Cohort Assignment

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:





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."

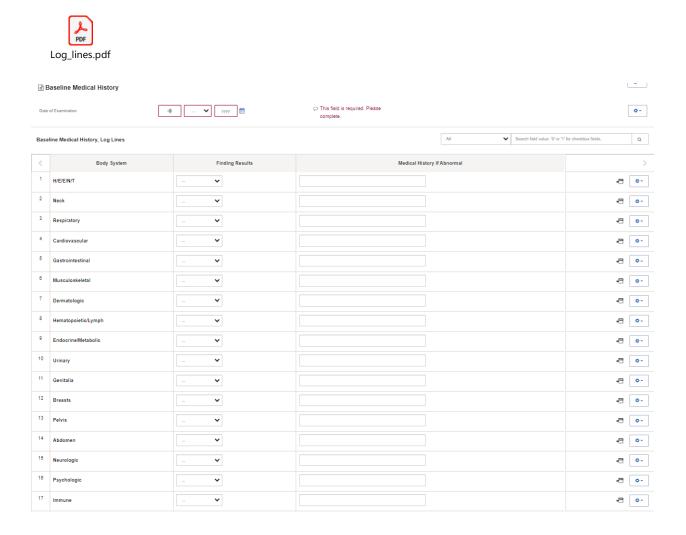
Code	Description	Resolutions
ARM01	Query will fire if there are duplicate Date(s) for Arm/Cohort assignment. "Two records have identical values for Date of Arm/Cohort assignment. Please correct."	Review Date in PRES.

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:



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)	Indicate whether the finding results for the particular body system were either: • Abnormal • Normal • Not Assessed • Not Applicable Comments are required for abnormal finding results. 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.	Use pick list.
Medical History if Abnormal	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). Enter the history for the appropriate body system to which the information refers. For "Other" indicate the body or organ system in the history.	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."

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

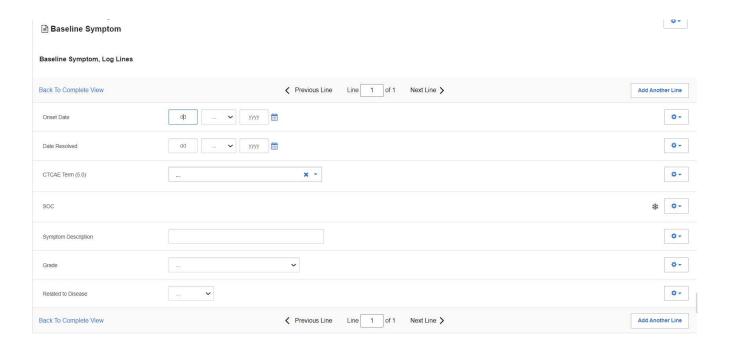
Purpose

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:





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)	Use the search list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term (v5.0). 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. Dictionary name – CTCAE5_TERM CTCAE5_TERM.pdf 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. Note: Visit CTEP's CTCAE webpage for latest version.	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.		

Field Name	Description / Instructions	Format
Symptom Description	Enter a succinct clinical description of the symptom.	
	Note: This field is mandatory for 'Other, Specify' CTCAE terms. For example: Immune system disorders - Other (Specify,).	100 characters
	It might be also used to further describe symptom such as "Eye pain" by entering "Left eye".	
Grade ^(m)	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: 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)	Indicate whether or not the symptom is related to the study disease by selecting one of the following options: • 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."

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

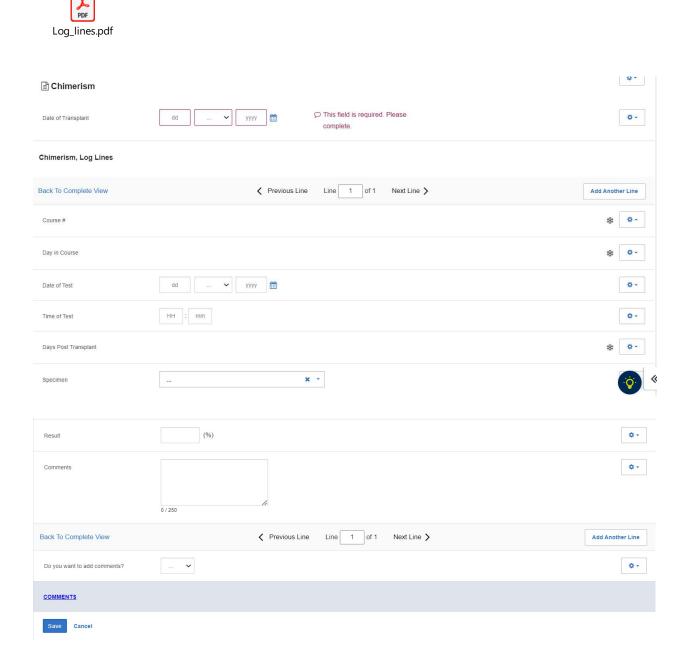
Code	Field Name	Description
AE1004	SOC Term	Broad classification of the CTC Adverse Event Term derived from the pick list selection.

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:



Field Descriptions and Instructions

Field Name	Description / Instructions	Format
Date of Transplant ^(m)	Date the transplant was performed.	DD-MMM-YYYY
Course # (d)	Indicates the course number the test is related to based on their date and the Course Initiation start dates. This is a derived field.	
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course ^(d)	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.	Derived field.
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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)	Select a specimen from the pick list. 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
	 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."

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

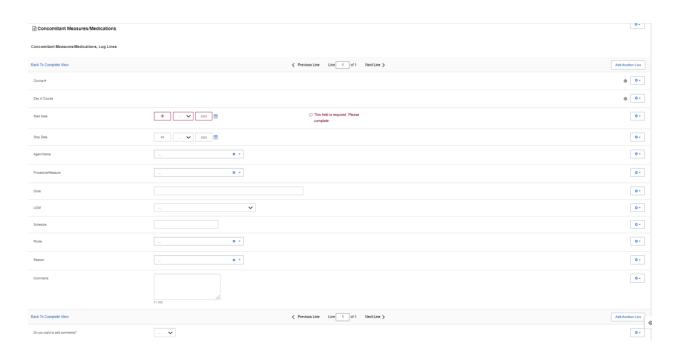
Purpose

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:





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
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	
Day in Course ^(d)	Indicates the day since the beginning of course that this concomitant measure / medication started as derived from the course initiation start date.	Derived field.
Day iii Course	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
	Enter the start date of the measure or medication.	
Start Date ^(m)	Note: Partial date is only acceptable for baseline measure or medication. Please enter UN for the "unknown" day value.	DD-MMM-YYYY
	Enter the stop date of the measure / medication.	
Stop Date	Note: Partial date is only acceptable for baseline measure or medication. Please enter UN for the "unknown" day value.	DD-MMM-YYYY
Agent Name	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). Dictionary Name - CONCOM_AGENTS_TH CONCOM_AGENTS_T H.pdf	Use pick list.

Field Name	Description / Instructions	Format
	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.	
	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.	
	Note: Do not select an agent name if a procedure has been entered.	
	If a procedure/measure, state e.g., oxygen administration, pleural tapping, etc.	
	Dictionary Name - CONCOM_PROCEDURES_TH	
Procedure /Measure	CONCOM_PROCEDU RES_TH.pdf	Use pick list.
	Note: Do not select a procedure if an agent name has been entered.	
	Enter the dose of the agent as appropriate.	
Dose	Note: This field is mandatory for agents. If a procedure/measure, leave blank.	100 characters
	In the case of combinations such as Bactrim, enter as single dose: Ex: Dose 1, Unit tab, schedule bid.	

Field Name	Description / Instructions	Format
	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.	
UOM	Select the total daily dose units of measurement. Dictionary Name - UOM_DOSE_TH_2 UOM_DOSE_TH_2.pd f Note: If a procedure/measure, leave blank.	Use pick list.
Schedule	Enter the frequency of medication administration or measure under schedule.	30 characters
Route	Select the route given. Dictionary Name – ACCESS_RTE_NM ACCESS_RTE_NM.pdf	Use pick list.
Reason ^(m)	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". Dictionary Name - CONCOM_REASONS_TH_2 CONCOM_REASONS _TH_2.pdf	Use pick list.
	Note: Do not enter the pharmacological classification of the medication (e.g., antibiotic, analgesic, etc.)	

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."

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

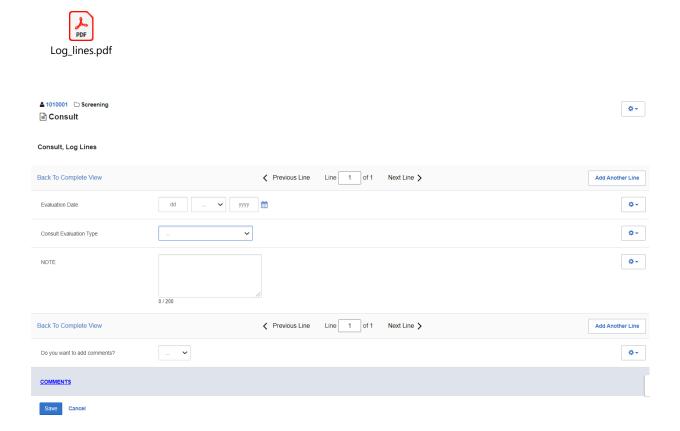
Code	Field Name	Description
CM1001_1002	Course #	Course number is derived based on the course initiation start dates and the concomitant measure / medication start date.
CM1001_1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the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



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: • ANESTHESIOLOGY • AUDIOLOGY • CARDIOLOGY	Use pick list.

Field Name	Description / Instructions	Format
	 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.

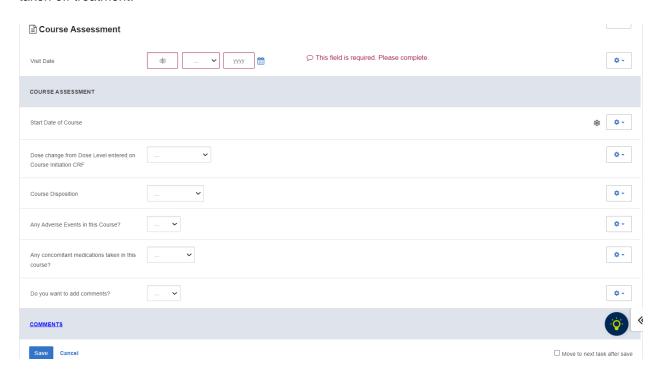
If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

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.



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
	Note: optional for non-CTEP sponsored studies.	
	 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)	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: • Completed • Discontinued	Use pick list.
Any Adverse Events in this Course? (m)	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.	Use pick list.
	Events case report form.	
Any concomitant medications taken in this course? (m)	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.	Use pick list.

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

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

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	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."	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.
CAS11	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."	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.
CAS12	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."	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.

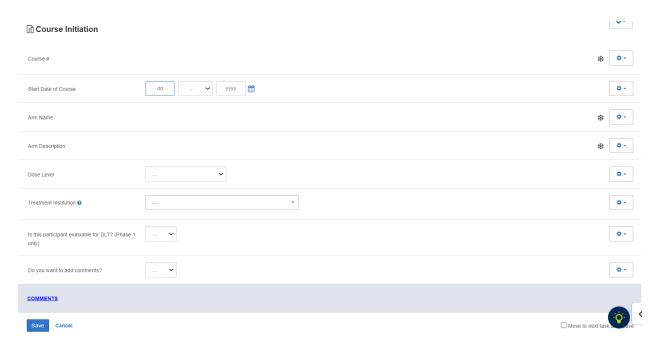
Derivations

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.



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	Select the appropriate code for the subject's treatment assignment Dose Level as specified.	Use pick list.

Field Name	Description / Instructions	Format
	Note: This is a study specific picklist.	
	"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.	
	Select the unique CTEP institution code where the subject actually receives this course of treatment.	
Treatment Institution (m)	Note: This is a study specific picklist.	Use pick list.
	Note: Optional for non-CTEP sponsored studies.	
	Select whether the participant is evaluable for DLT.	
Is this participant evaluable for DLT? (Phase 1 only) (m)	YesNo	Use pick list.
	Note: This field will only be visible for Phase I studies.	

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

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.

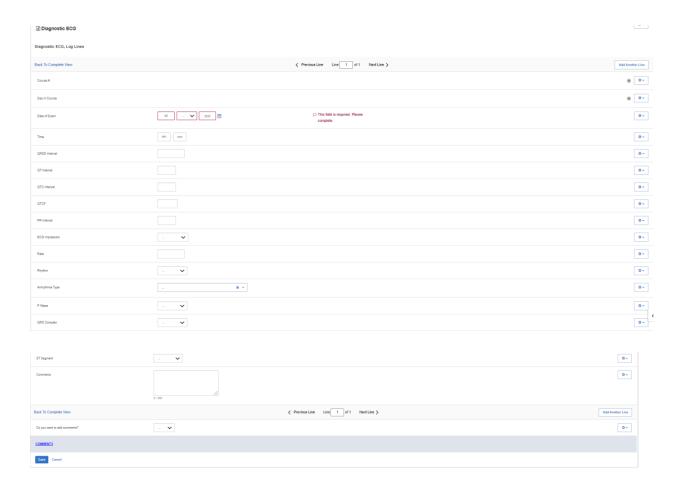
Diagnostic ECG

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:





Teld Descriptions and instructions			
Field Name	Description / Instructions	Format	
	Indicates the course number the ECGs are related to based on their date and time. This is a derived field.		
Course # ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.	
Day in Course (d)	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.	Derived field.	
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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	Select one of the following summary findings: • Abnormal	Use pick list.	

Field Name	Description / Instructions	Format
	Normal Borderline	
Rate ^(m)	Enter the subject's pulse rate.	5 digits and 3 decimals
Rhythm (m)	Select one of the following rhythm findings: 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: • Abnormal • Normal	Use pick list.
QRS Complex	Select one of the following QRS Complex finding: • Abnormal • Normal	Use pick list.
ST Segment	Select one of the following ST Segment finding: • 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.

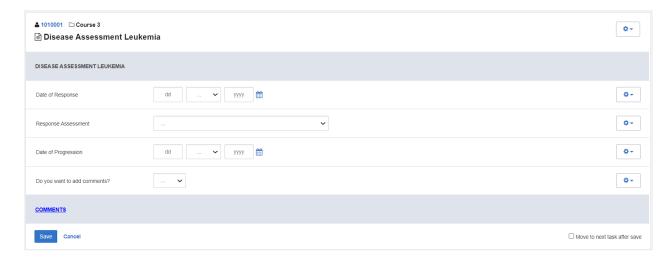
Derivations

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.



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 subject's disease was assessed and deemed to be Not Evaluable. Note: The original date of onset of response should be used for responses that persist through several courses.	DD-MMM-YYYY
Response Assessment (m)	Select the subject's best disease state as assessed during the course. This determination must be adequately documented in the subject's medical record. NE: Not Evaluable - State the reason in the "Response Note" field. NA: NOT ASSESSED - State the reason in the "Response Note" field. NP: Not Applicable per protocol - Protocol does not require	Use pick list.

Field Name	Description / Instructions	Format
	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.	
	Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed:	
	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. PR or MR: Partial Response or Marginal Response - Response is assessed relative to the baseline at start of treatment, 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. SD: Stable Disease - Tumor growth or shrinkage since the start of treatment 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. PD: Progressive Disease - Response relative to the best disease status (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". 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.	
	For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria. MX: Mixed Response RP: Response NR: No Response	
	*RECIST: *Many protocols specify that the following RECIST criteria be used in assessing response. Please use the following selections when assessing response using RECIST criteria only.	

Field Name	Description / Instructions	Format
	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)	
	Evaluation of target lesions: 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.	
	Evaluation of non-target lesions: 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.	
	Dictionary Name – RESPS_ASSMNT	
	RESPS_ASSMNT.pdf	

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

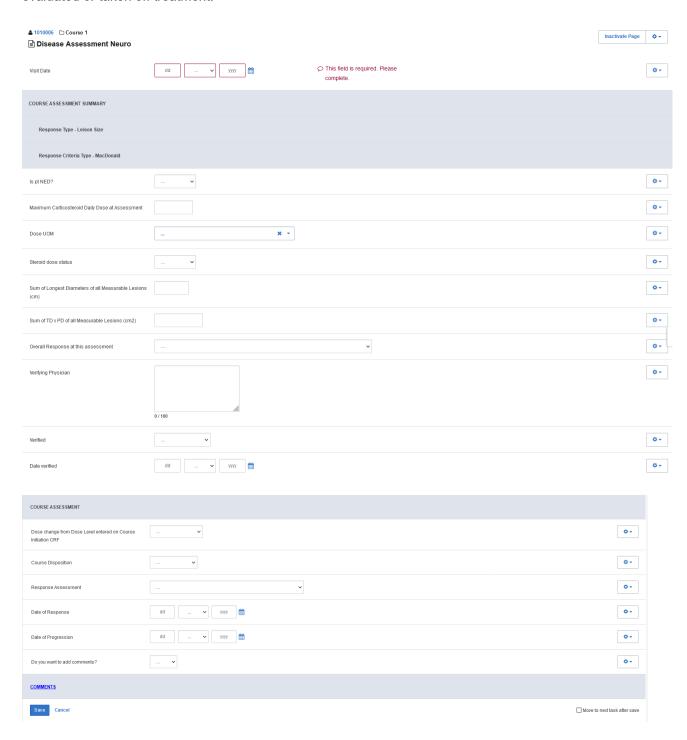
If field marked "(m) EDC mandatory" is empty the query will fire comment "This field is required. Please complete."

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.



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: 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: 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 (cm2)	Enter numeric value of total sum of products (transverse diameter multiplied by perpendicular diameter) for all measurable lesions described in square centimeters (cm2).	12 digits and 3 decimals

Field Name	Description / Instructions	Format
Overall Response at this assessment	 Enter Overall Response at this assessment. Choose an option from the list: 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	Choose an option from the list: Confirmed Needs Revision	Use pick list.
Date verified	Enter the Date of verification by Physician	DD-MMM-YYYY

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)	whether this was planned or unplanned, and record the reason, e.g. dose reduction due to toxicity, on the Comments tab of this CRF.	
	Note: optional for non-CTEP sponsored studies.	
	 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)	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: • Completed • Discontinued	Use pick list.
Response Assessment (m)	Select the subject's best disease state as assessed during the course. This determination must be adequately documented in the subject's medical record. NE: Not Evaluable - State the reason in the "Response Note" field. NA: NOT ASSESSED - State the reason in the "Response Note" field. NP: Not Applicable per protocol - Protocol does not require 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.	Use pick list.

Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed: 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	Field Name	Description / Instructions	Format
confirmed by repeat assessments to demonstrate a disappearance of all evidence of disease. PR or MR: Partial Response or Marginal Response - Response is assessed relative to the baseline at start of treatment, 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. SD: Stable Disease - Tumor growth or shrinkage since the start of treatment 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. PD: Progressive Disease - Response relative to the best disease status (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". 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. For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria. MX: Mixed response RP: Response NR: No Response *RECIST: *Many protocols specify that the following RECIST criteria be used in assessing response. Please use the following selections when assessing response using RECIST criteria only.		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. PR or MR: Partial Response or Marginal Response - Response is assessed relative to the baseline at start of treatment, 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. SD: Stable Disease - Tumor growth or shrinkage since the start of treatment 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. PD: Progressive Disease - Response relative to the best disease status (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". 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. For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria. MX: Mixed response RP: Response NR: No Response *RECIST: *Many protocols specify that the following RECIST criteria be used in assessing response. Please use the following selections when assessing response using RECIST	

Field Name	Description / Instructions	Format
	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)	
	Evaluation of target lesions: 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.	
	Evaluation of non-target lesions: 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.	
	Dictionary Name – RESPS_ASSMNT	
	RESPS_ASSMNT.pdf	

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

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

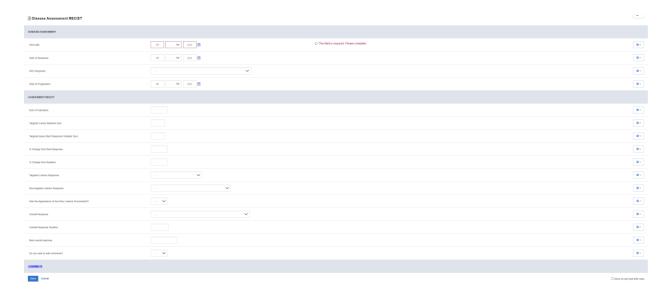
Code	Description	Resolutions
Medidata System Checks	Query will fire if Date verified / Date of Response / Date of Progression is a future date. "Future date has been entered. Please correct."	Change the date to a value no later than the current date.
NAS06	Response Assessment is "Not Evaluable" or "Not 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 Name	Description / Instructions	Format
Visit Date (m)	Enter the date the course started.	DD-MMM-YYYY
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 subject's disease was assessed and deemed to be Not Evaluable.	DD-MMM-YYYY
	Note: The original date of onset of response should be used for responses that persist through several courses.	

Field Name Description / Instructions		Format
irRC Response	 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	Response Target Lesions	
% 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	Select the response of targeted lesions from the picklist: CR: Complete Response NE: Inevaluable or not all evaluated PD: Progressive Disease PR: Partial Response SD: Stable Disease	Use picklist.
Non-targeted Lesions Response	Select the response of the non-targeted lesions from the picklist: 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?	Select 'Yes' or 'No' to record if the appearance of any new lesions was documented. • Yes • No	Use picklist.
Overall Response	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): 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	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.)	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



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

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.

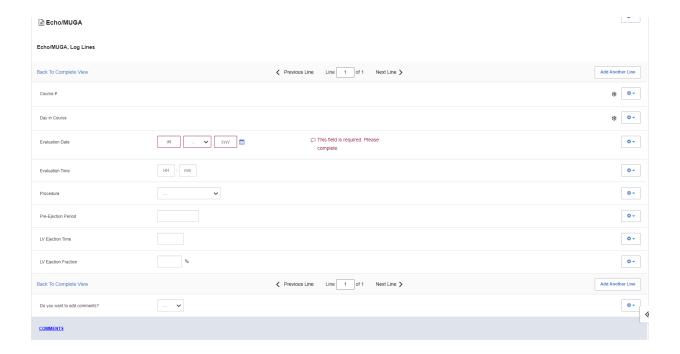
Echo/MUGA

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:





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
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	
Day in Course ^(d)	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.	Derived field.
Buy iii Godioo	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field:
Evaluation Date	Enter the date the procedure was performed.	DD-MMM-YYYY
Evaluation Time	Enter the time the procedure was performed.	HH(24):MM
Procedure (m)	Select one of the following procedures from the pick list:	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

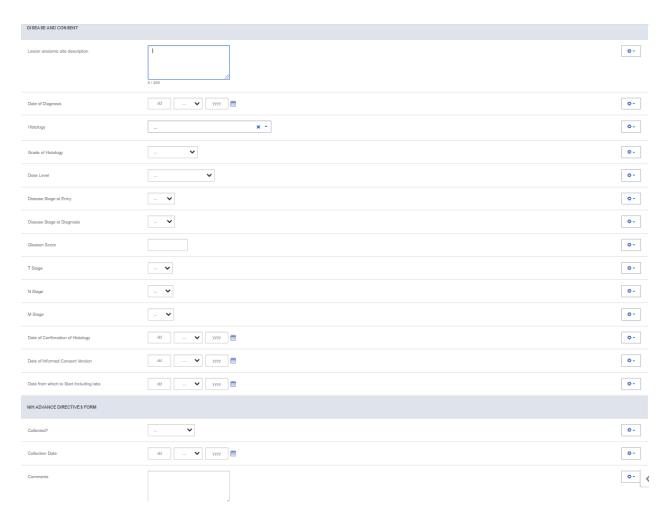
Code	Field Name	Description	
EM1001_1002	Course #	Course number is derived based on the course initiation start dates and the Evaluation Date.	
EM1001_1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the Evaluation Date.	

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.



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	Select the type of histology, Malignant Neoplasm Diagnosis, found at the time of original diagnosis Dictionary Name - MAL_NEO_DX_HIST_NM MAL_NEO_DX_HIST_ NM.pdf	Use pick list.
Grade of Histology	Enter the grade of histology at study entry, if appropriate. Leave it blank otherwise. Make a selection from the list: Unknown Well Moderately Poorly N/A Low Grade High Grade Undifferentiated NOS Not Done Note: Grade of Histology is the Gleason Score for Prostate Subject.	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
	Note: This is a study specific picklist.	
Disease Stage at Entry	Select the stage of the disease at the time of study entry if appropriate. Otherwise, leave it blank. IA IB III III IV DO DO D1 D2 D3 IIA IVA IVB A IVB A IB IIB IIIA IIB IIIA IIIB IIIC IIIE IIE IIC IIC IIC IVC	Use pick list.
Disease Stage at Diagnosis ^(m)	Select the stage of the disease at the time of diagnosis. IA IB III III DO DO D1 D2	Use pick list.

Field Name	Description / Instructions	Format
	 D3 IIA IVA IVB A B C D 0 IIB IIIA IIIB IIIC IE IC IIC IIC IIC IC IC IVC 	
Gleason Score	Enter subject's Gleason Score value	6 characters
Disease T Stage	Select the stage of disease based on the primary tumor. • T0 • T1 • T2 • T3 • T4 • TX	Use pick list.
Disease N Stage	Select the stage of disease based on the nodes present. • N0 • N1 • N2 • N3 • NX	Use pick list.
Disease M Stage	Select the stage of disease based on the metastases present. • 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	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 entitle: "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	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.	of lab data from usually prior to de the lab results DD-MMM-YYYY for subjects with r NIH as part of
Including Labs	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).	

Field Descriptions and Instructions

Enrollment - NIH Advance Directives Form

Field Name	Description / Instructions	Format
Collected?	 Has the form been collected? 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."

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.

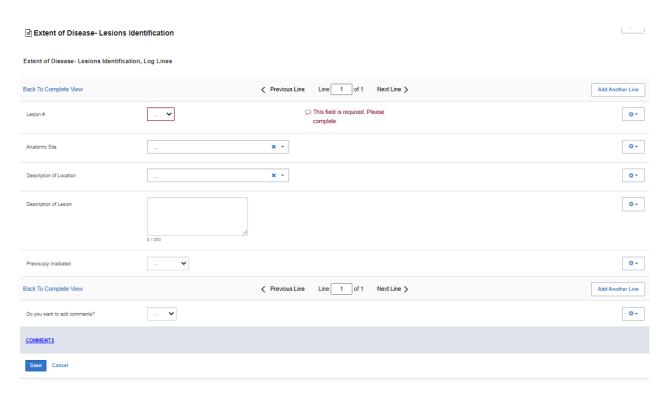
Extent of Disease - Lesions Identification

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:





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
	Note: This lesion number must appear at least once on the bottom repeating group.	
Anatomic Site	Select the anatomic position where the lesion is located, i.e., Lung, Skull, etc. Dictionary Name – ANAT_SITE_NM ANAT_SITE_NM.pdf	Use pick list.
Description of Location (m)	Select a brief description of the lesion location. Dictionary Name - LOC_DESCRPTR_TXT_NM LOC_DESCRPTR_TXT _NM.pdf	Use pick list.
Description of Lesion	If applicable, enter a brief description of each lesion, e.g., cystic, well-defined, encapsulated, necrotic appearing center.	200 characters
Previously Irradiated ^(m)	If the site or lesion has previously been irradiated, select "Yes", otherwise enter "No" or "Unknown". • 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."

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).

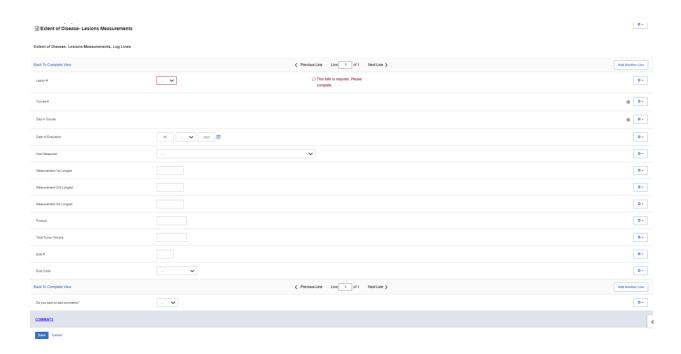
Extent of Disease - Lesions Measurements

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:





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

Field Name	Description / Instructions	Format
	Indicates the course number that this lesion evaluation was done in as derived from the course initiation start date. This is a derived field.	Derived field.
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course	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.	Derived field.
(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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	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. 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)	Use pick list.

Field Name	Description / Instructions	Format
	ELECTRON BEAM TOMOGRAPHY EBT: ELECTRON BEAM TOMOGRAPHY EBT EGD: Esophagogastroduodenoscopy MSWAT: Modified Severity Weighted Assessment Tool	
	Enter the longest lesion measurement in centimeters.	
Measurement- 1st Longest	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.	6 digits and 2 decimals
	Enter the second longest lesion measurement in centimeters.	
Measurement- 2nd Longest	Note: Not applicable for studies that use RECIST criteria.	6 digits and 2 decimals
	Enter the third longest lesion measurement in centimeters.	
Measurement- 3rd Longest	Note: Not applicable for studies that use RECIST criteria.	6 digits and 2 decimals
Product	Enter the tumor product which is the multiplication of the First and Second Longest Measurements.	8 digits and 2 decimals
Total Tumor Volume	Enter the total tumor volume which is the multiplication of all three measurements.	8 digits and 2 decimals
Eval # (m)	Number each evaluation sequentially for each lesion. Use 0 for the baseline evaluation, 1 for the first evaluation, 2 for the second evaluation, etc.	2 digits

Field Name	Description / Instructions	Format
	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.	
Eval Code	Select the status of non-measurable lesions at the time of each evaluation. 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	Query will fire if Date of Evaluation is in the future. "Future date has been entered. Please correct."	Change the date to a value no later than the current date.

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

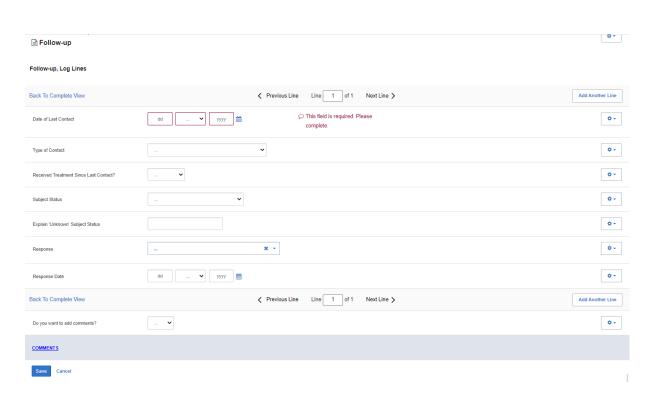
Purpose

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:





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	Select how the information was obtained: 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.
	Enter an explanation for selecting "Other" for Type of Contact.	
Explain 'Other' Type of Contact	Note: This field is invisible unless "Type of Contact" is answered with 'Other'.	50 characters
Received Treatment Since Last Contact? (m)	If the subject has received further treatment since the last contact, select No Yes Unknown	Use pick list.
Subject Status	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)". 1: Alive With Disease 2: Alive With No Evidence of Disease 3: Alive Disease Status Unknown	Use pick list.

Field Name	Description / Instructions	Format
	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 where made in order to obtain the subject's status (i.e.: no response to 5 messages left).	24 characters
Response (m)	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. Dictionary Name - RESPS_ASSMNT RESPS_ASSMNT.pdf	Use pick list.
Response Date	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.	DD-MMM-YYYY
(m)	Note: The original date of onset of response should be used for responses that persist through several courses.	



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.

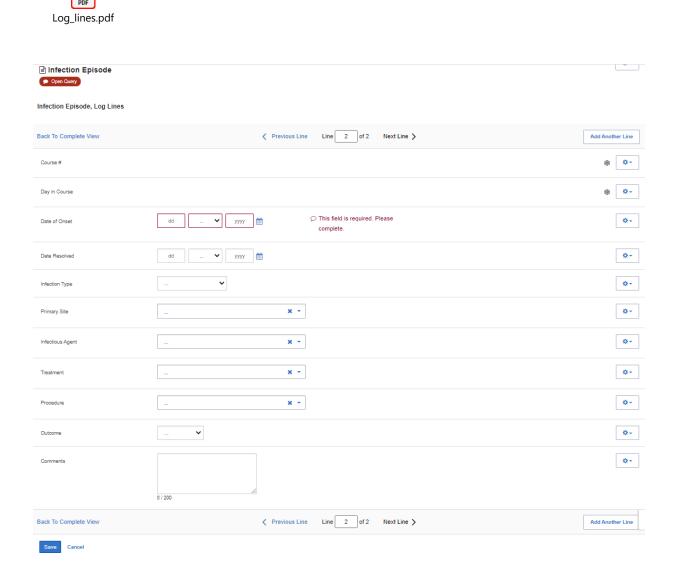
Code	Description	Resolutions
Medidata System Checks	Query will fire if Date of Last Contact or Response Date is in the future. "Future date has been entered. Please correct."	Enter a date earlier than, or equals to, the current date.
FLW06	Query will fire if Date of Last Contact is not within the Date 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".

Infection Episode

Purpose

Record information summarizing episodes of infection associated with treatment. This case report form is only to be used when the primary endpoint for the study is to assess infectious episodes, either types and or number of events. Additional comments may, if needed, be reported in the comment tab.

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



Field Name	Description / Instructions	Format
Course # (d)	Indicates the course number that this infection episode occurred in as derived from the course initiation start date. This is a derived field. Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course ^(d)	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. Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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)	Select the infection type. For example: pneumonia, UTI, URI, etc. 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_PROCEDU RES_TH.pdf	Use pick list.
Outcome	Select the outcome of this episode: 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."

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	

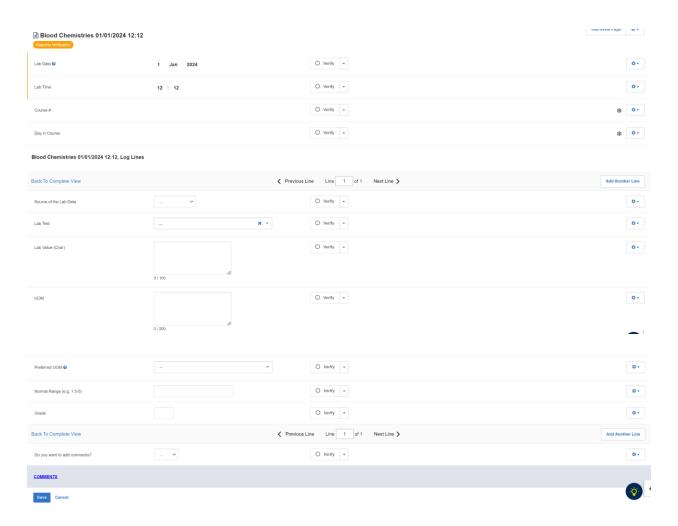


Appendix III - Lab Panels.pdf

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



Log_lines.pdf



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
	The lab sample collection time in military format (24 hours). This field is populated through lab loader or the CRF 'Add Lab Form'. Ex: 13:56 (for 1:56 PM)	
Lab Time ^(m)	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. There is no way to indicate an 'unknown' lab time right now.	HH(24):MM

Field Name	Description / Instructions	Format
	Indicates the course number that this lab started, as derived from the course initiation start date.	
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
	Indicates the day since the beginning of course that this lab started, as derived from the course initiation start date.	
Day in Course (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Source of the Lab Data	Select the source of the lab results. Dictionary name – Lab_Source	
	Lab_Source.pdf	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.
	Enter the preferred unit of measurement for the specified lab test.	
Preferred UOM	Lab Units of Measurement.pdf	Use pick list.

Field Name	Description / Instructions	Format
Normal Range (e.g. 1.5-5)	For labs loaded from the MIS/CRIS system, the range is automatically populated. For labs obtained outside the NCI Clinical Center, enter the appropriate normal range.	30 characters.
Grade	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. 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.

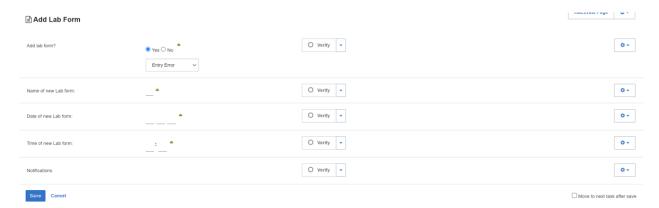
Code	Description	Resolutions
Medidata System Checks	Query will fire if Lab Date is in the future. "Future date has been entered. Please correct."	Enter a date that is earlier or equals to the current date.
LB04	Query will fire if Lab Value (Char) and UOM do not present together. "Lab Value (Char) and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

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 Name	Description / Instructions	Format
Add lab form?	Choose whether you want to add an additional lab form. • 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

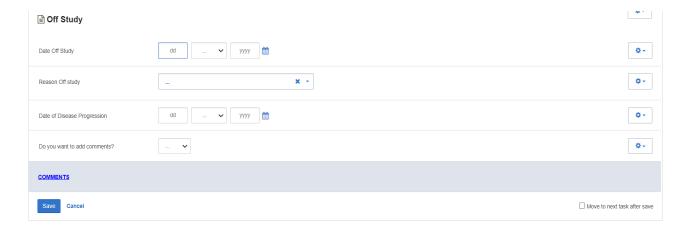
Purpose

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 Name	Description / Instructions	Format
Date Off Study	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.	
(m)	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
	date must be the same as the Date Off Therapy entered on the Off Therapy case report form.	
	The date off study will correspond to a progress note in the medical record stating that the subject has been taken off study.	
	For protocols without a protocol specific follow-up, use the same 'Reason Off Therapy entered on the Off Therapy case report form.	
	For protocols with a follow-up period, the following off study reasons are also available.	
	Dictionary name - OFF_TX_RSN_THRX_STD_34	
	OFF_TX_RSN_THRX_ STD_34.pdf	
Reason Off Study ^(m)	 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 Off Study - 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.

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".

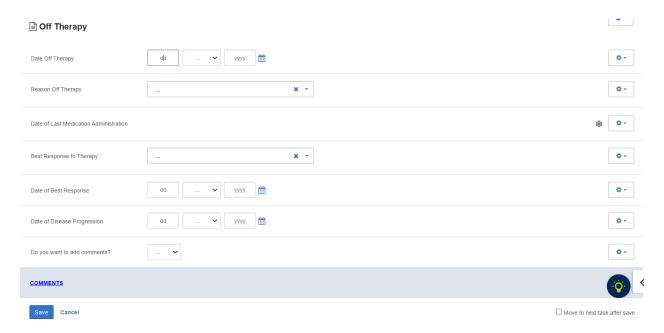
Code	Description	Resolutions
OSS24	Query will fire if Off Therapy Date of Disease Progression is blank, Off Study Date of Disease Progression doesn't fall between the Date Off Therapy and Date Off Study. "Off Therapy Date of Disease Progression is blank, Off Study Date of Disease Progression doesn't fall between the Date Off Therapy and Date Off Study. Please correct."	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.
OSS25	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."	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.
OSS27	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."	Enter the Off Therapy Date on Off Therapy form.

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.



Field Name	Description / Instructions	Format
Date Off Therapy	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 precourse 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
	OFF_TX_RSN_THRX_STD_20.pdf 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)	Select the best overall response to therapy while on protocol. 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
	For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria. • MX: Mixed Response • NR: No Response • RP: Response	
	According to RECIST and WHO guidelines this would be the best response assessed from the start of therapy until disease progression.	
	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.	
	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.	
	RECIST: Unless the protocol includes specific response evaluation criteria, the following RECIST and WHO guidelines should be observed:	
	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.	
	A response of PD is relative to the best disease status (smallest tumor measurement) since therapy began. Thus, a tumor regrowth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a CR.	
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
	Enter the date that progression (or relapse) was first observed (i.e.: date of scan). This date is required if the Reason for Off Therapy is for Disease Progression.	
Date of Disease Progression	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.	DD-MMM-YYYY
	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).	

✓ 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."

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.

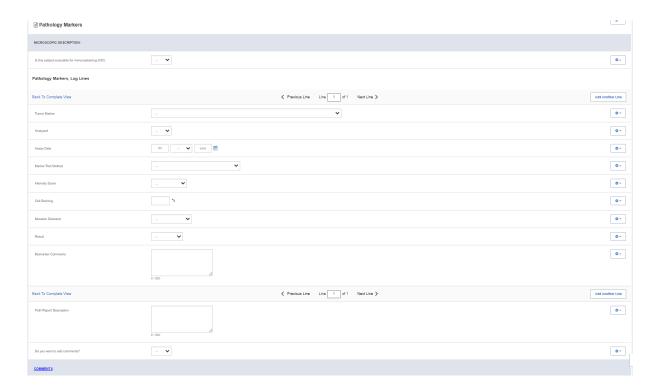
Pathology Markers

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:





Pathology eCRF - Microscopic Description

Field Name	Description / Instructions	Format
Is this subject evaluable for immunostaining (IHC)	Select an option from the list: 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: • 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: • ELISA • FLUORESCENCE IN SITU HYBRIDIZATION (FISH) • IMMUNOHISTOCHEMISTRY (IHC)	Use pick list.
Intensity Score	Select an intensity score from the picklist: • 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: INDETERMINATE NO	Use pick list.

Field Name	Description / Instructions	Format
	• YES	
Result	Select an option from the picklist: • 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."

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

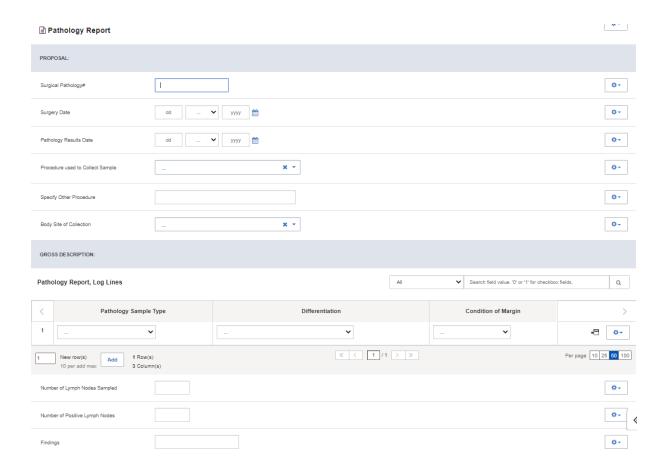
Pathology Report

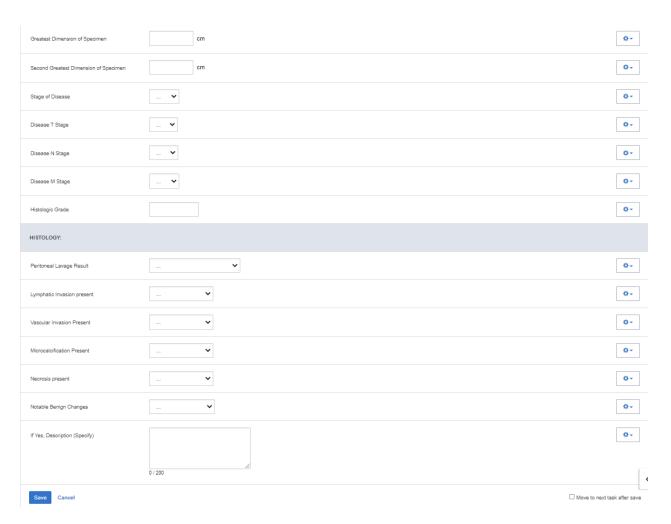
Purpose

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:







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: HIGH GRADE: HIGH GRADE LOW GRADE: LOW GRADE	Use pick list.

Field Name	Description / Instructions	Format
	MODERATELY: MODERATELY DIFFERENTIATED N/A: NOT APPLICABLE POORLY: POORLY DIFFERENTIATED WELL: WELL DIFFERENTIATED	
Condition of Margin	Select a margin condition from the picklist: 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 O IIA IIB IIIA IIIB IIIC	Use pick list.

Field Name	Description / Instructions	Format
Disease T Stage	Select the stage of disease T0 T1 T2 T3 T4	Use pick list.
Disease N Stage	Select the stage of disease N0 N1 N2 N3	Use pick list.
Disease M Stage	Select the stage of disease • 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: • 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: • INDETERMINATE • NO • YES	Use pick list.
Vascular Invasion Present	Select the condition of vascular invasion from the picklist: INDETERMINATE NO YES	Use pick list.
Microcalcification Present	Select the condition of microcalcification from the picklist: • INDETERMINATE • NO • YES	Use pick list.
Necrosis present	Select the condition of necrosis from the picklist: INDETERMINATE NO YES	Use pick list.
Notable Benign Changes	Select an option from the picklist: 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."

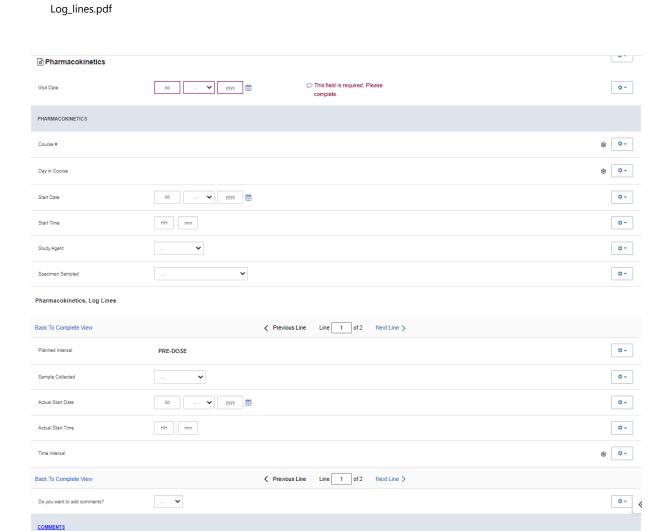
Code	Description	Resolutions
Medidata System Checks	Query will fire if Surgery Date / Pathology Results Date is in the future. "Future date has been entered. Please correct."	Enter a date that is equal to or prior to the current date

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:



Field Name	Description / Instructions	Format
	Enter the date the form was completed.	
Visit Date ^(m)	Note: If the information was obtained at multiple visits, please enter the date the form was completed.	DD-MMM-YYYY
	Course number derived from the study agent start date and course initiation start dates. This is a derived field.	
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course ^(d)	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.	Derived field.
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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
	Enter the name of the study agent (investigational or commercial) which is the subject of the pharmacokinetic study.	
Study Agent ^(m)	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.	Use pick list.
Specimen Sampled ^(m)	Select the body fluid that is being collected for the biological samples. Abdominal Effusion	Use pick list.

Field Name	Description / Instructions	Format
	 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)	Indicate whether or not the specimen is collected. 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."

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	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."	Verify that the pharmacokinetics study agent administration is recorded on the study medication form.	
	Note: Study Medications with the following routes are ignored: PO, CIV and Topical.		
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.	

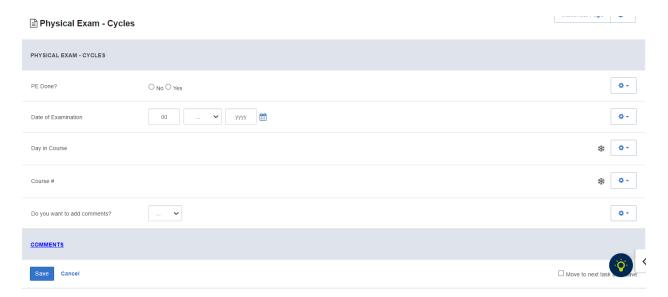
Derivations

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.



Field Name	Description / Instructions	Format
PE Done? (m)	Indicate whether the physical examination was performed: 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.	Dorived field
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.

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



Field Descriptions and Instructions

Field Name	Description / Instructions	Format
PE Done? (m)	Indicate whether the physical examination was performed: • No • Yes	Use radio buttons.
Date of Examination	Enter the date the physical examination took place.	DD-MM-YYYY



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

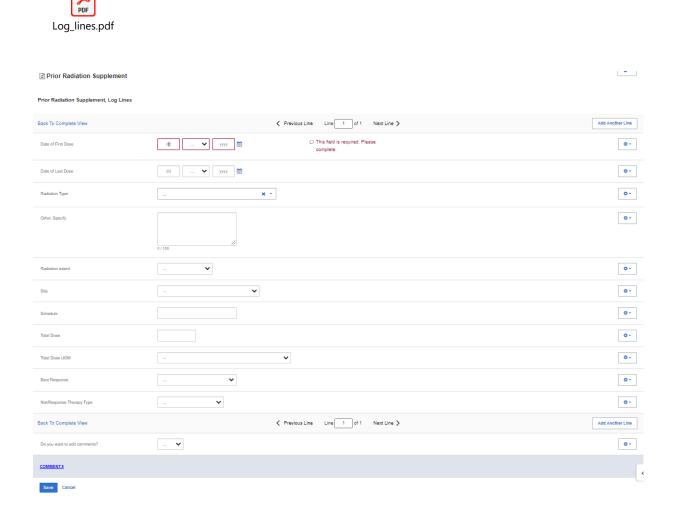
Code	Description	Resolutions
Medidata System Checks	Query will fire if Date of Examination is in the future. "Future date has been entered. Please correct."	Enter an earlier date.
PE07	Query will open if PE is done but the Date of Examination is not provided. "PE is done but the Date of Examination is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

Prior Radiation Supplement

Purpose

Record details of prior radiation therapy related to the disease being studies 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:



Field Name	Description / Instructions	Format
Date of First Dose	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. 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 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	Select the extent of the radiation therapy as follows: • Extensive Radiation • Limited Radiation	Use pick list.

Field Name	Description / Instructions	Format
	Radiation (NOS)	
Site (m)	Select the site of the radiation therapy. Dictionary name - RT_ANAT_SITE_NM RT_ANAT_SITE_NM.p df	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	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.pd f	Use pick list.
Best Response	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. 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	Select the therapy type for which the conventional response calls are not appropriate. • 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."

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.

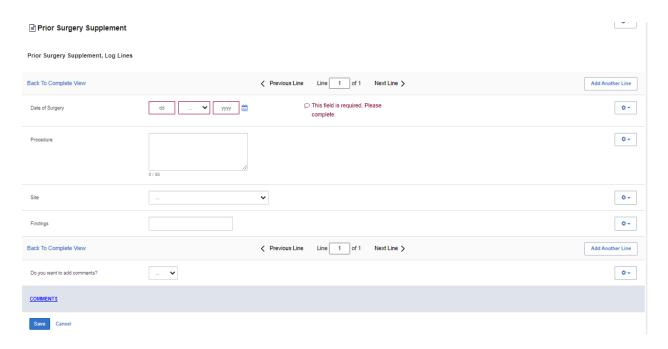
Prior Surgery Supplement

Purpose

Record details of prior surgery related to the disease being studies 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:





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)	Select the anatomical site of the procedure. Dictionary name - BODY_SITES_TH BODY_SITES_TH.pdf	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."

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.

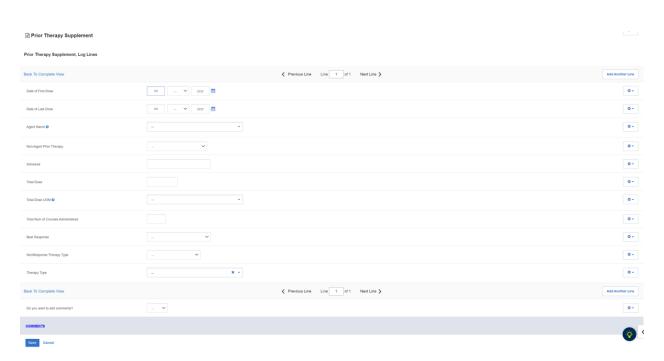
Prior Therapy Supplement

Purpose

Record details of prior therapies related to the disease being studies 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:





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

Field Name	Description / Instructions	Format
Date of Last Dose	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 Please enter UN for the "unknown" day value.	DD-MMM-YYYY
Agent Name	Select the generic name of the agent that was used. Note: For standard regimen (multiple agents given as one regimen), enter one record for each agent.	
	Dictionary name - THERAPY_AGENTS_2 THERAPY_AGENTS_2. pdf	Use pick list.
Non-Agent Prior Therapy	Select a non-agent therapy from the list: Phototherapy Photodynamic Therapy Tumor Treating Fields Therapy	Use pick list.
	This field will only be available for NCINOB studies.	
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	Enter the total dose units of measurement. Dictionary name – UOM_DOSE_TH_2	Use pick list.

Field Name	Description / Instructions	Format
	UOM_DOSE_TH_2.pd	
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: 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. • 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."	Only one of Agent Name or Non-Agent Prior Therapy should be entered.	
	This validation will only be applicable to NCINOB studies.		
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 studies by the protocol.

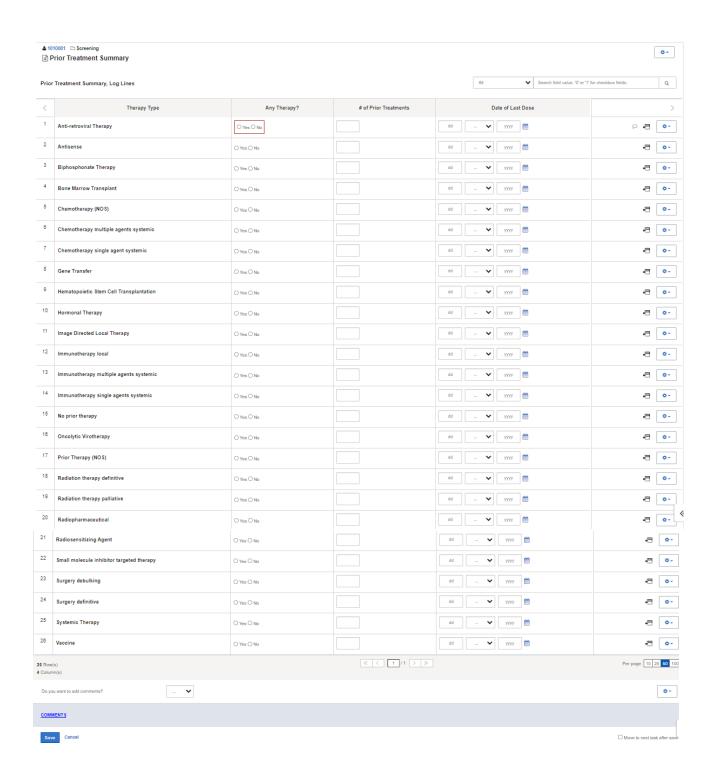
Details must be provided for the following on the appropriate Prior Therapy Case Report Form:

- 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



Field Descriptions and Instructions

Field Name	Description / Instructions	Format
	Name of the type of therapy.	
Therapy Type	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.	Text
Any Therapy? (m)	Indicate whether or not the subject has received any prior treatment for the type of therapy listed. • Yes • No	Use radio buttons.
# of Prior Treatments	Enter the number of prior regime types of therapies received.	2 digits
Date of Last Dose	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. For combination therapies, record the date of the last dose of medication for the combination.	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 regiments 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.

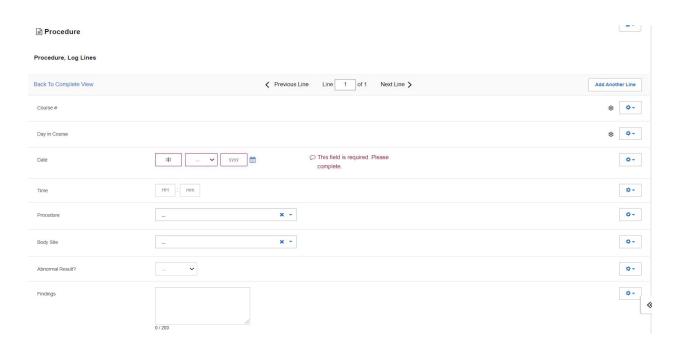
Procedure

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:





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

Field Name	Description / Instructions	Format
Day in Course	Indicates the day since the beginning of course the procedure is related to based on their date and time. This is a derived field.	
(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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)	Select the procedure from the pick list. Dictionary Name - NCI_PROCEDURES NCI_PROCEDURES.p df	Use pick list.
Body Site ^(m)	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. Dictionary Name - BODY_SITES_TH	Use pick list.
Abnormal Result? ^(m)	Select whether the finding results for the particular procedure / body site were either: 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.

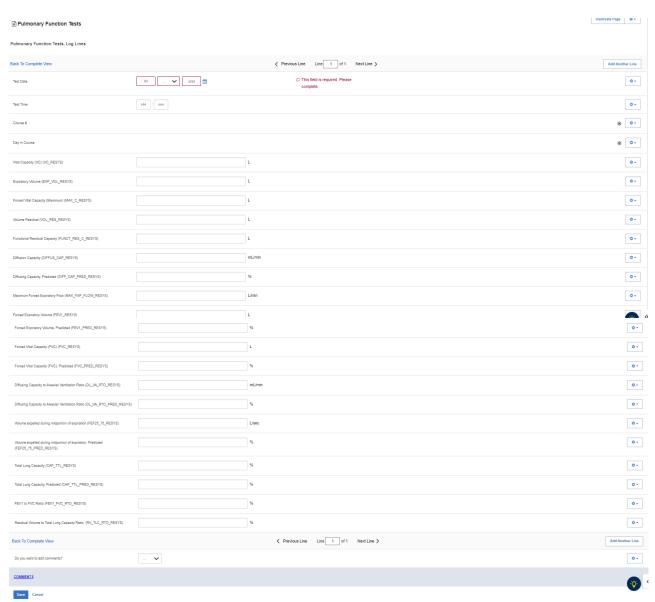
Pulmonary Function Tests

Purpose

Record the Pulmonary Function Test date and related test results.

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





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
	Indicates the course number the test is related to based on their date and the Course Initiation start dates. This is a derived field.	
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
	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.	Derived field.
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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_RESY S)	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.

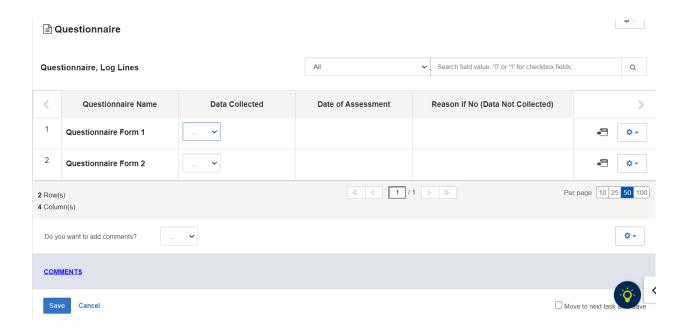
Questionnaire

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:





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
	Yes No	
	Enter the planned date of assessment.	
Date of Assessment (m)	Note: This field is invisible unless "Data Collected" is answered with 'Yes'.	DD-MMM-YYYY
Reason if No (Data Not Collected)	Enter description of reason if the questionnaire was not collected.	
	Note: This field is invisible unless "Data Collected" is answered with 'No'.	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'.

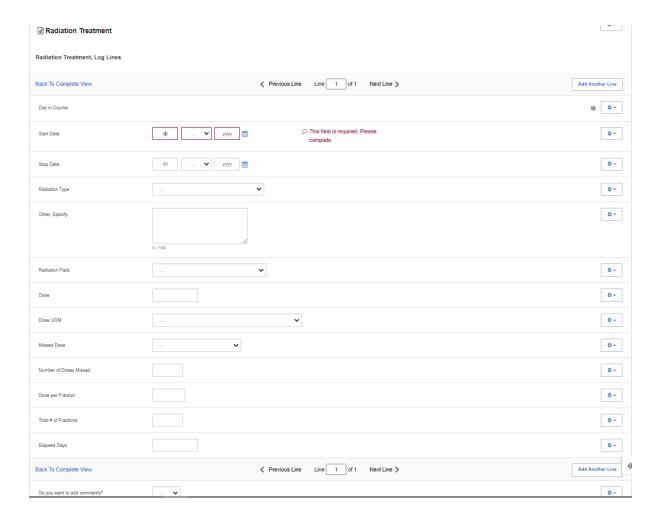
Radiation Treatment

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:





Field Name	Description / Instructions	Format
	Indicates the day since the beginning of course initiation. Derived from the course initiation start date. This is a derived field.	
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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	Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant". • 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 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.p df	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.pd f	Use pick list.
Missed Dose (m)	Select an option from the picklist: 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.

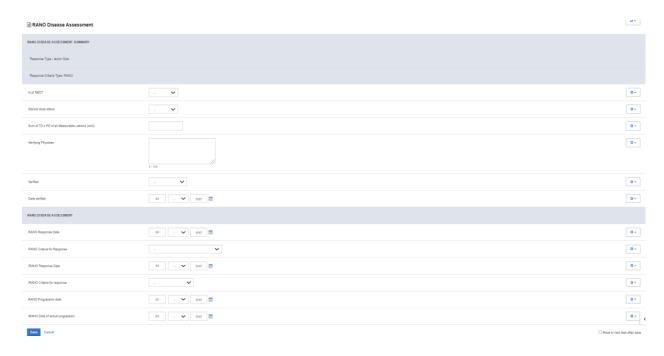
Derivations

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.



Field Name	Description / Instructions	Format
Is pt NED?	Question that asks whether there is evidence of disease (NED) at assessment. Choose an option from the list: No Unknown Yes	Use pick list.
Steroid dose status	Enter the status that represents the steroid therapy dose. Choose an option from the list: NONE STABLE Increase Decrease	

Field Name	Description / Instructions	Format
Sum of TD x PD of all Measurable Lesions (cm2)	Enter numeric value of total sum of products (transverse diameter multiplied by perpendicular diameter) for all measurable lesions described in square centimeters (cm2).	8 digits and 0 decimals
Verifying Physician	Enter the name of verifying physician	100 characters
Verified	Choose an option from the list:	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: AJ: Adjuvant Therapy CPD: Clinical Progression CR: Complete Response CRU: Complete Response Unconfirmed DU: Disease Unchanged IMR: Immunoresponse IPD: Immunoprogression MR: Minimal/Marginal response MX: Mixed 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: Pseudoprogression PR: Partial Response PSR: Pseudoresponse RD: Responsive Disease	Use pick list.

Field Name	Description / Instructions	Format
	 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:	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

 $\hfill \square$ Legend: $\hfill ^{(d)}$ derived field, $\hfill ^{(m)}$ EDC mandatory.

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

Validations

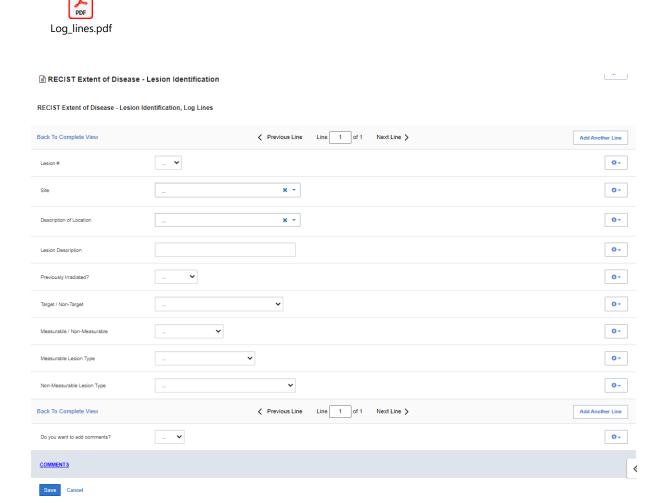
Code	Description	Resolutions
Medidata System Checks	Query will fire if Date verified / RANO Response Date / iRANO Response Date / RANO Progression Date or iRANO Date of actual progression is a future date. "Future date has been entered. Please correct."	
RAS06	RANO Criteria for Response is "Not Evaluable" 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 or review the Response is required when RANO Criteria for Response is CR, PR, MR, SD, or DU. Please correct."	
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:



Field Name	Description / Instructions Format	
Lesion#	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.
	Note: This lesion number must appear at least once on the bottom repeating group.	·
Site	Select the position where the lesion is located, i.e., Lung, Skull, etc. Dictionary Name – ANAT_SITE_NM ANAT_SITE_NM.pdf	Use pick list.
Description of Location ^(m)	Select a brief description of the lesion location. Dictionary Name - LOC_DESCRPTR_TXT_NM LOC_DESCRPTR_TXT _NM.pdf	Use pick list.
Lesion Description	If applicable, enter a brief description of each lesion, e.g., cystic, well-defined, encapsulated, necrotic appearing center.	200 characters
Previously Irradiated? ^(m)	If the site or lesion has previously been irradiated. • Yes • No • Unknown	
Target / Non- Target ^(m)	Select the Target / Non-Target from the picklist: NON-TARGET: Non-Target Lesion Identification TARGET: Target Lesion Identification	Use pick list.

Field Name	Description / Instructions	Format
	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.	
Measurable / Non- Measurable ^(m)	Enter "MEASURABLE", for measurable, "NON-MEASURABLE" for non-measurable, as defined in the protocol.	Use pick list.
Measurable Lesion Type	Select the type of measurable lesion from the picklist: • BONE LESIONS • CYSTIC LESIONS • MALIGNANT LYMPH NODE • METASTATIC LESION • PREVIOUSLY TREATED LESIONS • PRIMARY TUMOR	Use pick list.
Non-Measurable Lesion Type	Select the type of non-measurable lesion from the picklist: • 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).

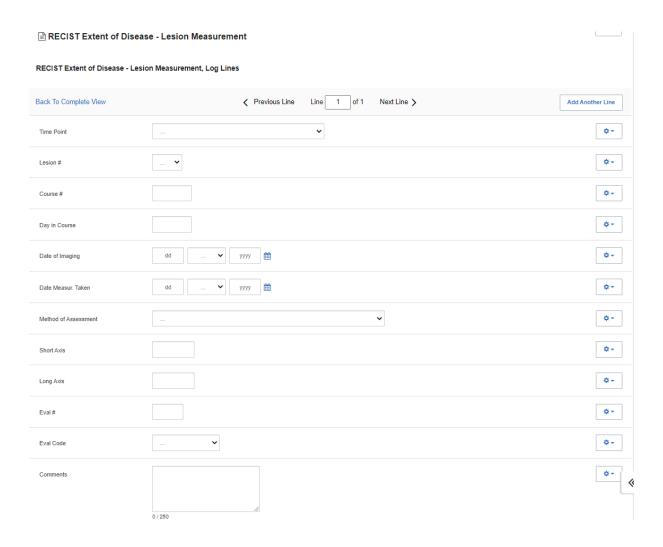
RECIST Extent of Disease - Lesion Measurement

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:





Field Name	Description / Instructions	Format
Time Point	Select a time point from the given picklist. Dictionary name - ASSESS_PD_TIME ASSESS_PD_TIME.pdf	Use pick list.
	Select a lesion number from the pick list.	
Lesion #	Note: This lesion number must appear in the description section (top repeating group).	
Course # (d)	Indicates the course number that this lesion evaluation was done in as derived from the course initiation start date. This is a derived field.	Derived field.
Course # (4)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course (d)	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.	Derived field.
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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)	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. • 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	Enter the longest lesion diameter measurement in centimeters. 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.	5 digits and 1 decimal
Long Axis (m)	Enter the longest lesion measurement in centimeters.	5 digits and 1 decimal
	Number each evaluation sequentially for each lesion. Use 0 for the baseline evaluation, 1 for the first evaluation, 2 for the second evaluation, etc.	
Eval #	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.	2 digits

Field Name	Description / Instructions	Format
Eval Code	Select the status of non-measurable lesions at the time of each evaluation. 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	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).

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

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.

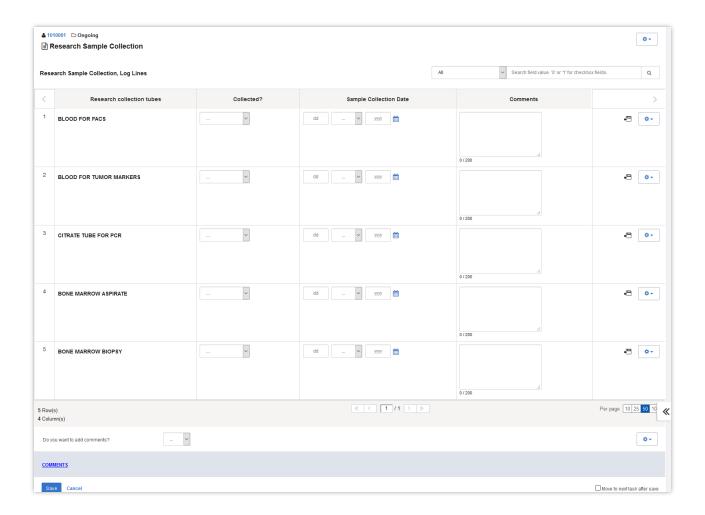
Research Sample Collection

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:





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?	Indicate whether the research samples are collected: 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."

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 doing.

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.

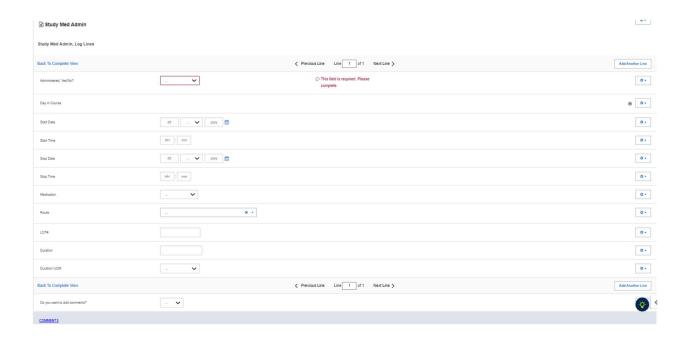
Two IV agents are administer, one on Day 1 and the other on Days 1 and 15

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.

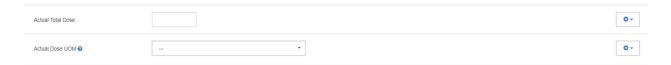
Note: this CRF contains loglines for data entry. For additional information on the functionality of the log lines, please refer to:



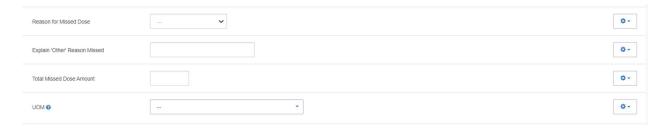
Log_lines.pdf



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



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



Field Name	Description / Instructions	Format
Administered, Yes/No?	Select an option indicating whether study drugs were administered. • Yes • No • Not Applicable	Use pick list.

Field Name	Description / Instructions	Format
	Indicates the day since the beginning of course initiation. Derived from the course initiation start date. This is a derived field.	D 15.11
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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
	Select a medication from the list (study dependent).	
Medication ^(m)	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.	Use pick list.
Reason for Missed Dose ^(m)	Select the reason the medication was missed. • MEDICATION ERROR • SUBJECT COMPLIANCE • TOXICITY • OTHER, SPECIFY	Use pick list.
	Note: This field will be visible when "Administered, Yes/No?" is answered "No".	

Field Name	Description / Instructions	Format
	Enter an explanation for selecting "Other" for Reason for Missed Dose.	
Explain 'Other' Reason Missed	Note: This field will be visible when "Administered, Yes/No?" is answered "No".	100 characters
	Enter the actual amount of medication missed for the date entered above.	
Total Missed Dose Amount ^(m)	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) 10 ⁷ as 1 and select 10E7 as the Missed Amount UOM.	6 characters
	Note: This field will be visible when "Administered, Yes/No?" is answered "No".	
UOM (m)	Select the Missed Dose Amount unit of measurement. Dictionary name - UOM_DOSE_TH_2 UOM_DOSE_TH_2.pd f	Use pick list.
	Note: This field will be visible when "Administered, Yes/No?" is answered "No".	
Actual Total Dose	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.	5 digits and 3 decimals

Field Name	Description / Instructions	Format
	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.	
	Note: This field will be visible when "Administered, Yes/No?" is answered "Yes".	
Select the Actual Dose Level unit of measurement. Dictionary name - UOM_DOSE_TH_2 Actual Dose UOM (m) UOM_DOSE_TH_2.pd f		Use pick list.
	Note: This field will be visible when "Administered, Yes/No?" is answered "Yes".	
Route ^(m)	Select the route from the list. Dictionary name - ACCESS_RTE_NM ACCESS_RTE_NM.pdf	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
	 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."

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?	
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 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	Male
	Female
	Ambiguous
	Unknown
Gender	Decline to answer-D
	Female-F
	Male-M
	 Neither exclusively male or female-N
	Other-O
	Transgender Female-MtF
	Transgender Male-FtM
Race	 American Indian or Alaska Native
	Asian
	Black or African American
	White
	 Unknown
	 Native Hawaiian or Other Pacific Islander
	Other
Ethnicity	Hispanic or Latino
	Not Hispanic or Latino
	 Unknown

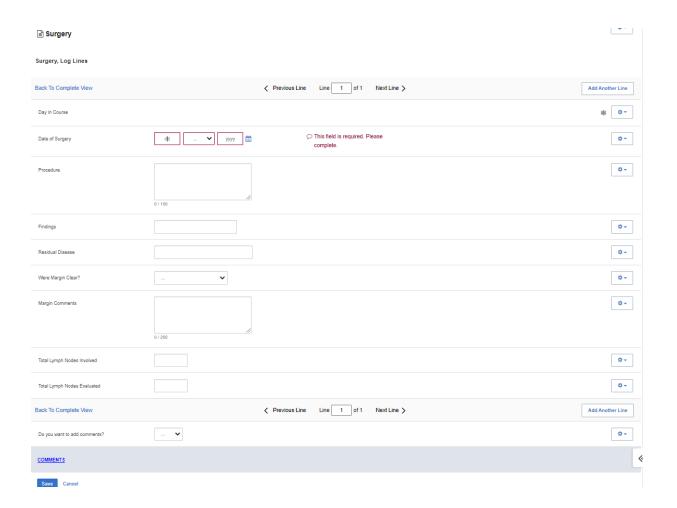
Surgery

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:





Field Name	Description / Instructions	Format
Davin Course (d)	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.	Derived field.
Day in Course ^(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Date of Surgery	Enter the date of the surgical procedure.	DD-MMM-YYYY
Procedure (m)	Enter the type of procedure performed to diagnose / to treat the subject's disease. Examples include, but not limited to biopsy, node dissection, cytology, bone marrow biopsy, FNA (fine needle aspiration).	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?	Select the results of tissue margin examination. 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.

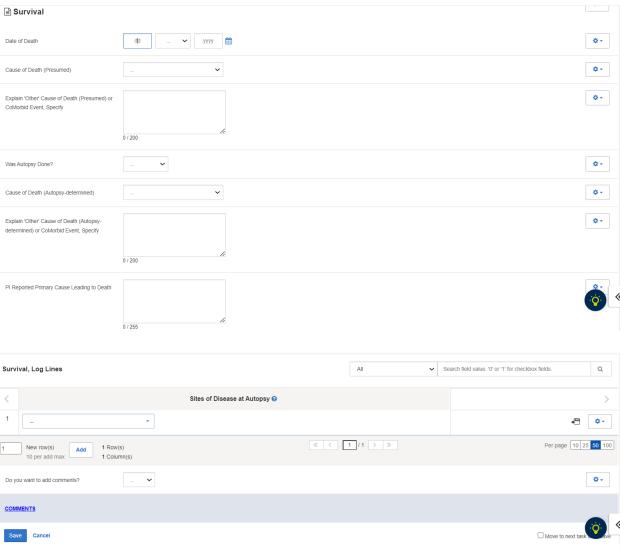
Survival

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:





Field Name	Description / Instructions	Format
Date of Death (m)	Enter the date the patient has died.	DD-MMM-YYYY
Cause of Death (Presumed) ^(m)	If the patient died without intervening therapy specific to the disease for which the patient was put on study, this section should be completed. Categorize the cause as due to: Malignant Disease Toxicity from Protocol Treatment Infection Other (Explain) CoMorbid Event, Specify 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".	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?	Select an option indicating whether an autopsy was performed. • Yes (Autopsy done.) • No (Autopsy not done.) • Unknown (Do not know if an autopsy was done.)	Use pick list.
Autopsy Results Available? (m)	Select an option indicating whether the results of an autopsy are available. • Yes (Autopsy results available.) • No (Autopsy results not yet available.)	Use pick list.

Field Name	Description / Instructions	Format
Cause of Death (Autopsy- determined)	If an autopsy was performed and a cause of death was determined at autopsy, it should be categorized according to: • Malignant Disease • Toxicity from Protocol Treatment • Infection • Other (Explain) • CoMorbid Event, Specify 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 (Autopsydetermined) or CoMorbid Event, Specify".	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	Select the major sites of malignant disease involvement found at the autopsy, i.e., heart, brain, lungs, etc. Dictionary name – BODY_SITES_TH BODY_SITES_TH.pdf	Use pick list.



Legend: $^{\text{(d)}}$ derived field, $^{\text{(m)}}$ EDC mandatory.

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

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 (Autopsydetermined) '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 (Autopsydetermined)' 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 (Autopsydetermined) 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 (Autopsydetermined) is not "Other (Explain)" or "CoMorbid Event, Specify". Please correct."	'Cause of Death (Autopsydetermined)' must be 'Other (Explain)' or 'CoMorbid Event, Specify' when an explanation is provided in the' Explain 'Other' Cause of Death (Autopsydetermined) or CoMorbid Event, Specify' field.

Code	Description	Resolutions
SUR06	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."	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.
SUR07	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."	"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.
SUR08	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."	Survival eCRF is not applicable as patient is off study.

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.

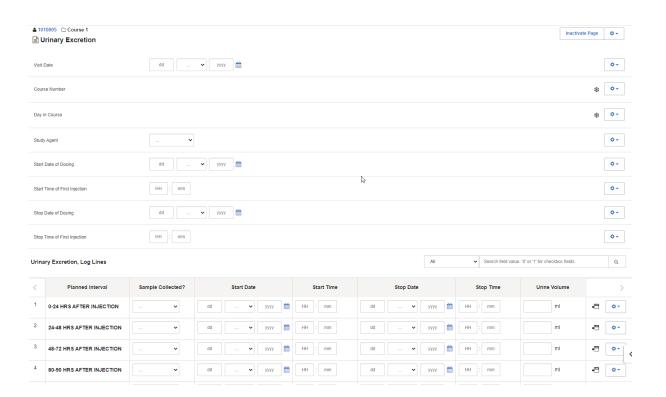


Note: This CRF will be put on the cycle section.

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



Log_lines.pdf



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	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.	Derived field.
(d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course ^(d)	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.	Derived field.
	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
	Enter the name of the study agent (investigational or commercial) which is the subject of the urinary excretion study.	
Study Agent (m)	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.	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	Enter the date the study agent administration was stopped.	
Dosing	Note: This field will be used for infusional therapies only.	DD-MMM-YYYY
Stop Time of First	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).	HH(24):MM
,	Note: This field will be used for infusional therapies only.	
Planned Interval	Planned interval pre-determined per protocol.	Text
Sample Collected? ^(m)	 Indicate whether or not the specimen is collected. 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."

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.

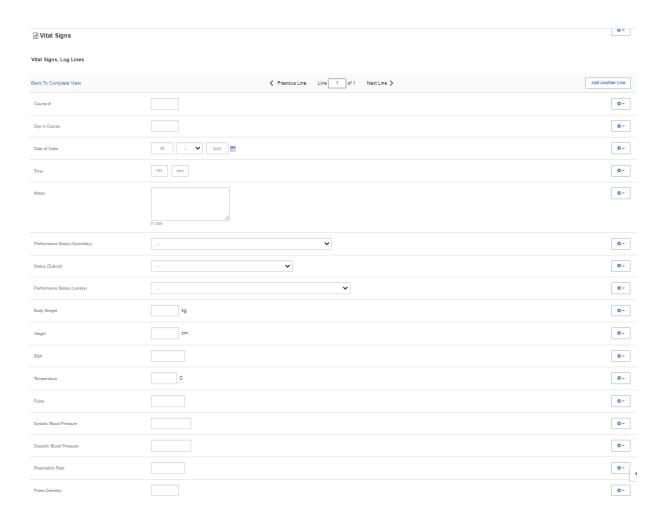
Vital Signs

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:





Field Name	Description / Instructions	Format
	Indicates the course number the vital signs are related to based on their date and time. This is a derived field.	
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course	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.	
Day in Course	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Date of Vitals	Enter the date the vital signs were taken.	DD-MMM-YYYY
Time	Enter the time the vital signs were taken.	HH(24):MM
	If necessary, enter some brief notes.	
Notes	Note: This information is not sent to the reporting agency.	200 characters
Performance Status (Karnofsky)	Select a value from the Karnofsky performance status scale. O: 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
	 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)	Select a value from the Zubrod/ECOG performance status scale. • 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)	 O: 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)	Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	3 digits and 2 decimals

Field Name	Description / Instructions	Format
Height (cm) ^(m)	Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	3 digits and 2 decimals
BSA (m)	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. Appendix I - Conversion Tables.pdf	5 digits and 3 decimals
Temperature (C)	Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	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."

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 (m²) = Height(cm)^0.725 x 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 (m²) = (CCRClinicalIT2: Height(cm) x 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.

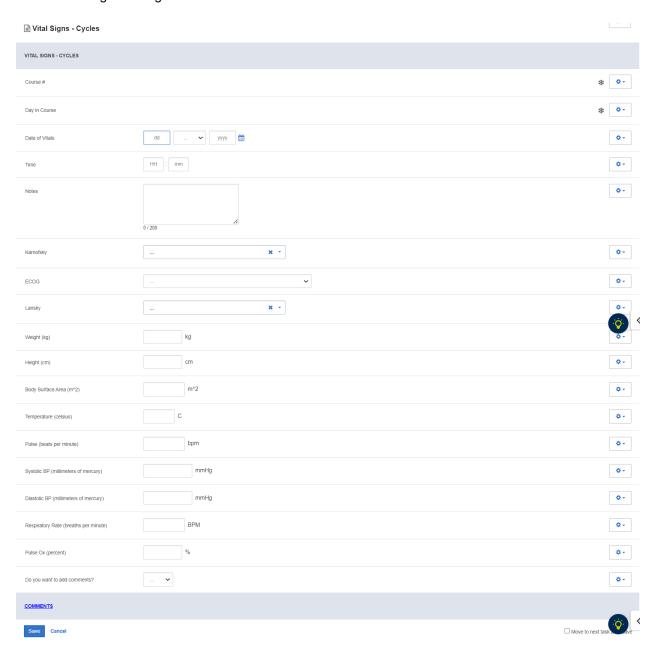
Derivations

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.



Field Name	Description / Instructions	Format
	Sequential number of this course of treatment: first course = 1, second course = 2, etc. This is a derived field.	
Course # (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	Derived field.
Day in Course (d)	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.	Derived field.
Day in Course (d)	Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	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	Select a value from the Karnofsky performance status scale. O: 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
	 90: Able to carry on normal activity but with minor signs of illness present 100: Normal with no complaints or evidence of disease 	
ECOG	Select a value from the Zubrod/ECOG performance status scale. • 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	 Select a value from the Lansky performance status scale. 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)	Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdl Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	5 digits and 2 decimals

Field Name	Description / Instructions	Format
Height (cm) (m)	Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	6 digits and 1 decimal
Body Surface Area (m^2) ^(m)	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. Appendix I - Conversion Tables.pd! Note: "Course" can be changed to "Cycle", "Visit", etc., based on study requirements.	5 digits and 3 decimals
Temperature (celsius)	Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	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."

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 (m²) = 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 (m²) = (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 integrated 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.

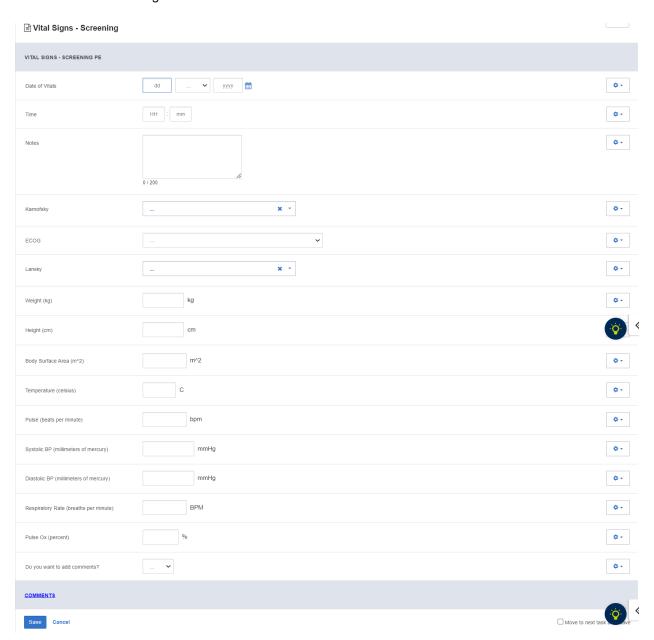
Derivations

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.



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	Select a value from the Karnofsky performance status scale. • 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	Select a value from the Zubrod/ECOG performance status scale. • 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	Select a value from the Lansky performance status scale. • 0: unresponsive • 10: No play; does not get out of bed	Use pick list.

Field Name	Description / Instructions	Format
	 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)	Enter the subject's weight only in kilograms. Use decimal places only for subjects under 10kg. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	5 digits and 2 decimals
Height (cm) ^(m)	Enter the subject's height only in centimeters, to one decimal place. See Appendix I for conversion factors. Appendix I - Conversion Tables.pdf	5 digits and 2 decimals
Body Surface Area (m^2) ^(m)	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. Appendix I - Conversion Tables.pdf	5 digits and 3 decimals
Temperature (celsius)	Enter the subject's temperature only in Celsius, to one decimal place. See Appendix I for conversion factors.	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 (m²) = Height(cm)^0.725 x 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 (m²) = (CCRClinicalIT2: Height(cm) x 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	 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	 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	 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	 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	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	 Updated query text for edit check BS03
	 Updated validation entry for edit check BS02
Baseline Medical History	 Updated query text for edit check MH02
Chimerism	Updated derivation codes
	 Updated future date validation entry in Validations
Concomitant	Updated derivation codes
Measures/Medications	
Diagnostic ECG	Updated derivation codes

Disease Assessment	Removed edit check LAS05 entry from Validations
Leukemia	
Disease Assessment	Removed edit check NAS05 entry from Validations
Neuro	
Echo/MUGA	Updated derivation codes
Extent of Disease -	Updated derivation codes
Lesion Measurements	Updated query text for edit check EXT03
Infection Episode	Updated derivation codes
Labs	Updated derivation codes
Pharmacokinetics	Updated derivation codes
Physical Exam -	 Removed 'BSA > 9' edit check in Validations
Screening	Removed Vitals Date future date check entry in Validations
Physical Exam - Cycles	Updated derivation codes
Procedure	Updated derivation codes
Radiation Treatment	Updated future date check entry in Validations
RANO Disease	Removed edit check RAS05 entry from Validations
Assessment	
RECIST Extent of	Updated derivation codes
Disease - Lesion	Removed "Under Development" from Validations
Measurement	·
Study Med Admin	Added the field "Route" to Fields and Descriptions section
	Updated screenshot
Study Med Missed	 Added entries for validations SD05.1 and SD06/07/08/09.1
Urinary Excretion	Updated derivation codes
Vital Signs	Updated derivation codes

Version 4.0 Changes

CRF	Changes in v4.0	
Adverse Events	 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	Changed "Date" field description from "Date of the Form" to "Date of the Cohort Arm Assignment"	
Enrollment	Updated picklist values in Disease Stage at Entry	
Labs	 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	Added OTS23	
Research Sample Collection	Added RSC01 Added RSC02	
Subject Enrollment	Added Sex field to field listUpdated screenshot	

Version 5.0 Changes

CRF	Changes in v5.0
Adverse Events	 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	Added PRES integration to Legend
Enrollment	 Added 'TX' in "T Stage" picklist Added 'NX' in "N Stage" picklist
Labs	 Preferred UOM format changed to pick list Added LAB05 to Validations list Updated screenshot
Pulmonary Function Test	Added new CRF to manual
Questionnaire	Added new CRF to manual
Research Sample Collection	Updated "Research collection tubes" format
Subject Enrollment	Added PRES integration to LegendAdded Field Picklists and Values table
Survival	 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	 Added Note in 'Course #' and 'Day in Course'
	Updated AE19 Resolution
Chimerism	 Added Note in 'Course #' and 'Day in Course'
Concomitant/Measures	 Added Note in 'Course #' and 'Day in Course'
MedicationsS	·
Diagnostic ECG	 Added Note in 'Course #' and 'Day in Course'
Echo/MUGA	 Added Note in 'Course #' and 'Day in Course'
Extent of Disease –	 Added Note in 'Course #' and 'Day in Course'
Lesion Measurements	·
Infection Episode	 Added Note in 'Course #' and 'Day in Course'
Labs	 Added Note in 'Course #' and 'Day in Course'
	 Removed Lab UOM derivation from Derivations table
	 Changed 'Grade' format from derived field to "1 character"

	Changed 'Lab Test' format from derived field to "Use pick list"
	Added embedded dictionary link in 'Preferred UOM'
Pharmacokinetics	Added Note in 'Course #' and 'Day in Course'
Physical Exam - Cycles	Added Note in 'Course #' and 'Day in Course'
Procedure	Added Note in 'Course #' and 'Day in Course'
PFT	Added Note in 'Course #' and 'Day in Course'
Radiation Treatment	Added Note in 'Course #' and 'Day in Course'
RECIST Extent of	Added Note in 'Course #' and 'Day in Course'
Measurement	·
Study Med Admin	Added combined Study Med Admin and Study Med Missed form
	manual
Study Med Missed	Removed CRF from the manual
Surgery	Added Note in 'Course #' and 'Day in Course'
Survival	Updated SUR04/05/06/07 validation queries
Urinary Excretion	Added Note in 'Course Number' and 'Day in Course'
Vitals Signs	Added Note in 'Course #' and 'Day in Course'
General	Added Introduction page

Version 7.0 Changes

CRF	Changes in v7.0
Adverse Events	 Updated AE20 query text and resolution
Course Assessment	 Added new question 'Any concomitant medications taken in this course?'
	 Added edit checks CAS11 and CAS12
	 Updated screenshot
Course Initiation	 Added new question 'ls this participant evaluable for DLT? (Phase 1 only)'
	Updated screenshot
Disease Assessment RECIST	 Updated picklists for 'Targeted Lesions Response', 'Non- targeted Lesions Response' and 'Overall Response'
Follow-up	 Added new question 'Explain 'Other' Type of Contact'
	 Added new edit check FLW10
Labs	 Added Lab panels list
	 Updated 'Lab Test' and 'Preferred UOM' formats
	Updated screenshot
Off Treatment	 Updated OTS08_28 and OTS9_18 query texts
Pharmacokinetics	 Updated PHM01 validation logic and query text
Physical Exam - Screening	 Split into two separate forms: 'Physical Exam - Screening' and 'Vital Signs - Screening'
	 Removed 'Zubrod' from 'ECOG/Zubrod'
	Updated screenshot
Physical Exam - Cycles	 Split into two separate forms: 'Physical Exam - Cycles' and 'Vital Signs - Cycles'
	 Removed 'Zubrod' from 'ECOG/Zubrod'
	Updated screenshot
Questionnaire	 Added a note for 'Date of Assessment'
Research Sample Collection	Updated RSC02 validation logic and query text
Vital Signs	Removed 'Zubrod' from 'Status (ECOG/Zubrod)'

Version 8.0 Changes

CRF	Changes in v8.0
Adverse Events	Updated AE19 description
Baseline Medical History	Updated screenshot
Consult	Removed 'OTHER' from the 'Consult Evaluation Type' picklist
Enrollment	Removed values (associated with other/specify) from the embedded 'Histology' picklist
Extent of Disease - Lesion Identification	 Removed values (associated with other/specify) from the embedded 'Description of Location' and 'Anatomic Site' picklists
Infection Episode	Removed values (associated with other/specify) from the embedded 'Primary Site' and 'Infectious Agent' picklists
Introduction	Added new meeting items to the Introduction page
Labs	Added new lab fields
	Updated screenshot
	 Updated LB03 validation description and resolution
	Added new 'Add Lab Form' CRF
Pathology Markers	 Removed a value (associated with other/specify) from the embedded 'Tumor Marker' picklist
	 Removed 'OTHER, SPECIFY' from the 'Marker Test Method' picklist
Pathology Report	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	Added 'Course #' as a field and a derivation
	Updated screenshot
Prior Radiation Supplement	 Removed a value (associated with other/specify) from the embedded 'Site' picklist
Prior Surgery Supplement	 Removed a value (associated with other/specify) from the embedded 'Site' picklist
Prior Treatment Summary	Changed the description for '# of Prior Regimens'
	 Updated PTX05 validation description and resolution
Procedure	 Removed a value (associated with other/specify) from the embedded 'Body Site' picklist
Radiation Treatment	Removed a value (associated with other/specify) from the embedded 'Radiation Field' picklist
RECIST Extent of Disease - Lesion Identification	Removed values (associated with other/specify) from the embedded 'Site' and 'Description of Location' picklists
RECIST Extent of Disease - Lesion Measurement	Removed values (associated with other/specify) from the embedded 'Time Point' picklist
Survival	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	Updated screenshot Demoved the field 'Regeneral Assessment'
	 Removed the field 'Response Assessment' Removed edit checks DAS06, DAS07 and DAS08

Follow-up	 Updated FLW06 Description and Resolution to replace 'Treatment' with 'Therapy'
Introduction	Added new item at the bottom of the Introductions page
Prior Therapy Supplement	Updated screenshot
	 Added the field 'Non-Agent Prior Therapy'
	 Added the edit checks PTS05 and PTS06
	 Removed mandatory flag from 'Agent Name'
Off Study	 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	 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	Updated screenshot
	Updated the Field Name 'Explain 'Other' Cause of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course of Death (Processed Vision 10th and Course Of Death (Processed Vision 10th and Course Vision 10th and Course Of Death (Processed Vision 10th and Course Vision 10th
	(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 Déath (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