Manual for the Completion

of the

NCI / CCR / C^{3}D

Case Report Forms

Prepared by:

Harris Enterprise Service Corporation

December 2006

Version 2.0

Manual for the Completion of the NCI / CCR / C^3D Case Report Forms

Disclaimer:

This manual was developed by Harris Enterprise Service Corporation for the National Cancer Institute's Center for Cancer Research (CCR). The material contained in it is solely for assisting data entry into CCR's Cancer Central Clinical Database (C^3D) electronic case report forms.

Table of Contents

Introduction

At the end of 2003, the National Cancer Institute's Center for Cancer Research (CCR) developed and started using the Cancer Central Clinical Database (C^3D) - a client-server computer system - to capture data for oncology clinical trials research trials conducted at the CCR.

This manual contains the instructions for the completion of the NCI's standard Case Report Forms used in C^3D.

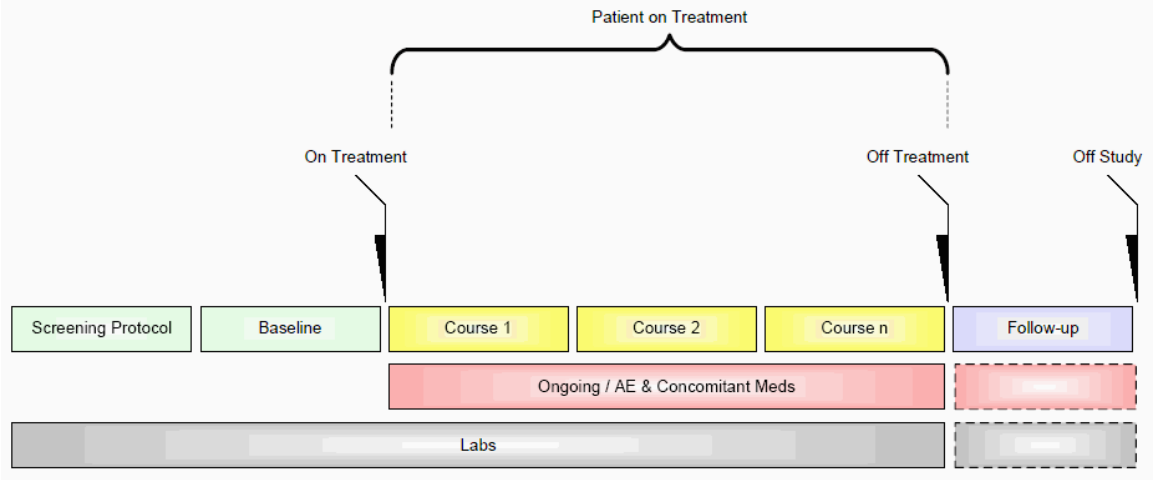
The eCRF instruction manual is preceeded by a General Instructions section which describes topics applicable to all eCRFs.This is followed by instuctions for each form which include how to complete each field, what the validation rules are for the CRF, and what fields will be derived by the database. The Appendices include conversion tables and useful Internet and Intranet references.

General Instructions

Data Entry Chronology

Case Report Forms should be created and completed in chronological order as follows:

1. Screening CRFs and any labs needed to support eligibility.
2. Each course in sequential order including:
   - Course Initiation,
   - Study Medication Administration,
   - Pharmacokinetics, if applicable
   - Physical Exam,
   - Course Assessment, and
   - Any additional cycle specific CRFs.
3. At completion of patient's treatment, Off Treatment CRF.
4. If the protocol specifies a follow-up period after the treatment, complete the Follow-up and any other applicable follow-up CRF - manually complete the labs CRFs done after the date off treatment since those will no longer be automatically loaded.
5. At end of study, when the follow-up period is completed, enter the Off Study CRF.
6. If the patient dies during treatment or follow-up period, complete the Survival, Off Treatment and Off Study CRFs.



Data Reporting

Complete the CRFs according to the protocol and in a timely manner. Studies reporting to CTMS submit data every two weeks. Studies reporting to CDUS submit data every three months. Other studies might have different reporting requirements.

General Instructions

Electronic Case Report Forms

An electronic CRF in Oracle Clinical is called a DCI - data collection instrument.
In C3D, these CRFs always have three fields at the top:

1. Visit Date (see Entering Dates below)
2. Blank check box (see Blank Case Report Forms below)
3. Comments (see Blank Case Report Forms below)

Below these fields, there are at least two tabs (also known as DCM - data collection module). For example: In the Prior Radiation CRF, the first tab is used to collect information about the patient's prior radiation treatments while the second tab is used to collect comments about the prior radiation treatments.

Blank Case Report Forms

Mark a complete CRF blank whenever there is no information to enter in it. For example: Place a check on the Prior Radiation CRF Blank check box to indicate that a patient has never received radiation treatment prior to enrollment. Optionally, enter some explanation, in the Comments field next to the Blank check box, to indicate why the entire CRF is blank.

Entering Comments

Each CRF has a section for entering multiple comments about the data entered in the CRF. This area is always the last tab in the CRF. Enter the date and the applicable comments.

Entering Dates

Ongoing CRFs:

Visit date is an optional field (can be left blank).

Course-specific CRFs:

Refer to each eCRF's instructions for specific directions on what must be entered as visit date. A visit date **cannot** be a partial date.

Note: The current version of Oracle Clinical does not permit the removal or change of the label of the visit date.

Complete dates (day, month, year):

Entered in the U.S. format: month, day and year. That is the default date format in the Oracle Clinical RDC. Dashes (-) and slashes (/) do not need to be entered, simply the numbers. To enter the year in a century format use YYYY, since years

higher than the current one default to the previous century. The recommended entry format for complete dates is: MMDDYYYY.

Partial dates (month and year or simply year):

Only acceptable in a few places such as baseline symptoms and patient's history.

- For year only, use 00-00-YYYY.
- For month and year, use 00-MON-YYYY.

Partial dates are not acceptable for dates that fall within the date of registration and date off study since the complete dates for events occurring during the study are known.

The use of 'Ongoing' is limited to the CRFs where patients may still be undergoing a particular cancer therapy, but are still eligible for the study, such as hormonal or radiation therapy.

Future dates:

Not allowed.

Entering Time

All times are to be recorded on a 24 hour clock. Enter 1:00 PM as 13:00 and midnight as 00:00.

Using Pick Lists

A pick list is a selection of acceptable values for a particular field. Once you place the cursor in the field where you will enter data, an ellipsis (···) is displayed to the right of the field which indicates there is a pick list available for you to use. Click on the ellipsis to display the pick list. Whenever possible, select from a pick list to assure accurate and consistent data entry. If a pick list does not contain the entry you need, type in the information. If the entry should be on the pick list or you are typing in a value that is not on the pick list repeatedly, request it to be added to the pick list.

Mandatory Fields

Some fields in a CRF are defined as mandatory. That means information must be entered in them when the form is created. Each CRF instruction sheet will identify mandatory items as a superscript to the right of the field name. (i.e.: $^{(m)}$)

Filler Page

Case Report Forms

Adverse Events

Purpose

This eCRF is an ongoing form to capture all adverse events experienced by the patient 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 either the NCI Common Toxicity Criteria (CTC) version 2.0 or the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0, as indicated in the protocol. 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 patient, 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 reported 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.

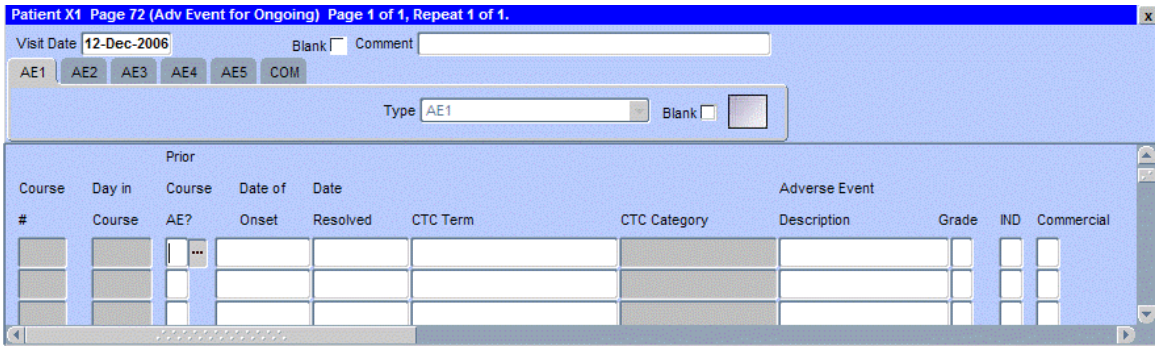
If an adverse event has not been resolved, leave the Resolved Date blank. The Resolved Date can be filled at a later time when the adverse event is considered resolved. Resolution means a change in grade to a higher or lower grade, to the normal grade (grade zero) or the return to the baseline symptom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

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

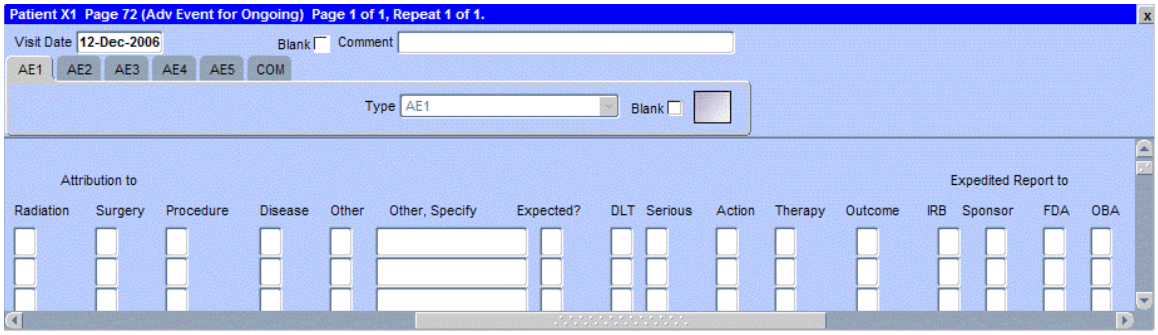
- If a pre-existing condition resolves, it does not need to be reported as an adverse event since it would have been already recorded on the Baseline Symptoms case report form. Enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form.
- If a pre-existing condition worsens (i.e.: the grade of the baseline symptom increases), that constitutes an adverse event entry which must be reported in full detail.
- If a pre-existing condition improves without a resolution, do not enter as an Adverse Event. When it resolves, enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form.

Adverse Events (cont'd)

Adverse Event eCRF



The following screen shot is the portion to the right of the Attribute to Commercial.



Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Prior Course Adverse Event field.	DD-MMM-YYYY
Course # (d)	Indicates the course number that this adverse event started in as derived from the course initiation start date. Late adverse event (For CTMS and CDS monitored studies, it means the adverse event observed after the date of off treatment) have no associated Course #.	5 digits
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.	5 digits
Prior Course Adverse Event (c)	For adverse events that begin on the first day of a course, indicate if related to the prior course by entering: Y- Related to a prior course N- Not related to a prior course For an adverse event that begins on the first day of the course **PRIOR** to any study medications being given, select "Y". For an adverse event that begins on the first day of the course **AFTER** study medications have been given, select "N". *Note: This field is optional for non-CTEP sponsored studies.*	Use pick list.
Date of Onset (m)	Enter the date of first observation of the adverse event and grade.	DD-MMM-YYYY

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Date Resolved	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.** Resolution means a change in grade to a higher or lower grade, to the normal grade (grade zero) or the return to the baseline symptom grade.	DD-MMM-YYYY
CTC Term (m)	Using either the Common Toxicity Criteria (CTC) version 2.0 or the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 as indicated in the protocol, select the appropriate general category with the appropriate adverse event term. Note: For CTCAE version 3.0, several terms are classified as supraordinate terms that have a select value associated with the term, both are included for selection of the Adverse Event term. Visit CTEP website for further explanation of supraordinate categories and usage of the select term (http://ctep.cancer.gov). 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.	Use pick list.
CTC Category (d)	Broad classification of adverse events based on anatomy and/or pathophysiology. Within each category there is the adverse event term/CTC Term Description. *Note: This field is derived from the selected CTC Term.*	40 Characters
Adverse Event Description	Enter a **succinct clinical description** of the adverse event. *Note: This field is mandatory, unless the CTCAE*	100 characters (Only 33 characters are reported for CTMS monitored

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	term is the same as the description (e.g. nausea, diarrhea). 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. For CTC 2.0: Enter the diagnosis, e.g. flu, and not each specific symptom (e.g. chills fever, muscle aches). For CTC 3.0: Use the syndrome category when appropriate (e.g.: Flu-like syndrome). For example: • Enter 'Low back pain' when selecting the term 'Pain: Back'. • Enter 'Intermittent headache' when selecting the term 'Pain Head/Headache' • Enter 'Left arm pain' when selecting the term 'Pain-Other'	studies.)
Grade (m)	Grade adverse events using either the Common Toxicity Criteria (CTC) version 2.0 or the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 as indicated in the protocol. *Note: Some grades are disallowed for some categories in the CTC/CTCAE. In the CTC/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.* If the protocol does not use either CTC or CTCAE, grade according to the following general criteria: 0. Normal – no adverse event or within normal limits 1. Mild – barely noticeable, does not influence functioning	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	2. Moderate – makes subject uncomfortable, influences functioning 3. Severe – severe discomfort, treatment given 4. Life threatening – immediate risk of death 5. Fatal – causes death of the patient – **Outcome must be 4-Died.**	
Attribution to IND [(m)] ...	Evaluate the toxicity's relationship to the investigational agent. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related	Use pick list.
Attribution to Commercial ...	Evaluate the toxicity's relationship to the commerical agent. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.
Attribution to Radiation ...	Evaluate the toxicity's relationship to the Radiation therapy. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Attribution to Surgery …	Evaluate the toxicity's relationship to the surgery. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.
Attribution to Procedure …	Evaluate the toxicity's relationship to the procedure. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.
Attribution to Disease …	Evaluate the toxicity's relationship to the disease. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Attribution to Other ▪▪▪	Evaluate the toxicity's relationship to other causes not listed above. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: This field is optional for some studies.*	Use pick list.
Other, Specify	Enter an explanation when 'Attribute to Other' is selected.	40 Characters
Expected? (m) ▪▪▪	Indicate if the adverse event is expected or not, by entering: Y- Yes N- No *Note: An expected event is any adverse experience identified in the current labeling for the drug or product (Package Insert/Investigator's Brochure), in the protocol, or in the consent form.*	Use pick list.
DLT (m) ▪▪▪	Indicate if the adverse event is dose limiting, as defined in the protocol, by entering: Y- Yes N- 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.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Serious (m) ▪▪▪	Indicate if the adverse event was a "serious" event by selecting from the following codes, as per the Code of Federal Regulations 21 Part 312. If multiple categories are applicable, select the worst. 1. Not serious. 2. Life-threatening. 3. Death as a result of the adverse event. 4. Disability: significant, persistent or permanent. 5. Hospitalized or prolonged hospitalization (not including emergency room visits). 6. Caused congenital anomaly in child of patient. 7. Jeopardizes patient / requires intervention to prevent permanent impairment or damage to patient.	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**. 1. None 2. Dose Reduced 3. Regimen Interrupted 4. Therapy Discontinued 5. Interrupted & Reduced If the "Action" for any adverse event is recorded as 2, 3, 4, or 5, the changes in medication administration must be reflected on the Study Medication Administration form. *Note: Interrupted also means therapy was delayed.*	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Therapy (m)	Indicate if additional therapy is required to treat the adverse event. 1. None 2. Symptomatic (i.e.: required medications to treat event) 3. Supportive (i.e.: required medications and/or IV fluids, blood products) 4. Vigorous Supportive (i.e.: required surgery, intubation) A corresponding entry of the therapy given to treat the adverse event must be recorded on the Concomitant Measures/Medication form.	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Outcome ▪▪▪	Select the final status of the patient when the adverse event is considered "resolved". 1- Recovered – the event (CTCAE term + grade) has resolved to normal or changed to a lower or higher grade. The recovery may be due to the suspension of study treatment or due to concomitant treatments that have ended. 4- Died - Record outcome of death only for adverse events that resulted in the patient's death. *Note: For ongoing adverse events, leave this and the Resolution Date fields empty.* *Note: For deaths on study, only the events which caused the death should have the outcome coded as a "4." The events that were still continuing at the time of the death would still be ongoing. Do not enter a resolved date, and outcome.*	Use pick list.
Expedited Report to IRB (m) ▪▪▪	Indicate if an expedited adverse event report was sent to IRB by entering: Y- Yes N- No	Use pick list.
Expedited Report to Sponsor (m) ▪▪▪	Indicate if an expedited adverse event report was sent to sponsor by entering: Y- Yes N- No For CTEP-sponsored studies, this means that an expedited adverse event report was sent to CTEP via CTEP's Adverse Event Expedited Reporting System (AdEERS). *Note: This field is optional for some studies.*	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Expedited Report to FDA ▪▪▪	Indicate if an expedited adverse event report was sent to FDA by entering: Y- Yes N- No For studies where the PI holds the IND, this means that the PI has sent an IND Safety Report to FDA. *Note: This field is optional for some studies.*	Use pick list.
Expedited Report to OBA ▪▪▪	Indicate if an expedited adverse event report was sent to OBA (Office of Biotechnology Activities) by entering: Y- Yes N- No *Note: This field is optional for some studies.*	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Validations		
Code	**Description**	**Resolutions**
AE01	Date Resolved is before Date of Onset.	Correct either the Date of Onset or Date Resolve.
AE03	Two Adverse Event records have identical values for Date of Onset, CTC Term and Grade.	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.	Correct the Onset and Resolution Dates for the Adverse Events in question or review/correct the CTC term/description.

Adverse Events (cont'd)

Validations		
Code	**Description**	**Resolutions**
AE08	Adverse Event Description missing for some certain CTC terms that require a clinical description.	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.	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.
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.	Verify that the Averse Event is supported by appropriate lab test result.
AE11	Adverse Event is resolved and there is no supporting lab test result.	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.
AE14, AE15	The Adverse Event Date of Onset or Date Resolved is in the future.	Correct the Onset or Resolution Dates. No future dates should be recorded.
AE16	The Adverse Event Date of Onset is less than the first Course Start Date.	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.	Enter a Grade that is permissible for the CTC Term.
AE19	Resolution date has been entered, but Outcome is not provided or vice-versa.	A Date Resolved must be accompanied by an Outcome and vice-versa.

Adverse Events (cont'd)

Validations		
Code	**Description**	**Resolutions**
AE20	Adverse Event is the cause of death but Grade is not 5-Fatal and/or Outcome is not 4-Died and/or Seriousness is not 3-Death.	Change the Adverse Event Grade, Outcome and Seriousness.
AE21	Prior Course checked 'Y', but there is no Course with a Start Date the same as the Adverse Event Onset Date.	Change the Adverse Onset Date, the Prior Course or the Course Initiation Start Date.
AE22	Adverse Event ’Attribute to Other' and 'Other, Specify' are not present together.	Enter ‘Other, Specify’ if ‘Attribute to Other’ is associated.

Derivations		
Code	**Field Name**	**Description**
AE1002	Course #	Course number is derived based on the course initiation start dates.
AE1003	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date.
AE1004	CTC Category	Broad classification of the CTC Adverse Event Term derived from the pick list selection.

(ADVERSE-EVENTS)

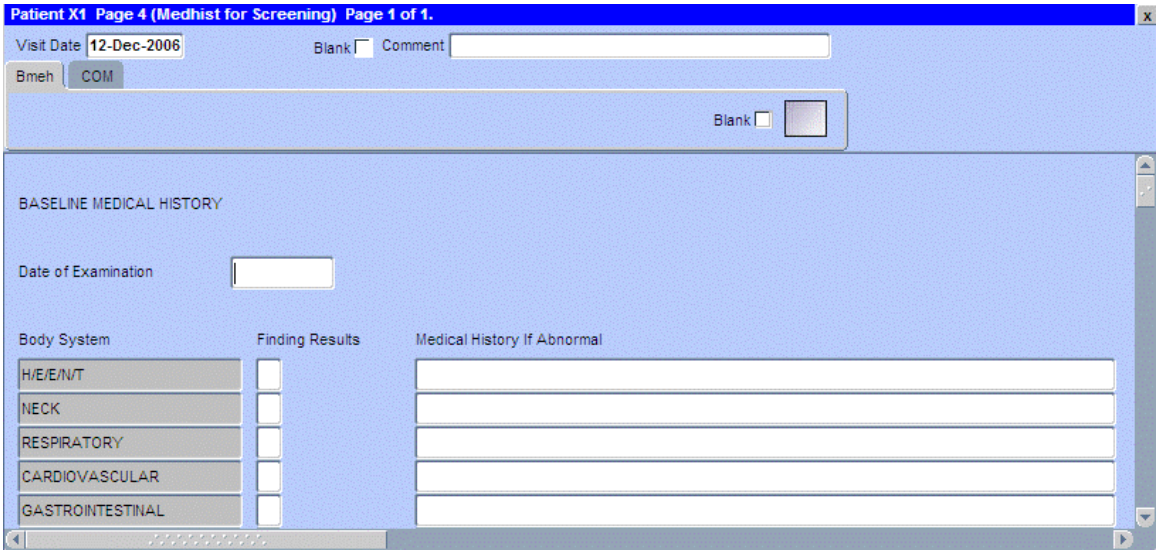
Baseline Medical History

Purpose

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

Screening Physical Exam findings should be entered on the Screening Physical Exam eCRF.

Baseline Medical History eCRF



Baseline Medical History (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Date of Examination (m)	Enter the date that the patient was examined and the medical history was documented. Since only one Baseline 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
Finding Results (m) ▪▪▪	Indicate whether the finding results for the particular body system were either: N- Normal A- Abnormal Z- Not Assessed 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 patient'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.	128 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Baseline Medical History (cont'd)

Validations		
Code	**Description**	**Resolution**
MH01	Date of Examination is in the future.	Enter a date that is earlier or equals to the current date.
MH02	Date of Examination is after the first Course Initiation Start Date.	Review the Date of Examination and/or the first Course Initiation Start Date.
MH03	'Finding Result's is marked abnormal and 'Medical History if Abnormal' details were not provided.	Enter the details of the 'Medical History if Abnormal' or change the 'Finding Results' selection.
MH04	'Medical History if Abnormal' details were specified and 'Finding Results' is not marked abnormal.	Change the 'Finding Results' to abnormal or remove the provided 'Medical History if Abnormal' details.

(BASELINE-MEDICAL-HISTORY)

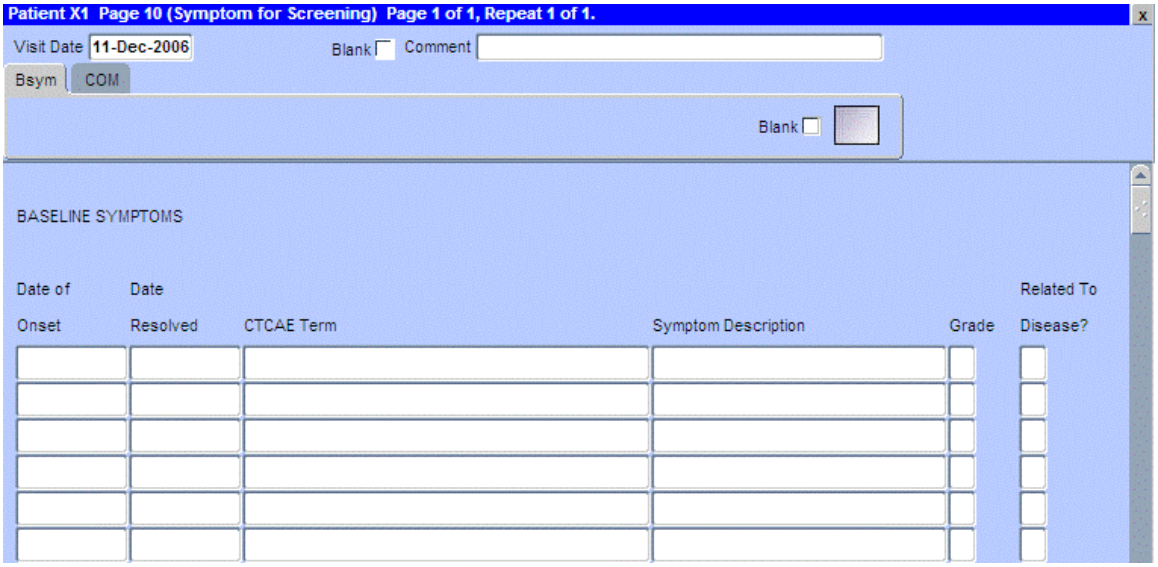
Filler Page

Baseline Symptoms

Purpose

Record the patient's baseline symptoms prior to starting treatment.

Baseline Symptoms eCRF



Baseline Symptoms (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed. *Note: If the information was obtained at multiple visits, please enter the date the form was completed.* *Note: If a new baseline symptom is revealed once treatment has begun, do not change the visit date. Record the new symptom information in the appropriate fields as indicated below.*	DD-MMM-YYYY
Date of Onset (m)	Enter the date that the symptom was first observed/experienced.	DD-MMM-YYYY, MMM-YYYY
Date Resolved	Enter the date the baseline symptom was resolved.	DD-MMM-YYYY
CTCAE Term (m) ...	Using either the Common Toxicity Criteria (CTC) version 2.0 or the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 as indicated in the protocol, select the appropriate general category with the appropriate adverse event term. *Note: For CTCAE version 3.0, several terms are classified as supraordinate term that has a select value associated with the term; both are included for selection of the Adverse Event term. Visit CTEP website for further explanation of supraordinate categories and usage of the select term (http://ctep.cancer.gov).*	Use pick list.
Symptom Description	Enter a **succinct clinical description** of the symptom. *Note: This field is mandatory for 'Other' CTCAE terms, but may be used to further describe symptom such as "left arm pain". For example: Allergy/Immunology - Other (Specify, __).* For CTC 2.0: Enter the diagnosis, e.g. flu, and not	33 characters

Baseline Symptoms (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	each specific symptom (e.g. chills fever, muscle aches). For CTC 3.0: Use the syndrome category when appropriate (e.g.: Flu-like syndrome). For example: • Enter 'Low back pain' when selecting the term 'Pain: Back'. • Enter 'Intermittent headache' when selecting the term 'Pain Head/Headache' • Enter 'Left arm pain' when selecting the term 'Pain-Other'	
Grade (m) ▪▪▪	Enter the severity of the symptom by using the protocol specified version of CTC version 2.0 or CTCAE version 3.0. 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 – barely noticeable, does not influence functioning 2. Moderate – makes subject uncomfortable, influences functioning 3. Severe – severe discomfort, treatment given 4. Life threatening – immediate risk of death	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: Y- Yes N- No U- Unknown	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Baseline Symptoms (cont'd)

Validations		
Code	**Description**	**Resolution**
BS01	Date of Onset is in the future.	Enter a Date of Onset that is equal or earlier than the current date.
BS02	Baseline Symptom CTC/CTCAE Term Grade is not valid or is missing.	Select a Grade from the pick list.
BS03	Date of Onset is after the first Course Initiation Start Date.	Date of Onset must be earlier than or equal to the first Course Initiation Start Date.
BS09	Resolved Date is prior to Date of Onset.	Resolved Date must be after or equals to the Date of Onset.
BS10	Symptom Description missing for CTCAE Term that requires a description. (Allergy/Immunology - Other (Specify, __))	Enter a Symptom Description for the corresponding CTCAE Term.

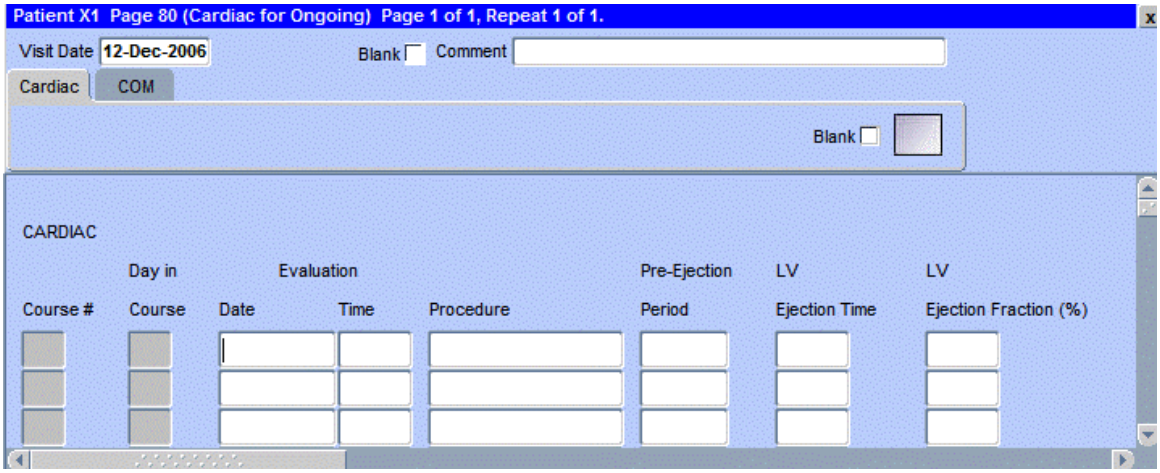
(BASELINE-SYMPTOMS)

Cardiac

Purpose

Record the patient's cardiac ejection fraction.

Cardiac eCRF



Cardiac (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the start date of the first course in this field.	DD-MMM-YYYY
Course # (d)	Indicates the course number the cardiac ejection fraction results are related to based on their date and time.	5 digits
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.	5 digits
Evaluation Date (m)	Enter the date the procedure was performed.	DD-MMM-YYYY
Evaluation Time (m)	Enter the time the procedure was performed.	HH(24):MM
Procedure (m) ▪▪▪	Select on of the following procedures from the pick list: • MUGA • MRI • Echocardiogram • Cardiac Catheterization. • Nuclear stress test.	Use pick list.
Pre-Ejection Period	Enter the Pre-Ejection Period.	8 digits and 3 decimals
LV Ejection Time	Enter the Left Ventricular Ejection Time.	8 digits and 3 decimals
LV Ejection Fraction (%) (m)	Enter the Left Ventricular Fraction percentage.	8 digits and 3 decimals
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Cardiac (cont'd)

Validations		
Code	**Description**	**Resolution**
CAR01	Evaluation Date is in the future.	Enter a date that is equal to or prior to the current date.
CAR02	Check for duplicate Cardiac evaluation entries – Same Date, Time and Procedure.	Correct the Evaluation Date, Time and Procedure.

Derivations		
Code	**Field Name**	**Description**
CAR1001	Course #	Course number is derived based on the course initiation start dates and the Evaluation Date.
CAR1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the Evaluation Date.

(CARDIAC)

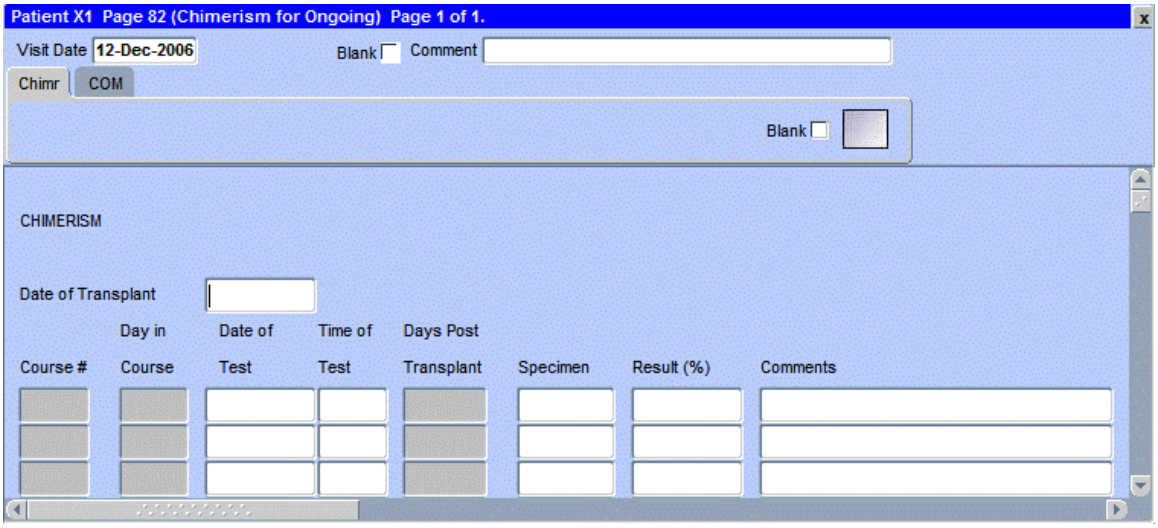
Filler Page

Chimerism

Purpose

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

Chimerism eCRF



Chimerism (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Date the first test was performed.	DD-MMM-YYYY
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.	5 digits
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.	5 digits
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.	5 digits
Specimen (m) ...	Select a specimen from the pick list. A- Apheresis Cells B- Whole Blood C- CSF D- CD33 Myeloid Cells L- CD33 Lymphoid Cells M- PBMC O- Bone Marrow P- Plasma S- Serum T- Tumor Tissue U- Urine V- Saliva Y- CD14/15 Myeloid	Use pick list.
Result (%) (m)	Test results in percentage.	12 digits and 5 decimal

Chimerism (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Comments	Enter comments applicable to the test.	200 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Chimerism (cont'd)

Validations		
Code	**Description**	**Resolution**
CHM01	Duplicate Specimen, Date of Test and Time of Test.	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.
CHM02	Result (%) is out of range.	Result % must be between 0 and 100%.

Derivations		
Code	**Field Name**	**Description**
CHM1001	Course #	Course number is derived based on the course initiation start dates and the Date of Test.
CHM1002	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.

(CHIMERISM)

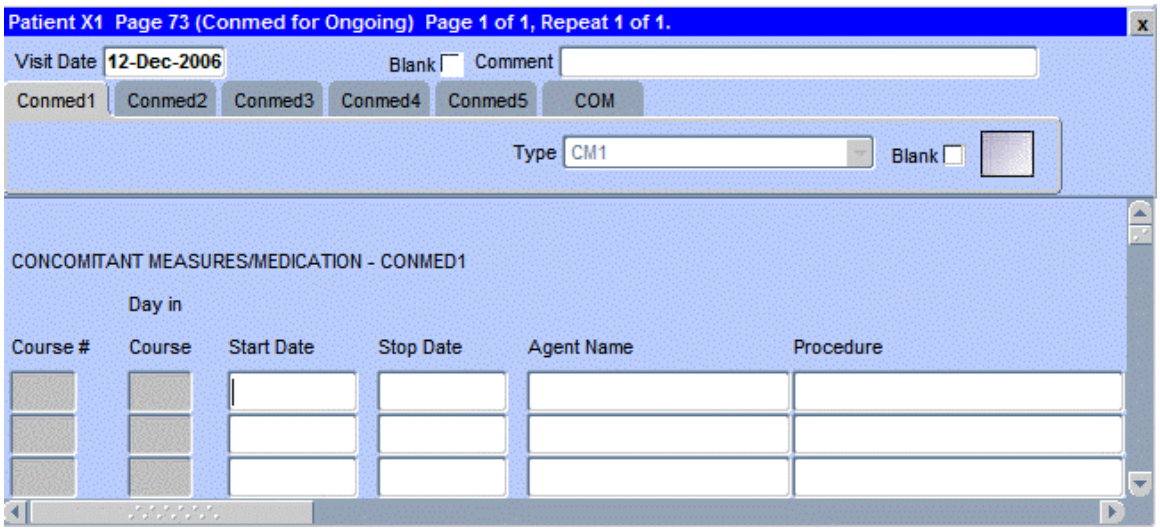
Concomitant Measures / Medications

Purpose

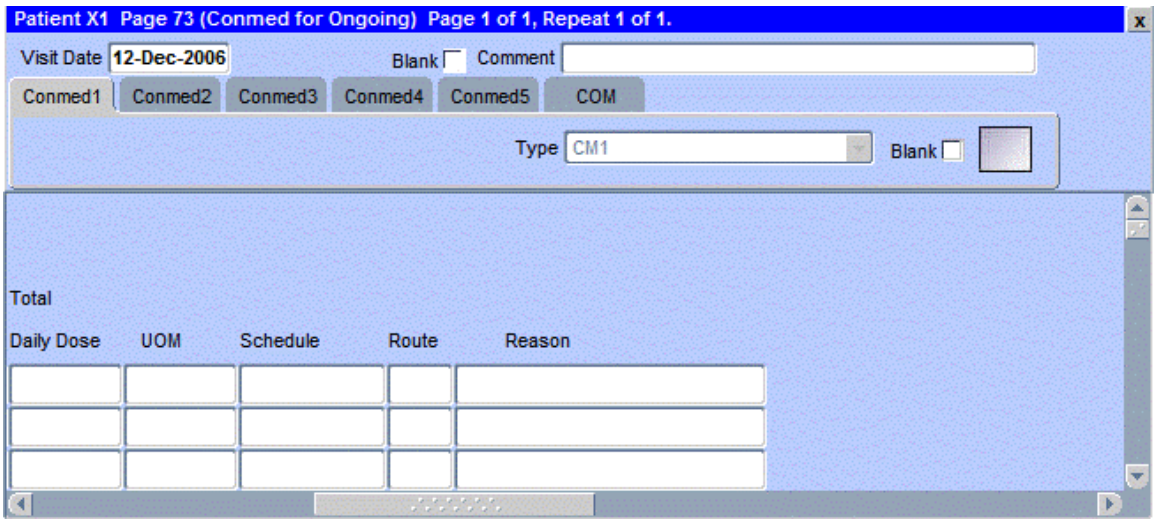
Record all concomitant medications, including therapies given to treat adverse events.

If a patient 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.

Concomitant Measures / Medications eCRF



The following screen shot is the portion to the right of the Procedure field.



Concomitant Measures / Medications (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Start Date field.	DD-MMM-YYYY
Course # (d)	Indicates the course number that this concomitant measure / medication started in as derived from the course initiation start date.	5 digits
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.	5 digits
Start Date (m)	Enter the start date of the measure or medication. *Note: Partial date is only acceptable for baseline measure or medication.*	DD-MMM-YYYY or MMM-YYYY
Stop Date ...	Enter the stop date of the measure / medication. *Note: Partial date is only acceptable for baseline measure or medication.*	DD-MMM-YYYY or 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). *Note: Pre and post medications specified in the protocol and administered as part of the patient'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.*	Use pick list.
Procedure ...	If a procedure/measure, state e.g., oxygen administration, pleural tapping, etc. *Note: Do not select a procedure if an agent name has been entered.*	Use pick list.

Concomitant Measures / Medications (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Total Daily Dose	Enter the total daily dose of the agent as appropriate. In the case of combinations such as Bactrim, enter the total number of combination tablets taken daily. Enter the maximum possible dose in a 24-hour period when the schedule is PRN. For example: enter 12 when taking 2 tabs of Percocet PRN every four hours. This field is mandatory for CTMS studies. *Note: If a procedure/measure, leave blank.*	8 characters
UOM ▪▪▪	Select the total daily dose units of measurement. *Note: If a procedure/measure, leave blank.*	Use pick list.
Schedule ▪▪▪	Select the frequency of medication administration or measure under schedule.	Use pick list.
Route (m) ▪▪▪	Select the route given: IM- intramuscular ID- intradermal IV- intravenous bolus (less than 30 minutes) IVI- intravenous infusion (greater than 30 minutes, but less than 24 hours) CIV- continuous intravenous infusion (greater than 24 hours) IA- intra-arterial IT- intrathecal IP- intraperitoneal IH- intrahepatic IHI- intrahepatic infusion SC- subcutaneous T- topical PO- oral RT- radiation or other route as specified in the protocol.	Use pick list.

Concomitant Measures / Medications (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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". *Note: Do not enter the pharmacological classification of the medication (e.g. antibiotic, analgesic, etc.)*	Use pick list.
Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Concomitant Measures / Medications (cont'd)

Validations		
Code	**Description**	**Resolution**
CM01	Agent and Procedure are missing.	An Agent or Procedure must be present.
CM02	Both Agent and Procedure are filled.	Agent and Procedure cannot be both selected at the same time.
CM03	Stop Date is before the Start Date.	Stop Date must not be earlier than Start Date.
CM04	Agent entered and Total Daily Dose and/or Units of Measurement are/is missing.	If Agent is entered, Total Daily Dose and Unit of Measurement must be present.
CM05	Total Daily Dose and/or Unit of Measurement entered and Procedure also entered.	If Procedure is entered, Agent, Total Daily Dose and Unit of Measurement must not be present.
CM06, CM07	Start and/or Stop Date are/is in the future.	Enter a date that is equal to or prior to the current date.
CM10, CM11	Partial Start Date and/or Stop Date are/is after the first Course Initiation Date.	Partial Start and Stop Dates are only acceptable for baseline measures and/or procedures.
CM12	Total Daily Dose is not a valid numeric value.	Enter a valid numeric value.

Concomitant Measures / Medications (cont'd)

Derivations		
Code	**Field Name**	**Description**
CM1001	Course #	Course number is derived based on the course initiation start dates and the concomitant measure / medication start date.
CM1002	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.

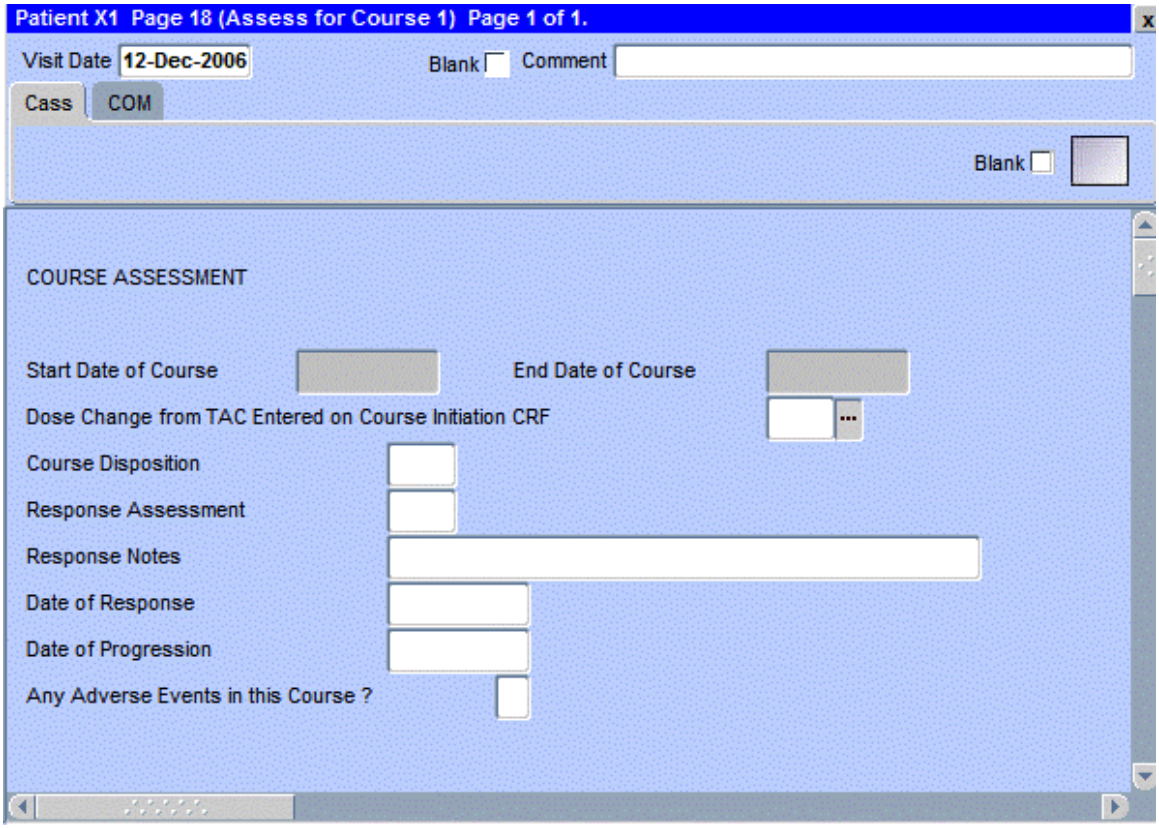
(CONCOMITANT-MEASURES-MEDICATIONS)

Course Assessment

Purpose

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

Course Assessment eCRF



Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the course started.	DD-MMM-YYYY
Start Date of Course (d)	Shows the Start Date of Course entered in the Course Initiation case report form.	DD-MMM-YYYY
End Date of Course (d)	Shows the derived end date of the course which is the day before the start date of the following course or the off treatment date.	DD-MMM-YYYY
Dose change from TAC entered on Course Initiation CRF (m)	Indicate if the patient's treatment was different from that specified by the Treatment Assignment Code (TAC) 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. *Note: optional for non-CTEP sponsored studies.* 1- **Yes, Planned** - change in treatment had been decided before the **start** of the course, e.g., due to toxicity on a previous course. 2- **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. 3- **No** - patient received the treatment specified in the Course Initiation TAC. 9- **Unknown** - only when the actual treatment **cannot be determined**, e.g., when the patient is uncooperative in reporting self-administration of study medication.	Use pick list.

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
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: Comp- Completed Dis- Discontinued	Use pick list.
Response Assessment (m) ...	Select the patient's best disease state as assessed during the course. This determination must be adequately documented in the patient'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- Protocol does not require a response assessment during the specific course. TE- Too Early to confirm a response. 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	Use pick list.

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
	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. 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". 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. DU- Disease Unchanged - Patient'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. **RECIST:** Many protocols specify that the following RECIST criteria are to be used in assessing response. Please use the following selections when assessing response using RECIST criteria only. 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	

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
	target lesions, taking as reference the baseline sum LD. 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 since the treatment started or the appearance of one or more new lesions. 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. <u>Evaluation of non-target lesions</u>: CR- Complete Response - Disappearance of all non-target lesions and normalization of tumor marker level. SD- Incomplete Response/Stable Disease - Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits. PD- Progressive Disease - Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions.	
Response Notes	Enter the reason why the Response Assessment is Not Evaluable (NE) or Not Assessed (NA). Some examples could include: protocol not followed, poor quality of scan, patient already treated.	32 characters

Course Assessment (cont'd)

Field Descriptions / Instructions		
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. *Note: The original date of onset of response should be used for responses that persist through several courses.*	DD-MMM-YYYY
Date of Progression	Enter the date of the evaluation used to determine the patient'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
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. *Note: The event(s) must be recorded on the Adverse Events case report form.*	Use pick list.
Legend: ▪▪▪pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Course Assessment (cont'd)

Validations		
Code	**Description**	**Resolution**
CAS02, CAS03	Date of Response or Onset Date of Progress must not be future dates.	Change the date to a value no later than the current date.
CAS05	Response Notes entered and Response Assessment is different than "Not Evaluable" and "Not Assessed".	Remove the Response Notes if Response Assessment is different than "Not Evaluable" and "Not Assessed". Otherwise change the Response Assessment to "Not Evaluable" and "Not Assessed".
CAS06	Response Assessment is "Not Evaluable" or "Not Assessed" and no Response Notes were entered.	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".
CAS07	Date of Response is required when Response Assessment is CR, PR, MR, SD, DU or NE.	Enter the Date of Response or Review the Response Assessment.
CAS08	Date of Progression is required when Response Assessment is PD.	Enter the Date of Progression or Review the Response Assessment.
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.	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.
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.	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.

Course Assessment (cont'd)

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.

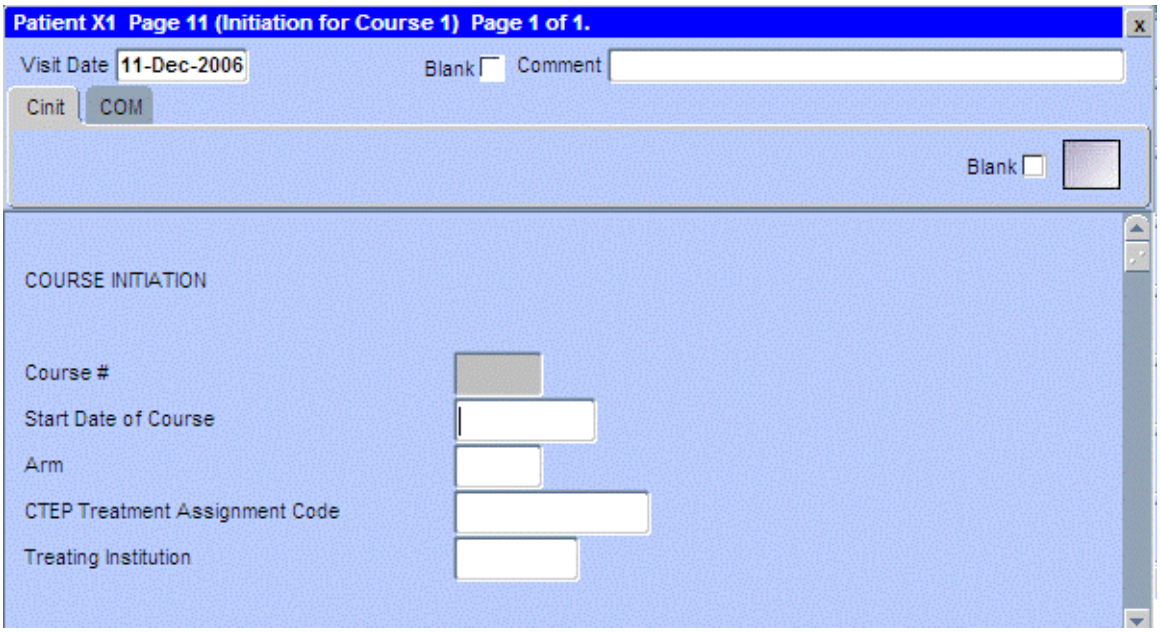
(COURSE-ASSESSMENT)

Course Initiation

Purpose

Record course initiation Start Date, Arm, Treatment Assignment Code (TAC) and Treating Institution.

Course Initiation eCRF



Course Initiation (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the course started.	DD-MMM-YYYY
Course # (d)	Sequential number of this course of treatment: first course = 1, second course = 2, etc.	5 digits
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
Arm (m) ...	Select the "Arm" of the protocol-specific treatment regimen the patient is to receive, as designated in the activation letter. *Note: Only mandatory for CTMS monitored, CTEP - sponsored studies.*	Use pick list.
CTEP Treatment Assignment Code (m) (c) ...	Select the appropriate Treatment Assignment Code (TAC) for the regimen and dose level of this course. "Treatment Assignment Codes" are provided by CTEP to the investigator at the time of protocol approval, and are updated as required following approval of protocol amendments. Each TAC will have a description that will outline the treatment schedule for the intended course. **A new TAC is selected if the dose was**: • reduced for a dose limiting toxicity (DLT), as defined in the protocol; • escalated, as defined in the protocol for intrapatient dose escalation; • changed or crossed over to another dosing schedule or set of medications due to progression or new treatment, as defined in the protocol. **A new TAC is not selected if the dose was**: • modified for a non-dose limiting toxicity; • titrated to patient tolerance.	Use pick list.

Course Initiation (cont'd)

	See CTEP's Treatment Assignment Instructions and Guidelines for further details at: http://ctep.cancer.gov/forms/TreatmentAssignment.pdf Advice on TACs is available from the CTEP's Protocol and Information Office (pio@ctep.nci.nih.gov).	
Treating Institution (m) ▪▪▪	Select the unique CTEP institution code where the patient actually receives this course of treatment. *Note: Optional for non-CTEP sponsored studies.*	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Course Initiation (cont'd)

Validations		
Code	**Description**	**Resolution**
CINI01	Start Date of Course cannot be in the future.	Change the Start Date of Course to a date no later than the current date.
CINI03, CINI04	Course start dates must be unique and in order.	Ensure that no course start dates are repeated and that they appear in the correct chronological order (from the oldest to the more recent).

Derivations		
Code	**Field Name**	**Description**
CINI1002	Course #	Course number derived by the system based on the dates the courses started.

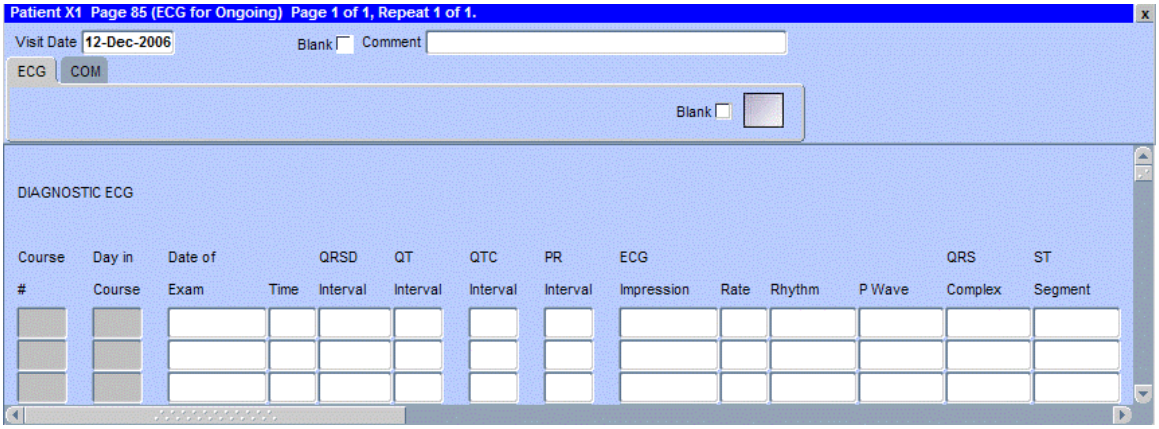
(COURSE-INITIATION)

ECG

Purpose

Record the patient's ECG.

ECG eCRF



ECG (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date field.	DD-MMM-YYYY
Course # (d)	Indicates the course number the ECGs are related to based on their date and time.	5 digits
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.	5 digits
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.
PR Interval	Enter the PR interval in milliseconds.	3 digits.
ECG Impression (m) ...	Select one of the following summary finding: A- Abnormal B- Borderline N- Normal	Use pick list.
Rate (m)	Enter the patient's pulse rate.	3 digits.
Rhythm (m) ...	Select one of the following rhythm finding: A- Abnormal N- Normal	Use pick list.

ECG (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
P Wave ▪▪▪	Select one of the following P Wave finding: A- Abnormal N- Normal	Use pick list.
QRS Complex ▪▪▪	Select one of the following QRS Complex finding: A- Abnormal N- Normal	Use pick list.
ST Segment ▪▪▪	Select one of the following ST Segment finding: A- Abnormal N- Normal	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

ECG (cont'd)

Validations		
Code	**Description**	**Resolution**
ECG01	Date of Exam is in the future.	Enter a date that is equal to or prior to the current date.

Derivations		
Code	**Field Name**	**Description**
ECG1001	Course #	Course number is derived based on the course initiation start dates and the Evaluation Date.
ECG1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the Evaluation Date.

(ECG)

Eligibility Checklist

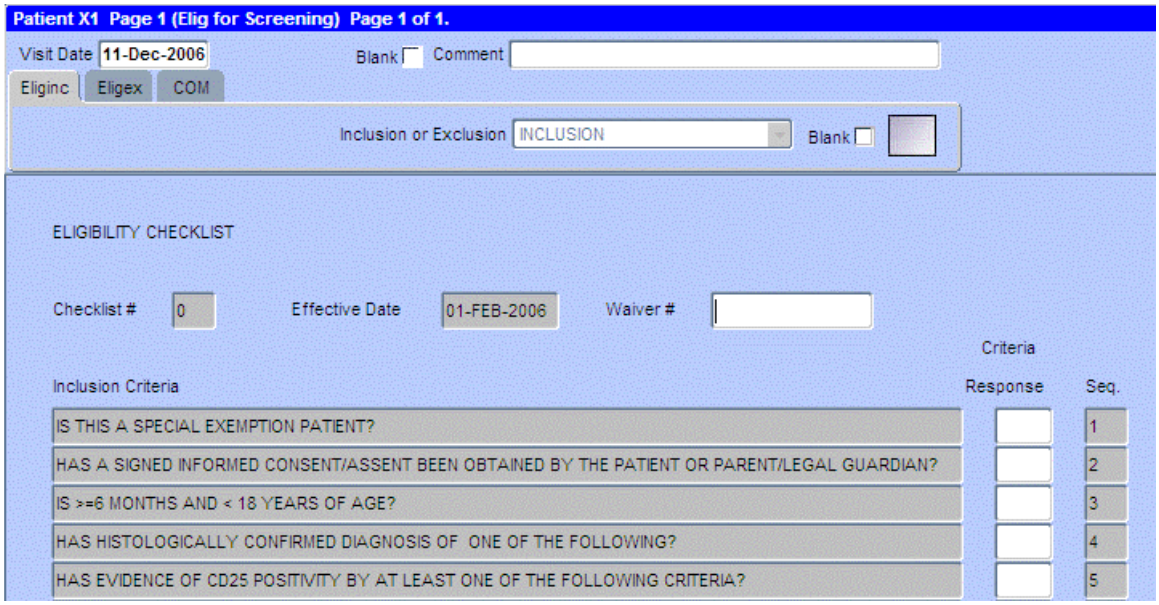
Purpose

Record the patient's status for each item of the eligibility checklist.

Each activated protocol has a customized eligibility checklist.

Eligibility Checklist eCRF

Inclusion Criteria tab (sample criteria)



Eligibility Checklist (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date [(m)]	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Checklist Number	Checklists are numbered sequentially based on NCI approval of amendments that change the eligibility criteria. The eligibility checklist from the original protocol must number 0. Each time the eligibility criteria for a protocol are amended, the checklist number is incremented. (The checklist number may not be the same as the amendment number, since some amendments do not affect the criteria.) The appropriate checklist number is provided by CTMS along with a new customized CRF each time a revised protocol-specific Eligibility Checklist is formulated. *Note: This field cannot be modified by the user.*	2 digits
Effective Date	Date of approval of the eligibility criteria by NCI. For the original protocol, the effective date is the date of NCI approval of the study. For revised eligibility criteria, the effective date is the date of NCI approval of the relevant amendment. This date is updated by CTMS at the time the protocol specific checklist is completed or amended by CTMS. *Note: This field cannot be modified by the user.*	DD-MMM-YYYY
Waiver Number	The waiver number when the patient is not formally eligible, but is admitted to the study. A reason must be entered in "Eligibility Waiver Reason" field of the Exclusion Criteria tab. *Note: Not applicable for NCI/DCTD/CTEP sponsored studies.*	12 characters

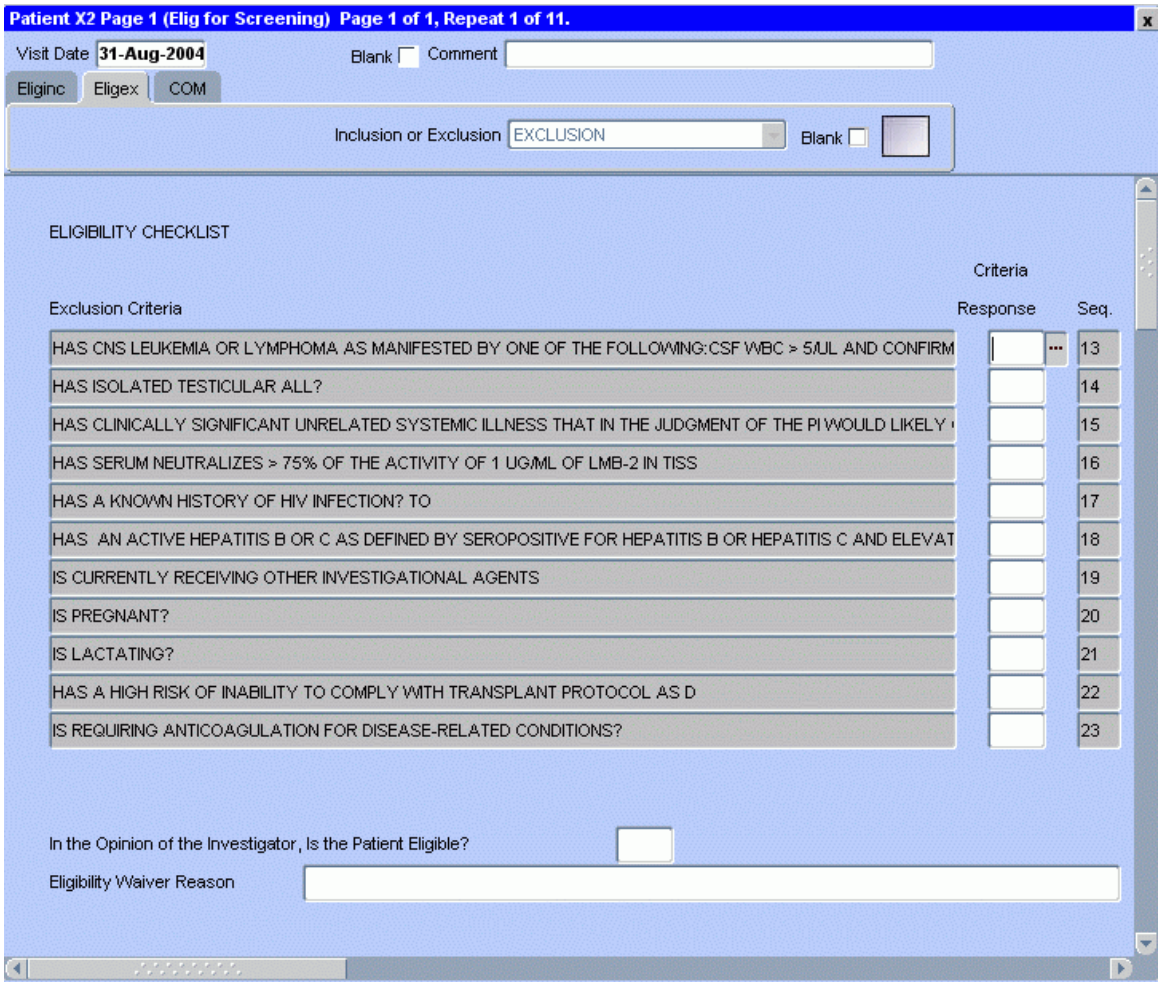
Eligibility Checklist (cont'd)

Criterion Response (m) ▪▪▪	Select the patient's status relative to the eligibility inclusion criterion. Y- Yes N- No X- Not Applicable *Note: Do not leave this field empty. Select one of the above responses.*	Use pick list.
Sequence	The inclusion criterion sequence number. *Note: This field cannot be modified by the user.*	2 digits
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Validations		
Code	**Description**	**Resolution**
EC01	Waiver Number provided but no Eligibility Waiver Reason has been provided and vice-versa.	An Eligibility Waiver Reason must accompany a Waiver Number.

Eligibility Checklist eCRF

Exclusion Criteria tab (sample)



Eligibility Checklist (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Criterion Response (m) ▪▪▪	Select the patient's status relative to the eligibility exclusion criterion. Y- Yes N- No X- Not Applicable *Note: Do not leave this field empty. Select one of the above responses.*	Use pick list.
Sequence	The exclusion criterion sequence number. *Note: This field cannot be modified by the user.*	2 digits
In the opinion of the investigator, is the patient eligible? (m) ▪▪▪	Select the investigator's decision. Y- Yes N- No X- Not Applicable	Use pick list.
Eligibility Waiver Reason	Patients who are not eligible as per protocol criteria should not be entered on study. If after an appropriate review of the patient's status it is determined that the patient violates one or more of the eligibility criteria, or if no information is available for some of the criteria, the Principal Investigator should state concisely and clearly why the patient has been admitted to the study. *Note: since CTEP does not issue or approve any waivers, providing this explanation will not make the patient eligible for the study.*	64 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Eligibility Checklist (cont'd)

Validations		
Code	**Description**	**Resolution**
EC01	Waiver Number provided but no Eligibility Waiver Reason has been provided and vice-versa.	An Eligibility Waiver Reason must accompany a Waiver Number.

(ELIGIBILITY-CHECKLIST)

Filler Page

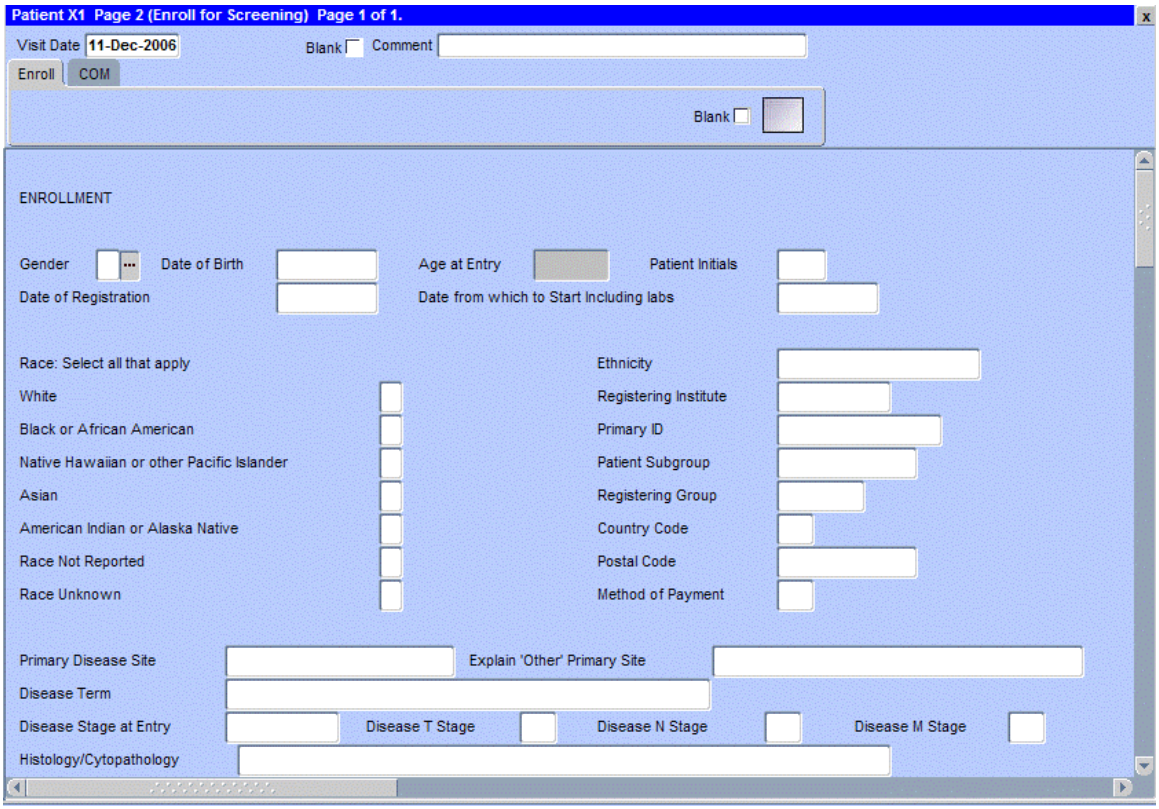
Enrollment

Purpose

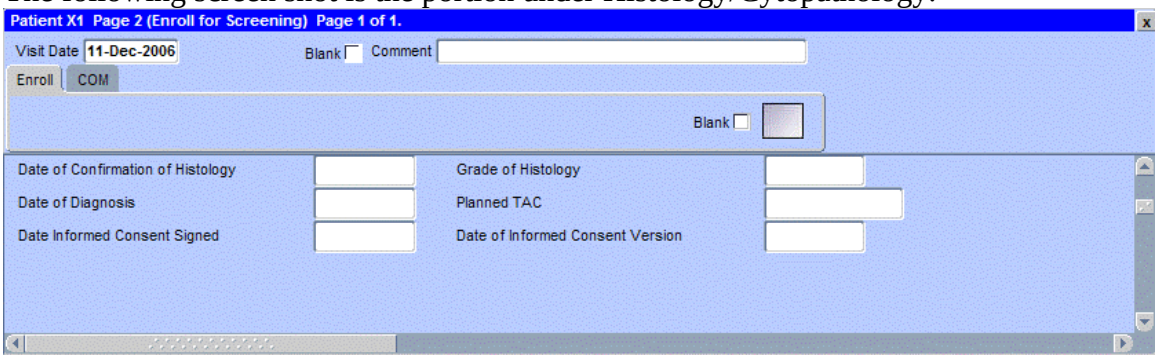
Record the patient's enrollment information at the time of study entry.

For studies that require de-identified patient data, fields such as Date of Birth (year only is acceptable), Patient Initials, Date from which to Start Including Labs, Primary ID, Country Code, Postal Code, Method of Payment will not be used.

Enrollment eCRF



The following screen shot is the portion under Histology/Cytopathology.



Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the patient's registration date.	DD-MMM-YYYY
Gender (m) ...	Select the patient's gender: M- Male F- Female U- Unknown	Use pick list.
Date of Birth (m)	Enter the patient's date of birth.	DD-MMM-YYYY
Age at Entry (d)	Age is derived from the patient's birth date at the enrollment and it remains the same throughout the study. Note: For children less than 5, a fractional age (rounding to one decimal place is sufficient) will be derived to indicate the number of months since the last birthday. (For example, a child with a birth date of January 1 having passed his fourth birthday and entering the study on July 1 would have his age recorded as 4.5 years.)	5 digits and 2 decimal
Patient Initials (m)	Enter the patient's initials. Usually 3 characters – first, middle and last name initials.	4 characters
Date of Registration (m)	Enter the date when patient was registered to the study. *Note: For CCR protocols, this date is the same as the Date Informed Consent Signed.*	DD-MMM-YYYY
Date from which to Start Including Labs (m)	Enter the date indicating when lab results data should be start being loaded from the centralized lab. Usually prior to the patient's informed consent.	DD-MMM-YYYY

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Race (m)	Select Yes or No for the following OMB race categories (when subject is multi-racial, answer YES to all the apply and No to the other race categories): • White: a person having origins in any of the original peoples of Europe, the Middle East, or North Africa. • Black or African American: a person having origins in any of the black racial groups of Africa. • Asian: a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent (including the Philippine Islands). • American Indian or Alaska Native: a person having origins in any of the original peoples of North, South, and Central America and who maintains tribal affiliation or community attachment. • Native Hawaiian or other Pacific Islander: a person having origins in any of the original peoples of Hawaii, or other Pacific Islands. • Not Reported: patient refused or data not available. • Unknown: patient is unsure of their race(s) *Note: If "Not Reported" or "Unknown" is selected, then no other race can be selected.*	Use pick list.

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Ethnicity (m)	Select one of the following OMB ethnicity categories: • Hispanic or Latino: a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. • Non-Hispanic or Latino: a person not meeting the definition for Hispanic or Latino. • Unknown: a person of unknown ethnicity. • Not Reported: Not provided or available	Use pick list.
Registering Institution (m) (c)	Enter the unique CTEP institution code where the patient was originally registered on study (e.g., institution where the patient signed the informed consent form). *Note: This field is not mandatory for non-CTEP studies.*	Use pick list.
Primary ID (m)	Enter the patient's medical record number for the selected Institution. The Clinical Center's medical record numbers have the following format:: 99-99-99-9 For non clinical center patients, enter the 900-xx-xxxx number provided by the Central Registration Office. These medical record numbers are used to load the patient's lab data.	12 characters

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Patient Subgroup (c) ▪▪▪	Select the appropriate unique code for identification of uniform groups of patients for separate analysis or treatment as defined in the Clinical Data System (CDS). Patient "Subgroup" codes are provided by CTEP to the investigator at the time of protocol approval, and are updated as required following approval of protocol amendments.	Use pick list.
Registering Group (c) ▪▪▪	Enter the unique CTEP Group code (as listed on the CTEP Web site) from which the patient was originally registered on study. *Note: This is required for Inter-Group trials only – otherwise leave blank.*	Use pick list.
Country Code (c) ▪▪▪	Required for non-US residents. For patients from outside the U.S., enter the foreign country code. Please use the International Standards Organization (ISO) Country codes which can found at CTEP web site for Country codes list.	Use pick list.
Postal Code (c)	For U.S. residents, enter the patient's home 5 digit zip code. Do not enter the last 4 digits of the complete zip code to assure patient confidentiality. Also do not enter the dash "-".	10 characters

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Method of Payment (c) ▪▪▪	Select the patient's primary method of payment using the following codes: 1- Private Insurance 2- Medicare 3- Medicare and Private Insurance 4- Medicaid 5- Medicaid and Medicare 6- Military or Veterans Sponsored NOS 6A- Military (including CHAMPUS or TRICARE) 6B- Veterans Sponsored 7- Self pay (no insurance) 8- No means of payment (no insurance) 98- Other 99- Unknown *Note: Currently the only acceptable entry is "98-Other".*	Use pick list.
Primary Disease Site (m) ▪▪▪	Select the primary disease site of the malignancy from the pick list. If the primary site is unknown, or it is for healthy volunteer or donor, select 'Other Site'.	Use pick list.
Explain 'Other' Primary Site	Enter an explanation for selecting 'Other Site' for Primary Disease Site. *Note: If the primary site is unknown, enter the comment 'Unknown Primary'. If the subject is a healthy volunteer or donor, enter 'Healthy Volunteer' or 'Donor' as appropriate.*	100 characters
Disease Term (m) ▪▪▪	Select a disease term. Use the list of Disease Terms ("MedDRA") as listed on the CTEP Web site.	Use pick list.

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Disease Stage at Entry ▪▪▪	Select the stage of the disease at the time of study entry if appropriate. Otherwise, leave it blank.	Use pick list.
Disease T Stage ▪▪▪	Select the stage of disease based on the primary tumor.	Use pick list.
Disease N Stage ▪▪▪	Select the stage of disease based on the nodes present.	Use pick list.
Disease M Stage ▪▪▪	Select the stage of disease based on the metastases present.	Use pick list.
Histology / Cytopathology	State briefly the type of histology or cytopathology found at the time of original diagnosis. Do not state broad categories (e.g., "lymphoma", but rather state "Non-Hodgkin's lymphoma").	50 characters (40 reported)
Date of Confirmation of Histology	Enter the date when the patient's disease status was confirmed, at the treating institution, prior to study entry (if required by the protocol).	DD-MMM-YYYY
Grade of Histology	Enter the grade of histology at study entry, if appropriate. Leave it blank otherwise.	10 characters (4 reported)
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 or MMM-YY
Planned TAC (m) (c) ▪▪▪	Select the appropriate code for the patient's treatment assignment as specified by CTEP. "Treatment Assignment" codes are provided by CTEP to the investigator at the time of protocol approval, and are updated as required following approval of protocol amendments. Advice on TACs is available from the CTEP's Protocol and Information Office (pio@ctep.nci.nih.gov).	Use pick list.

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Date Informed Consent Signed (m)	Enter the date the patient signed the informed consent form.	DD-MMM-YYYY
Date of Informed Consent Version (m)	Enter the date of the informed consent version of the IRB-approved informed consent form that was signed by the patient 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
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only, (u) for CDS reporting only.		

Enrollment (cont'd)

Validations		
Code	**Description**	**Resolution**
ENR01	Date Informed Consent Signed is before Date of Birth.	Change the Date Informed Consent Signed to be after the Date of Birth.
ENR02, ENR03, ENR04, ENR05, ENR06, ENR17	Date of Birth, Date of Registration, Date of Confirmation of Histology, Date of Diagnosis, Date Informed Consent Signed, Date of Informed Consent Version are in the future.	Enter a date that is prior or equals to today's date.
ENR07	All Races are unchecked.	Select at least one Race.
ENR08, ENR09, ENR10, ENR11, ENR12	Birth Date is after the Date of Registration, Date from which to include labs, Date of Confirmation of Histology, Date of Diagnosis, Date Informed Consent Signed, Informed Consent Version Date.	Correct the Date of Birth or the other date fields.
ENR13	In CTMS study, Date of Registration is not the same as Date Informed Consent Signed.	In CTMS study, Date of Registration should be the same as Date Informed Consent Date
ENR14	Date of Diagnosis is after Date of Histology Confirmation (if provided).	Correct Diagnosis Date or Date of Histology Confirmation.
ENR15, ENR16	Cannot select another Race when "Unknown" or "Not Reported" Race is selected.	Unselect the other Races and select only "Unknown" or "Not Reported". Or unselect both "Unknown" or "Not Reported" and select other Races.
ENR18	Registering Institution not found on the patient's Medical Record Numbers case report form.	Please review the Institutions on both case report forms.
ENR19	Date of Registration is before Date of Informed Consent Version.	Correct the one of the Dates.

Enrollment (cont’d)

ENR20	Enrollment only has part of the TNM Disease Stage information available	If one of the TNM fields is answered, the rest should be available.
ENR21	Primary Disease Site and 'Other' Primary Site are not present together.	Enter ‘Explain Other Primary Site’ if ‘Other Site’ is associated.

Derivations		
Code	**Field Name**	**Description**
DM1001	Age	The age is derived from the patient's enrollment registration date and the date of birth. Note: Age is expressed in decimals to accommodate patients under the age of 5.

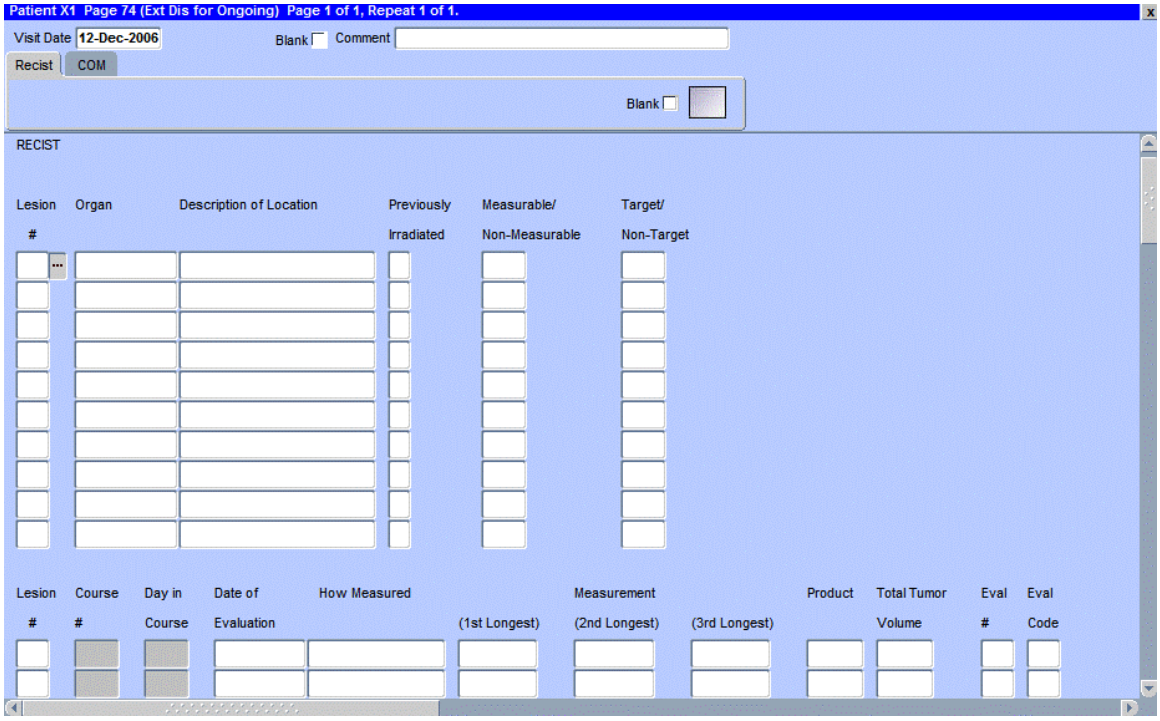
(ENROLLMENT)

Extent of Disease

Purpose

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

Extent of Disease eCRF



Extent of Disease (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Lesion # field.	DD-MMM-YYYY
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. *Note: This lesion number must appear at least once on the bottom repeating group.*	Use pick list.
Organ (m) ...	Select the organ or system where the lesion is located, i.e. Lung, Brain, etc.	Use pick list.
Description of Location (m) ...	Select a brief description of the lesion location.	Use pick list.
Previously Irradiated (m) ...	If the site or lesion has previously been irradiated, enter "Y" for Yes, otherwise enter "N" for No.	Use pick list.
Measurable / Non-Measurable (m) ...	Enter "M", for measurable, and "N" for non-measurable, as defined in the protocol.	Use pick list.
Target / Non-Target (m) ...	Enter "Target" for target lesions that will be assessed for response (e.g. using the RECIST response criteria). Enter "NonTarget" for non target lesions. *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. For CTMS studies, 'Target' will be submitted as 'Y', 'NonTarget' will be submitted as 'N'.*	Use pick list.

Extent of Disease (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Lesion # (m)	Select a lesion number from the pick list. *Note: This lesion number must appear in the description section (top repeating group).*	Use pick list.
Course # (d)	Indicates the course number that this lesion evaluation was done in as derived from the course initiation start date.	5 digits
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.	5 digits
Evaluation Date (m)	Enter the date of the evaluation (i.e.: date of CT scan). Do not enter the date of the report or when the results were received.	DD-MMM-YYYY
How Measured (m)	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.	Use pick list.
First Longest Measurement (m)	Enter the longest lesion measurement in centimeters. *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
Second Longest Measurement	Enter the second longest lesion measurement in centimeters. *Note: not applicable for studies that use RECIST criteria.*	6 digits and 2 decimals
Third Longest Measurement	Enter the third longest lesion measurement in centimeters. *Note: not applicable for studies that use RECIST criteria.*	6 digits and 2 decimals

Extent of Disease (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Product	Enter the tumor product.	8 digits and 2 decimals
Total Tumor Volume	Enter the total tumor volume.	8 digits and 2 decimals
Evaluation # (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. *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
Evaluation Code ▪▪▪	Select the status of non-measurable lesions at the time of each evaluation. B- Baseline (use for the initial lesion evaluation that was when the treatment started.) D- Decreasing I- Increasing N- New (use for lesions that appear after treatment has started.) R- Resolved S- Stable X- Not Evaluable	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Extent of Disease (cont'd)

Validations		
Code	**Description**	**Resolution**
EXT01	Lesion Number appears more than once on the description section (top repeating group).	Extent of Disease Lesion Number should be unique in the description section (top repeating group).
EXT02	Lesion Number in the measurement section (bottom repeating group) does not have a corresponding number in the description section (top repeating group).	Verify that lesion number in the measurement section is recorded in the description section (top repeating group).
EXT03	Evaluation Number of a measurable lesion is "0" and Evaluation Code is not "B-Baseline" or "N-New". And vice-versa.	If Evaluation Number of a measurable lesion is "0", Evaluation Code should be "B-Baseline" or "N-New".
EXT12	Lesion is marked as "Measurable" and longest measurement do not exist.	Enter the lesion's longest measurement.
EXT05	Date of Evaluation is in the future.	Enter a date that is equal to or prior to the current date.
EXT09	Lesion is marked as "Non-Measurable" and Evaluation Code was not provided.	Lesion is marked as "Non-Measurable" should have an Evaluation Code.
EXT13	The lesion has an Evaluation Code of "B-Baseline" and the Evaluation Date is not prior to Start Date of the first course.	Correct the lesion's Evaluation Date or the Evaluation Code.
EXT14	Evaluation Date for New lesion is prior to the Start Date of first course.	Enter a date that is equal or after the first course Start Date.
EXT15	Evaluation number for New lesion (with Evaluation Code 'N-New') is 0.	Enter a correct sequential number.
EXT16	New lesion (with Evaluation Code 'N-New') does not have the lowest evaluation number for the corresponding lesion.	Enter a correct sequential number.

Extent of Disease (cont'd)

Derivations		
Code	**Field Name**	**Description**
EXT1001	Course #	Course number is derived based on the course initiation start dates and the extent of disease evaluation date.
EXT1002	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.

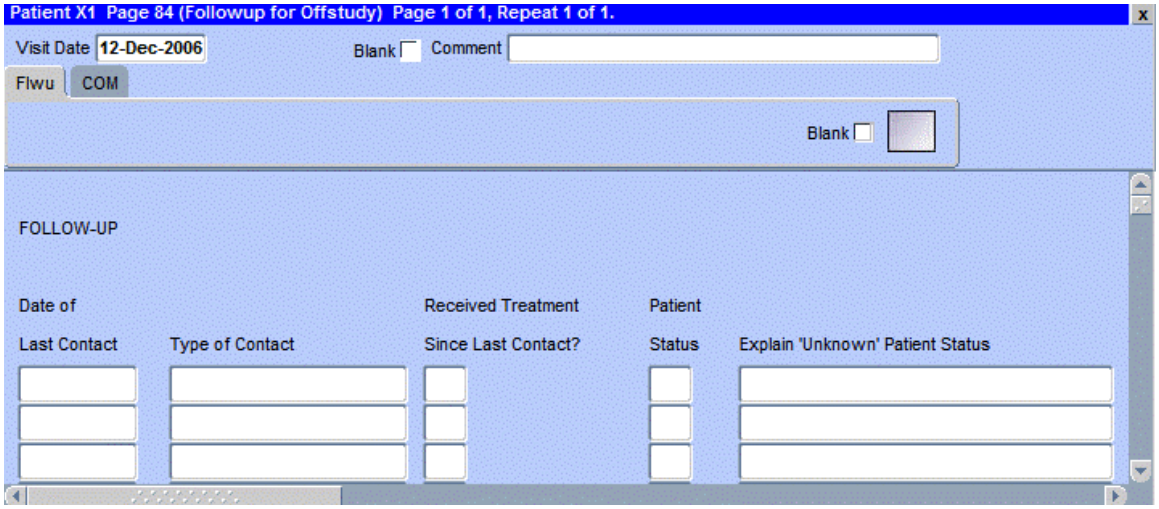
(EXTENT-OF-DISEASE)

Follow-up

Purpose

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

Follow-up eCRF



Follow-up (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Last Contact field.	DD-MMM-YYYY
Date of Last Contact (m)	Enter the date the patient was last contacted. If the patient is being considered lost to follow-up (i.e.: unsuccessful contact with the patient / family / health care provider), please indicate the date that no further follow-up will be attempted.	DD-MMM-YYYY
Type of Contact (m)	Select how the information was obtained: 1. Telephone contact with patient 2. Telephone contact with patient's family 3. Telephone contact with patient's local physician 4. Social Security Death Index (SSDI) 5. Clinic Appointment 6. Mail contact with the patient 7. E-Mail contact with the patient	Use pick list.
Received Treatment Since Last Contact? (m)	If the patient has received further treatment since the last contact, select Y- Yes N- No *Note: When answering 'Yes' and the patient has died during the follow-up period, only the Date of Death, entered on the Survival case report form, is sent to CTMS. Cause of Death and Autopsy information are not sent.*	Use pick list.

Follow-up (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Patient Status (m) ▪▪▪	Select one of the options below that indicates the patient's last known status. If the patient 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 4. Unknown (Explain) 5. Died	Use pick list.
Explain 'Unknown' Patient Status	If Patient Status is unknown, enter some explanation here. Include what attempts were made and how many attempts where made in order to obtain the patient's status (i.e.: no response to 5 messages left).	24 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Follow-up (cont'd)

Validations		
Code	**Description**	**Resolution**
FLW05	Date of Last Contact is in the future.	Enter a date earlier than, or equals to, the current date.
FLW06	Date of Last Contact is not within the Date Off Treatment and Date Off Study.	Date of Last Contact must fall between the Date Off Treatment and Date Off Study.
FLW07	Duplicate Date of Last Contact.	Date of Last Contact must be unique.
FLW08	Patient Status is "Unknown" and explanation is missing.	Patient Status "Unknown" requires an explanation.
FLW09	Explain "Unknown" Patient Status was provided, but Patient Status is not "Unknown".	Patient Status "Unknown" is required if an explanation for "Unknown" Patient Status is provided.

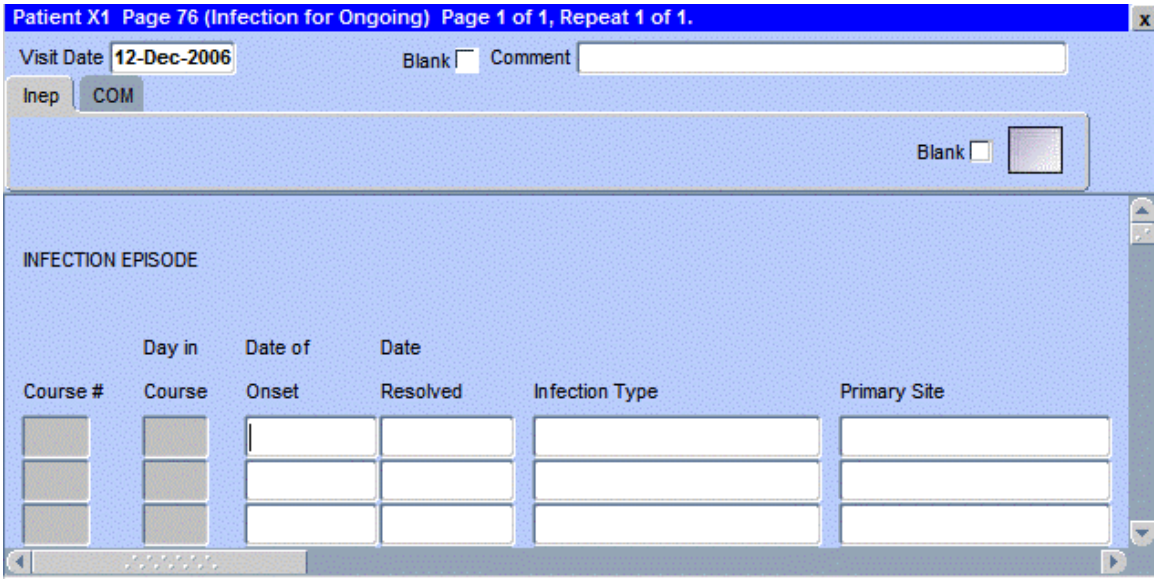
(FOLLOW-UP)

Infection Episode

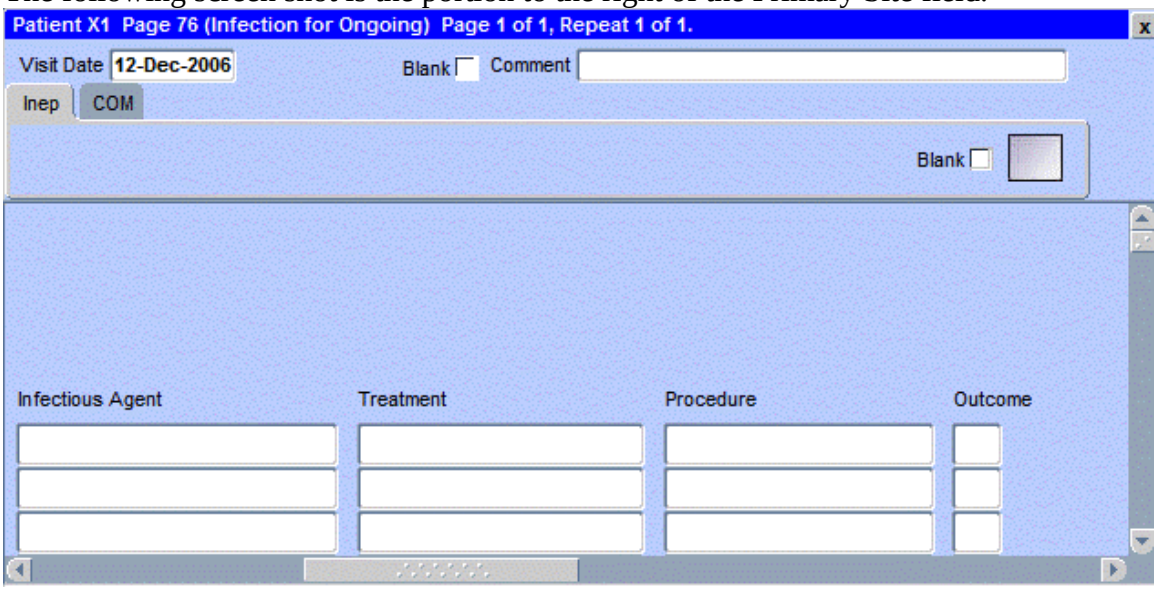
Purpose

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 assessing infectious episodes, either types and or number of events**. Additional comments may, if needed, be reported in the comment tab.

Infection Episode eCRF



The following screen shot is the portion to the right of the Primary Site field.



Infection Episode (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Onset field.	DD-MMM-YYYY
Course # (d)	Indicates the course number that this infection episode occurred in as derived from the course initiation start date.	5 digits
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.	5 digits
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.	Use pick list.
Primary Site (m) ▪▪▪	Select the primary site of the infection.	Use pick list.
Infectious Agent ▪▪▪	Select the actual infectious agent, determined from culture or other appropriate test.	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.	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.	Use pick list.
Outcome ▪▪▪	Select the outcome of this episode. 1. Recovered 4. Died	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Infection Episode (cont'd)

Validations		
Code	**Description**	**Resolution**
IFE01	Date of Onset of the Infection Episode is greater than the Resolve Date.	Date of Onset must be prior than Resolve Date
IFE02, IFE03	Date of Onset and/or Date Resolved are/is in the future.	Enter a date that is equal to or prior to the current date.
IFE05	Date of Onset, Infection Type, Treatment and Procedure appear more than once.	An Infection Type, Treatment and Procedure can only be entered once for a particular Date of Onset.
IFE06	Resolved Date provided, but Outcome is missing.	Outcome must be entered if Date Resolved is provided.
IFE07	Date Resolved is missing, but Outcome was provided.	Date Resolved must be entered if Outcome is provided.
IFE08	A Concomitant Measure / Medication with an Agent matching the Infection Episode Treatment with the same Start Date and Date of Onset was not found.	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.
IFE09	A Concomitant Measure / Medication with a Procedure matching the Infection Episode Procedure with the same Start Date and Date of Onset was not found.	An Infection Episode Procedure must have an entry in the Concomitant Measure / Medication case report form with the Start Date the same as the Date of Onset.

Infection Episode (cont'd)

Derivations		
Code	**Field Name**	**Description**
IFE1001	Course #	Course number is derived based on the course initiation start dates and the infection episode Date of Onset.
IFE1002	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.

(INFECTION-EPISODES)

Labs

Purpose

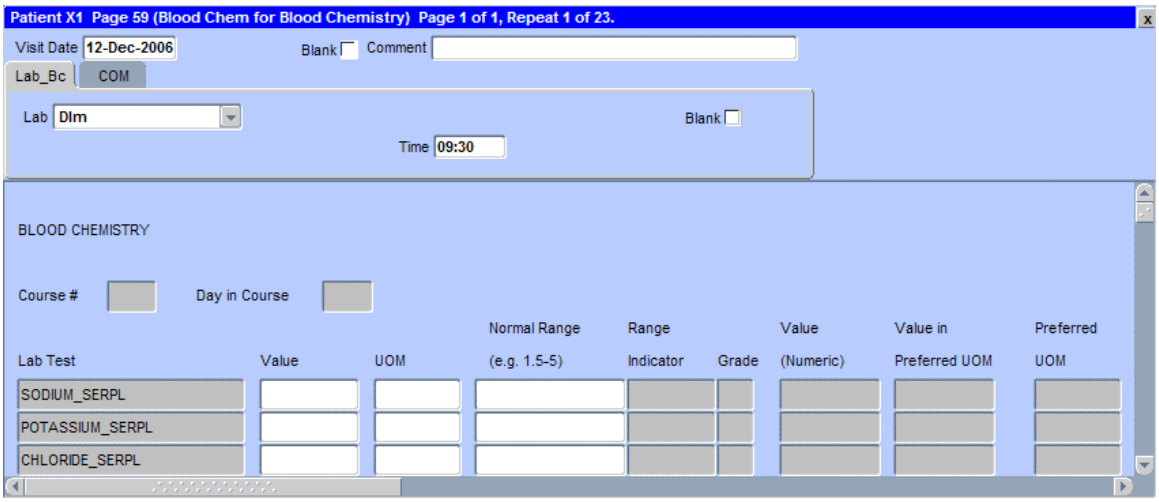
Record the patient's lab results.

Patients on intramural studies who have their labs drawn at the Clinical Center will have the lab results automatically loaded onto the CRF overnight from another system. It is common to have several forms of the same kind of lab for a patient. Click on the C3D RDC worksheet column header labeled "Show unplanned visit" to see all these extra lab results.

The following lab CRFs collect the same data as is automatically loaded and are documented here as a group. At the end of this document is a list of the lab tests applicable for each lab.

• Blood Chemistry • Blood Gases • Bone Marrow • Coagulation • CSF • Flow Cytometry • Genetic Analysis • Hematology • Immune Parameters	• Other Serum Chemistries • Other Urinary Results • Pulmonary Function • Red Cell Indices • Serology • Serum Electro • Urinalysis • Urine Immune Electro

Labs eCRF



Labs (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the lab sample was collected.	DD-MMM-YYYY
Time (m)	Enter the time the lab sample was collected. Enter midnight as 24:00 since 00:00 is used when time is not known.	HH(24):MM
Lab ...	Select the source of the lab results. Dlm- Lab results automatically loaded from another system. Dlm$Diabetic- Not in use. **Do not use.** Outside- Outside lab results entered manually. Respfunc- Not in use. **Do not use.**	Use pick list.
Course # (d)	Indicates the course number this lab is related to.	5 digits
Day in Course (d)	Indicates the day since the beginning of course this lab is related to.	5 digits
Lab Test (d)	Pre-defined name of the lab test. Each lab has a different set of tests which are listed at the end of this document.	25 characters

Labs (cont'd)

<table>
<tr><th colspan="3">Field Descriptions and Instructions</th></tr>
<tr><th>Field Name</th><th>Description / Instructions</th><th>Format</th></tr>
<tr><td>Value</td><td>Enter the lab test result value. Except for Bone Marrow and Urinalysis, all other lab values are numeric.

The following coding scheme should be used for lab tests where results may be qualitative.

<table>
<tr><th>WBC, RBC</th><th>Ketones, Bile</th></tr>
<tr><td>0. None
1. Few
2. Several
3. Many
4. Too numerous to count</td><td>0. None
1. +
2. ++
3. +++
4. ++++</td></tr>
<tr><td colspan="2">Note: these terms may be institution or lab dependent. Please be consistent throughout the protocol.</td></tr>
</table>

HIV, HbsAg, Pregnancy, Stool Guiac
1- Positive
0- Negative

M-Rating
1-7: integer part of the standard M-Rating</td><td>20 characters.</td></tr>
<tr><td>UOM ▪▪▪</td><td>Select the appropriate lab test value unit of measurement.</td><td>Use pick list.</td></tr>
<tr><td>Normal Range</td><td>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.</td><td>30 characters</td></tr>
</table>

Labs (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Range Indicator (d)	Indicates how the lab result value compares to the lab test normal range. NORMAL- Falls within the normal range. HIGH- Above the normal range. LOW- Below the normal range. NONNUM- Not a valid number (e.g. "No Data"). NORANG- No normal values are provided.	6 characters
Grade (d)	Derived from the lab test result value and the lab test ranges from the NCI Common Toxicity Criteria (CTC) version 2.0 or the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0. *Note: The age and gender is also factor in some cases.*	13 characters
Value (Numeric) (d)	Derived from lab test result value	12 characters
Value in Preferred UOM (d)	Derived the lab test result value in the preferred unit of measurement which are pre-defined by the institute.	12 characters
Preferred UOM (d)	Derived the preferred unit of measurement for the specified lab test.	20 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Labs (cont'd)

Validations		
Code	**Description**	**Resolution**
LB01	Lab test has a grade higher than zero or the baseline lab test grade, but no relevant Adverse Event exists.	Correct the lab grade or make sure a relevant Adverse Event exists.
LB03	Two labs exist for the same date and time.	Review both labs and delete/correct one of them.
LB04	Lab record is not complete.	Enter the correct value and appropriate UOM

Derivations		
Code	**Field Name**	**Description**
LBAL1003	Course #	Course number is derived from the course initiation start date and the lab date (visit date).
LBAL1004	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the lab date (visit date).
Not Applicable	Lab Test	The lab tests are pre-defined. See the following table for a list of the pre-define lab tests for each lab.
Not Applicable	Panel #	The panel number is pre-defined and is provided on the CTMS Protocol Start-Up Letter.
LBAL1001	Range Indicator	Derived based on the lab value result and normal high/low range.
LBAL1002	Grade	Derived from the lab test result value, unit of measurement and the lab test normal range.

Labs (cont'd)

Lab Tests		
Lab	**Test**	**Description**
BLOOD CHEMISTRY	SODIUM_SERPL	Sodium, Serum/Plasma
	POTASSIUM_SERPL	Potassium, Serum/Plasma
	CHLORIDE_SERPL	Chloride, Serum/Plasma
	BICARBONATE_SER	Bicarbonate, Serum
	GLUCOSE_FAST_SERPL	Glucose, Fasting, Serum/Plasma
	GLUCOSE_SERPL	Glucose, Serum/Plasma
	BUN_SERPL	Blood Urea Nitrogen, Serum/Plasma
	ALB_SERPL	Albumin, Serum/Plasma
	CALCIUM_SERPL	Calcium, Serum/Plasma
	MAGNESIUM_SERPL	Magnesium, Serum/Plasma
	PHOSPHATE_SERPL	Phosphate (Inorganic Phosphorus), Serum/Plasma
	ALP_SERPL	Alkaline Phosphatase, Serum/Plasma
	ALT_SGPT_SERPL	Alanine Aminotransferase, Serum/Plasma
	AST_SGOT_SERPL	Aspartate Aminotransferase, Serum/Plasma
	BILIRUB_TTL_SERPL	Bilirubin, Total, Serum/Plasma
	BILI_DIRECT_SERPL	Bilirubin, Direct, Serum/Plasma
	LDH_SERPL	Lactate Dehydrogenase, Serum/Plasma

Labs (cont'd)

	CK_SERPL	Creatine Kinase, Serum/Plasma
	URATE_SERPL	Uric Acid, Serum/Plasma
	CREAT_SERPL	Creatinine, Serum/Plasma
	TP_SERPL	Total Protein, Serum/Plasma
	NT5_SER	5'-Nucleotidase, Serum
	CHOLEST_SERPL	Cholesterol, Serum/Plasma
BLOOD GASES	PH_BLDA	pH, Arterial Blood
	PCO2_BLDA	Percent Carbon Dioxide (CO2), Arterial Blood
	PO2_BLDA	Percent Oxygen (O2), Arterial Blood
	HCO3_BLDA	Bicarbonate, Arterial Blood
	BASE_DEFICIT_BLD	Base Deficit, Blood
	O2_SATN_BLD	Oxygen Saturation, Arterial Blood
	CO_HGB_BLDA	Carboxyhemoglobin, Arterial Blood
	METHGB_BLDA	Methemoglobin, Arterial Blood
BONE MARROW	MYELOBLASTS_PC_MAR	Myeloblasts, %, Bone Marrow
	PROMYELOCYTE_PC_MAR	Promyelocytes, %, Bone Marrow
	MYELOCYTE_PC_MAR	Myelocytes, %, Bone Marrow
	METAMYELOCYTE_PC_MAR	Metamyelocytes, %, Bone Marrow
	BAND_PC_MAR	
	NEUT_MYEL_PC_MAR	Neutrophilic Myelocytes, %, Bone Marrow

Labs (cont'd)

	EOSIN_MYEL_PC_MAR	Eosinophilic Myelocytes, %, Bone Marrow
	BASO_MYEL_PC_MAR	Basophilic Myelocytes, %, Bone Marrow
	LYMPH_PC_MAR	Lymphocytes, %, Bone Marrow
	MONO_PC_MAR	Monocytes, %, Bone Marrow
	PLASMA_CELL_PC_MAR	Plasma Cells, %, Bone Marrow
	PRONORMOBLAST_PC__MAR)	Pronormoblasts, %, Bone Marrow
	M_RATING_MAR	M Rating, Bone Marrow
	POLY_NEUT_PC_MAR	Polymorphic Neutrophils, %, Bone Marrow
	POLY_EOSIN_PC_MAR	Polymorphic Eosinophils, %, Bone Marrow
	POLY_BASO_PC_MAR	Polymorphic Basophils, %, Bone Marrow
	RETIC_PC_MAR	Reticulocyte, %, Bone Marrow
	MEGAKARYOCYTE_PC_BLD (_MAR)	Megakaryocytes, %, Bone Marrow
	NORMOBLASTS	Normoblasts, %, Bone Marrow
COAGULATION	PT_BLD	Prothrombin Time, Blood
	PTT_BLD	Partial Thromboplastin Time, Blood
	INR_BLD	Coagulation Tissue Factor Induced, Blood
	FIBRINOGEN_PPP	Fibrinogen, Platelet Poor Plasma
	THROMBIN_TM_BLD	Thrombin Time, Blood

Labs (cont'd)

	CLOT_TIME_BLD	Clotting Time, Blood
	CLOT_RETRACT_BLD	Clot Retraction, Blood
	BLEED_TIME_BLD	Bleeding Time, Patient, Blood
	FDP_BLD	Fibrin Degradation Products, Blood
CSF	WBC_NUM_CSF	White Blood Cells, #, Cerebrospinal Fluid
	RBC_NUM_CSF	Red Blood Cells, #, Cerebrospinal Fluid
	OTHER_CELL_CSF	Other Cell Count, Cerebrospinal Fluid
	LYMPH_PC_CSF	Lymphocytes, %, Cerebrospinal Fluid
	CELL_CT_CSF	Cell Count, Cerebrospinal Fluid
	MBP_CSF	Myelin Basic Protein, Cerebrospinal Fluid
	GLUCOSE_CSF	Glucose, CSF
	COLOR_CSF	Color, Cerebrospinal Fluid
	APPEAR_CSF	Appearance, CSF
FLOW CYTOMETRY	CD3_NUM_BLD	CD3 Cells, #, Blood
	CD3_PC_FC_BLD	CD3 Cells, %, Flow Cytometry, Blood
	CD4_CD3_NUM_BLD	CD4 Cells to CD3 Cells, #, Blood
	CD4_CD3_PC_BLD	CD4 Cells to CD3 Cells, %, Blood
	CD4_CD8_RTO_BLD	CD4 Cells to CD8 Cells, Blood
	CD4_NUM_BLD	CD4 Cells, #, Blood

Labs (cont'd)

	CD4_PC_FC_BLD	CD4 Cells, %, Flow Cytometry, Blood
	CD8_NUM_BLD	CD8 Cells, #, Blood
	CD8_PC_FC_BLD	CD8 Cells, %, Flow Cytometry, Blood
GENETIC ANALYSIS	HHV8_DNA_PCR_SER	Herpes Virus 8, DNA, Polymerase Chain Reaction, Serum
	CMV_DNA_PCR_CSF	Cytomegalovirus, DNA, Polymerase Chain Reaction, Cerebrospinal Fluid
	CMV_PCR_BLD	Cytomegalovirus, Polymerase Chain Reaction, Blood
HEMATOLOGY	WBC_NUM_BLD	White Blood Cells, #, Blood
	RBC_NUM_BLD	Red Blood Cells, #, Blood
	HGB_BLD	Hemoglobin, Blood
	HCT_BLD	Hematocrit, Blood
	MCV_RBC	Mean Corpuscular Volume, Red Blood Cells
	RDW_RBC	Red Cell Distribution Width, Red Blood Cells
	PLATELET_BLD	Platelets, Blood
	POLY_PC_BLD	Polymorphonuclear Cells, %, Blood
	POLY_NUM_BLD	Polymorphonuclear Cells, #, Blood
	BANDS_NUM_BLD	Neutrophil Bands, #, Blood
	LYMPH_PC_BLD	Lymphocytes, %, Blood
	LYMPH_NUM_BLD	Lymphocytes, #, Blood
	MONO_PC_BLD	Monocytes, %, Blood

Labs (cont'd)

	MONO_NUM_BLD	Monocytes, #, Blood
	EOSINOPHIL_PC_BLD	Eosinophils, %, Blood
	NEUT_NUM_BLD	Neutrophils, #, Blood
	EOSINOPHIL_NUM_BLD	Eosinophils, #, Blood
	BASO_PC_BLD	Basophils, %, Blood
	BASO_NUM_BLD	Basophils, #, Blood
IMMUNE PARAMETERS	LYMPHOBLAST_PC_BLD	Lymphoblasts, %, Blood
	B_LYMPH_NUM_BLD	B Lymphocytes, #, Blood
	T_LYMPH_PC_BLD	T Lymphocytes, %, Blood
	T_LYMPH_HLPR_BLD	T Lymphocyte Helper Cells, Blood
	T_LYMPH_SUPP_BLD	T Lymphocyte Suppressor Cells , Blood
	T_LYMPH_DTH_BLD	T Lymphocytes, Delayed Hypersensitivity Testing, Blood
	T_LYMPH_CTL_BLD	(T Lymphocytes, Cutaneous T Cell, Blood) Cytotoxic T lymphocytes, Blood
	NK_ACTIVITY_BLD	Natural Killer Cell Activity, Blood
	ADCC_BLD	Antibody-Dependent Cell-medinated Cytotoxicity
	MACROS_CYTOTXITY_BLD	Macrophage Cytotoxicity, Blood
	MACROS_CYTOSTASI_BLD	Macrophage Cytostasis, Blood
	PEROXIDE_GENER_BLD	Peroxide Generation, Blood
	INTERFERON_SER	Interferon, Serum
OTHER SERUM	ALDOLASE_SERPL	Aldolase, Serum/Plasma

Labs (cont'd)

CHEMISTRIES	AMMONIA_SER	Ammonia, Serum
	CAI_SERPL	Calcium, Ionized, Serum/Plasma
	COOPER_SERPL	Copper, Serum/Plasma
	FERRITIN_SERPL	Ferritin, Serum/Plasma
	HDLC_SERPL	High Density Lipids, Cholesterol, Serum/Plasma
	INSULIN_SERPL	Insulin, Serum/Plasma
	IRON_SERPL	Iron, Serum/Plasma
	TIBC_SERPL	Total Iron Binding Capacity, Serum/Plasma
	IRON_SATN_RTO_SERPL	Iron Saturation, Ratio, Serum/Plasma
	LDLC_SERPL	Low Density Lipids, Cholesterol, Serum/Plasma
	LIPASE_SERPL	Lipase, Serum/Plasma
	OSMOLALITY_SERPL	Osmolality, Serum/Plasma
	ACP_SERPL	Acid Phosphatase, Serum/Plasma
	TRANSFERRIN_SERPL	Transferrin, Serum/Plasma
	TRIGL_SERPL	Triglyceride, Serum/Plasma
	T3_SERPL	Triiodothyronine (T3), Serum/Plasma
	T4_SERPL	Thyroxine (T4), Serum/Plasma
	TSH_SERPL	Thyrotropin (Thyroid Stimulating Hormone), Serum/Plasma
OTHER URINARY	CALCIUM_24H_UR	Calcium, 24 hour, Urine
	CHLORIDE_24H_UR	Chloride, 24 hour, Urine

Labs (cont'd)

RESULTS	OSMOLALITY_24H_UR	Osmolality, 24 hour, Urine
	OXALATE_24H_UR	Oxalate, 24 hour, Urine
	POTASSIUM_24H_UR	Potassium, 24 hour, Urine
	SODIUM_24H_UR	Sodium, 24 hour, Urine
	UNU_24H_UR	Urea Nitrogen, 24 hour, Urine
	URATE_24H_UR	Uric Acid, 24 hour, Urine
	ALBUMIN_PEP_URN	Albumin, Protein Electrophoresis, Urine
	ALPHA1_GLOB_EP_TURN	Alpha 1 Globulin, Electrophoresis, Timed Urine
	ALPHA2_GLOB_EP_TURN	Alpha 2 Globulin, Electrophoresis, Timed Urine
	BETA_GLOB_EP_TURN	Beta Globulin, Electrophoresis, Timed Urine
	GAMMA_GLOB_EP_TURN	Gamma Globulin, Electrophoresis, Timed Urine
PULMONARY FUNCTION	VC_RESYS	Vital Capacity, Respiratory System
	EXP_VOL_RES	Expiratory Volume, Respiratory
	MAX_C_RESYS	Forced Vital Capacity (Maximum), Respiratory System
	VOL_RES_RESYS	Volume Residual, Respiratory System
	BASE_EXCESS_BLD	Base Excess, Blood
	TIDAL_VOL_RESYS	Tidal Volume, Respiratory System
	FUNCT_RES_C_RES	Capacity, Functional Residual, Respiratory

Labs (cont'd)

	PULM_COMPLIANCE_	Pulmonary Compliance
	DIFFUS_CAP_RES	Diffusion Capacity, Respiratory
	MAX_FXP_FLOW_RESYS	Maximum Forced Expiratory Flow, Respiratory System
RED CELL INDICES	TP_SERPL	Total Protein, Serum/Plasma
	ALPHA1_GLOB_EP_SERPL	Alpha 1 Globulin, Protein Electrophoresis, Serum/Plasma
	ALPHA2_GLOB_EP_SERPL	Alpha 2 Globulin, Protein Electrophoresis, Serum/Plasma
	BETA_GLOB_EP_SERPL	Beta Globulin, Protein Electrophoresis, Serum/Plasma
	GAMMA_GLOB_EP_SERPL	Gamma Globulin, Protein Electrophoresis, Serum/Plasma
	CH50_SERPL	CH50 Complement, Serum/Plasma
	DAT_RBC	Direct Antiglobulin Test (Coombs), Red Blood Cells
	MCHC_RBC	Mean Corpuscular Hemoglobin Concentration, Red Blood Cells
	MCH_RBC	Mean Corpuscular Hemoglobin, Red Blood Cells
	ALPHA1_GLOB_EP_SERPL	Alpha 1 Globulin, Protein Electrophoresis, Serum/Plasma
	QUANTITIVE	Lab Test
	SEMI_QUANT	Lab Test
SEROLOGY	PSA_SERPL	Prostate Specific Antigen, Serum/Plasma
	CA125_SERPL	Carcinogenic Antigen 125, Serum/Plasma

Labs (cont'd)

	CEA_SERPL	Carcinoembryonic Antigen, Serum/Plasma
	CA19_9_SERPL	Carcinogenic Antigen 19-9, Serum/Plasma
	CA15_3_SERPL	Carcinogenic Antigen 15-3, Serum/Plasma
	CA27_29_SERPL	Cancer Antigen 27-29, Serum/Plasma
	AFP_SER	Alpha-1-Fetoprotein, Serum
	HCG_SERPL	Human Choriogonadotropin, Serum/Plasma
	HIV_1_2_AB_SER	Human Immunodeficiency Virus, 1-2 Antibody, Serum
	HBSAG_SER	Hepatitis B Surface Antigen, Serum
	BHCG_PREG_SER	Beta Human Choriogonadotropin, Pregnancy Test, Serum
	GUAIAC_STL	Occult Blood (Guaiac), Stool
	NEUT_AB_BL22_SER	Neutralizing Antibody BL22, Serum
SERUM ELECTRO	IGA_SER	Immunoglobulin A, Serum
	IGD_SER	Immunoglobulin D, Serum
	IGE_SER	Immunoglobulin E, Serum
	IGG_SER	Immunoglobulin G, Serum
	IGM_SER	Immunoglobulin M, Serum
	M_PROT_ELPH_SERPL	Monoclonal Protein, Electrophoresis, Serum/Plasma
	P_PROT_ELPH_SERPL	Polyclonal Protein, Electrophoresis, Serum/Plasma

Labs (cont'd)

	KAPPA_LC_ELPH_SER	Kappa Light Chain, Electrophoresis, Serum
	LAMBDA_LC_ELPH_SER	Lambda Light Chain, Electrophoresis, Serum
	BJ_PROTEIN_SER	Bence Jones Protein, Electrophoresis, Serum
URINALYSIS	PROTEIN_24H_UR	Protein, 24 hour, Urine
	GLUCOSE_UR	Glucose, Spot Urine
	KETONES_UR	Ketones, Spot Urine
	BILIRUB_UR	Bile (Bilirubin or Urobilinogen), Spot Urine
	UROBILINOGEN_URN	Urobilinogen, Urine
	LEUK_EST_UR	Leukocyte Esterase, Urine
	NITRITE_UR	Nitrite, Urine
	PH_UR	pH, Spot Urine
	SP_GR_UR	Specific Gravity, Spot Urine
	BHCG_PREG_URN	B-HCG, Pregnancy Test, Urine
	CREATININE_UR	Creatinine, Spot Urine
	WBC_UR	White Blood Cells, Urine
	RBC_NUM_UR	Red Blood Cells, #, Urine
	CRCL_24H_UR	Creatinine Clearance, 24 hour, Urine
	CASTS_UR	Casts, Urine
	SPEC_COLL_PD_UR	Specimen Collection Period, Urine
	SPEC_VOL_UR	Specimen Volume, Urine

Labs (cont'd)

URINE IMMUNE ELECTRO	IGA_IEP_UR	Immunoglobulin A, Immunoelectrophoresis, Urine
	IGD_IEP_UR	Immunoglobulin D, Immunoelectrophoresis, Urine
	IGE_IEP_UR	Immunoglobulin E, Immunoelectrophoresis, Urine
	IGG_IEP_UR	Immunoglobulin G, Immunoelectrophoresis, Urine
	IGM_IEP_UR	Immunoglobulin M. Immunoelectrophoresis, Urine
	M_PROT_ELPH_UR	Monoclonal Protein, Electrophoresis, Urine
	P_PROT_ELPH_UR	Polyclonal Protein, Electrophoresis, Urine
	KAPPA_LC_ELPH_UR	Kappa Light Chain, Electrophoresis, Urine
	LAMBDA_LC_ELPH_UR	Lambda Light Chain, Electrophoresis, Urine
	BJ_PROTEIN_UR	Bence Jones Protein, Electrophoresis, Urine

(LABS)

Filler Page

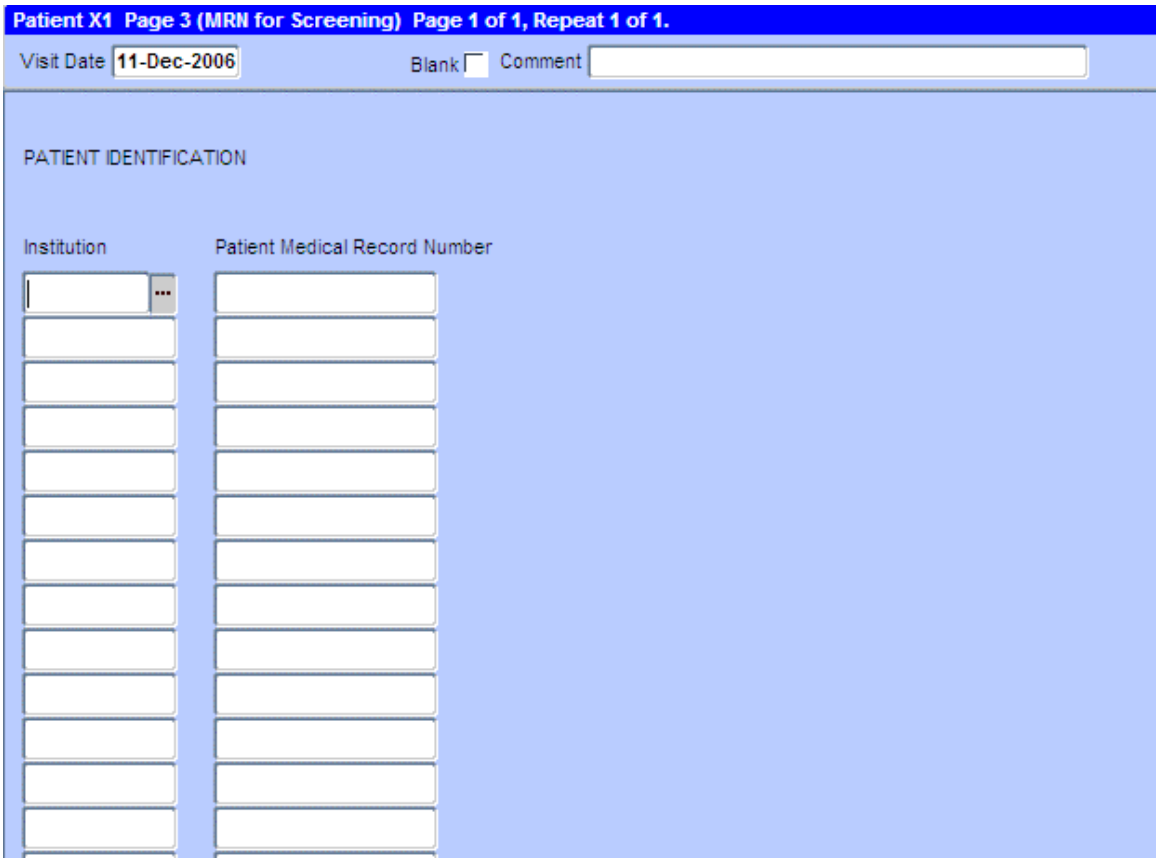
Medical Record Numbers

Purpose

Record the patient's medical record number(s).

This CRF is not used for studies that require patient data de-identification.

Medical Record Numbers eCRF



Medical Record Numbers (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the patient's registration date.	DD-MMM-YYYY
Institution (m) ...	Select one of the CTEP Registering Institutions.	Use pick list.
Patient Medical Record Number (m)	Enter the patient's medical record number for the selected Institution. The Clinical Center's medical record numbers have the following format:: 99-99-99-9 For NCINAV and other institutions, enter the medical record number following the institution's format. These medical record numbers are used to load the patient's lab data.	12 characters
Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Validations		
Code	**Description**	**Resolution**
MRN01	An NCI Institution has been selected (except for NCINAV) and Patient Medical Record Number does not have 10 characters.	For NCI Institutions (except NCINAV) the Patient Medical Record Number must be entered in the following format: 99-99-99-9
MRN02	An NCI Institution has been selected (except for NCINAV) and Patient Medical Record Number checksum is invalid.	Enter the correct Patient Medical Record Number.
MRN03	Patient Medical Record Number is the same for different Institutions.	Verify and correct the Institution and/or Patient Medical Record Number.

(MEDICAL-RECORD-NUMBERS)

Off Study

Purpose

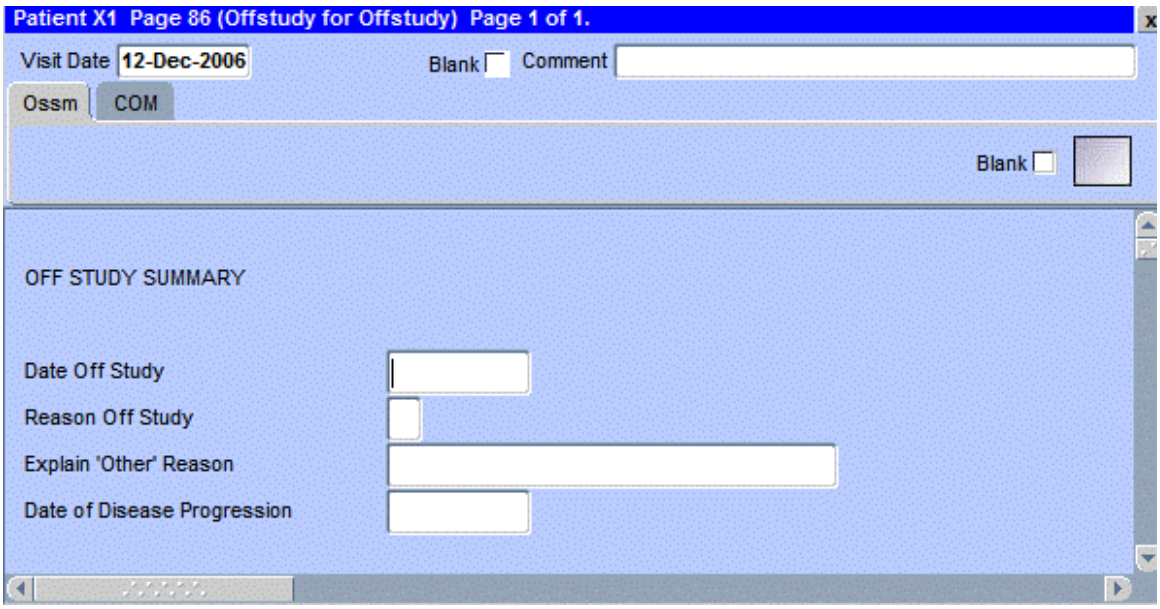
Record information concerning the patient's off study date and reason. Complete this form after the patient has been taken off study.

For studies without a protocol specified follow-up period, this form is completed when the patient is taken off treatment. The off study date, reason and explanation must be the same as the off treatment case report form date off treatment, reason and explanation 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 patient dies within the follow-up period or if follow-up period ends for any other reason. If the off treatment reason prevents the follow-up period from occurring, then the off study date, reason and explanation must be the same.

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

Off Study eCRF



Off Study (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form is being completed.	DD-MMM-YYYY
Date Off Study (m)	For protocols with a specific follow-up period, enter the date that corresponds to the date when all protocol specific follow-up has been completed. For protocols without a protocol specific follow-up, enter the date that the patient came off treatment, i.e. courses have been completed (including the normal observation period) or discontinued and no further treatment courses are planned. **This date must be the same as the Date Off Treatment entered on the Off Treatment case report form**. The date off study will correspond to a progress note in the medical record stating that the patient has been taken off study. Note: For CTMS studies, this is the 'Date off follow-up period'.	DD-MMM-YYYY
Reason Off Study (m) ...	For protocols without a protocol specific follow-up, **use the same 'Reason Off Treatment' entered on the Off Treatment case report form**. For protocols with a follow-up period, the following off study reasons are also available. **Y-** Completed treatment period but refused the Protocol-Specified Follow-up. Date Off Treatment and Date Off Study must be the same. **H-** **Follow-up Period Completed**: The patient completed all protocol specified follow-up evaluations. **L-** **Lost to Further Follow-up**: Follow-up information could not be obtained because contact with the patient was lost. Every effort to locate patient needs to be considering including: contact with family members, referring physicians, sending	Use pick list.

Off Study (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	certificate letter, checking SSDI. **W- Refused Further Follow-up**: The patient has refused to have any further follow-up evaluations. **M- Death during Follow-up Period**: The patient died during the follow-up phase of the protocol. The Date Off Study must coincide with the date of death (located on the Survival case report form). **J- Disease Progression during Follow-up Period**: The patient was taken off study for disease progression during the follow-up period. **A Date of Progression must be entered.** *Note: For CTMS protocols, the actual Reason Off Study sent is 'K' and the explanation text is* - 'Disease Progression during Follow-up Phase'. **K- Other Reasons**: Other reasons may be given for taking the patient off study. Enter an explanation in the "Explain 'Other' Reason" field.	
Explain 'Other' Reason	Enter an explanation for selecting "Other" for a Reason Off Study. For protocols without a protocol specific follow-up, **repeat the same explanation entered on the Off Treatment case report form**.	24 characters
Date of Disease Progression	If disease progression is selected as the reason the patient came off study, enter the date the disease assessment (i.e.: CT scan) was performed. *Note: This date is not sent to Theradex since only Disease Progression during treatment is to be reported.*	DD-MMM-YYYY
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Off Study (cont'd)

Validations		
Code	**Description**	**Resolution**
OSS13, OSS14	Date Off Study and/or Date of Progression cannot be a date in the future.	Enter a date earlier than, or equals to, the current date.
OSS01	Reason Off Study is 'Death' and Date Off Study is not equal to Date of Death on Survival form.	If patient died during the protocol follow-up period or during treatment, Date Off Study must coincide with Date of Death.
OSS03	Reason Off Study is Protocol Violation and a comment with the off study date does not exist.	If patient treatment was terminated due to Protocol Violation, then reason must be stated in the Comments tab of this form.
OSS18	Explain 'Other' Reason provided, but Reason Off Study is not 'U', 'O' or 'K'.	Only 'Other' reasons can have an explanation.
OSS19	Reason Off Study is 'U', 'O' or 'K' and Explain 'Other' Reason not provided.	'Other' reasons must have an explanation in the Explain 'Other' Reason field.
OSS20	Date Off Study and Date Off Treatment are the same, but Reason Off Study is not "Y- Refused participation in follow-up", or "K - Other" or the same as the Reason Off Treatment.	When the Date Off Treatment and Off Study are the same, the Reason Off Study must be the same as the Off Treatment Reason or "Y" or "K".
OSS21	Date of Disease Progression cannot be after Date Off Study	Enter a Date of Disease Progression that is earlier than or equal to the Date Off Study.
OSS22	Disease Progression selected as Reason Off Study and Date of Disease Progression is missing.	A Disease Progression for Reason Off Study requires a Date of Disease Progression.
OSS23	Date of Disease Progression provided and Reason Off Study is not Disease Progression.	Date of Disease Progression must be accompanied by a Reason Off Study of 'Disease Progression'.

Off Study (cont'd)

Validations		
Code	**Description**	**Resolution**
OSS24	Off Treatment Date of Disease Progression is blank, Off Study Date of Disease Progression is not blank and it doesn't fall between the Date Off Treatment and Date Off Study.	Date of Disease Progression must be between Date Off Treatment and Date Off Study when progression did not occur during treatment – it occurred during the follow-up period.
OSS25	Reason Off Treatment is Disease Progression, Date Off Treatment and Date Off Study are the same and Date of Disease Progression is not the same as the one in the Off Treatment form.	When Disease Progression is the Reason for Off Treatment and Off Study, then Date of Disease Progression must be the same on both forms.
OSS27	Off Study Date is provided but the Off Treatment Date is absent.	Enter the Off Treatment Date on Off Treatment form.

(OFF-STUDY)

Filler Page

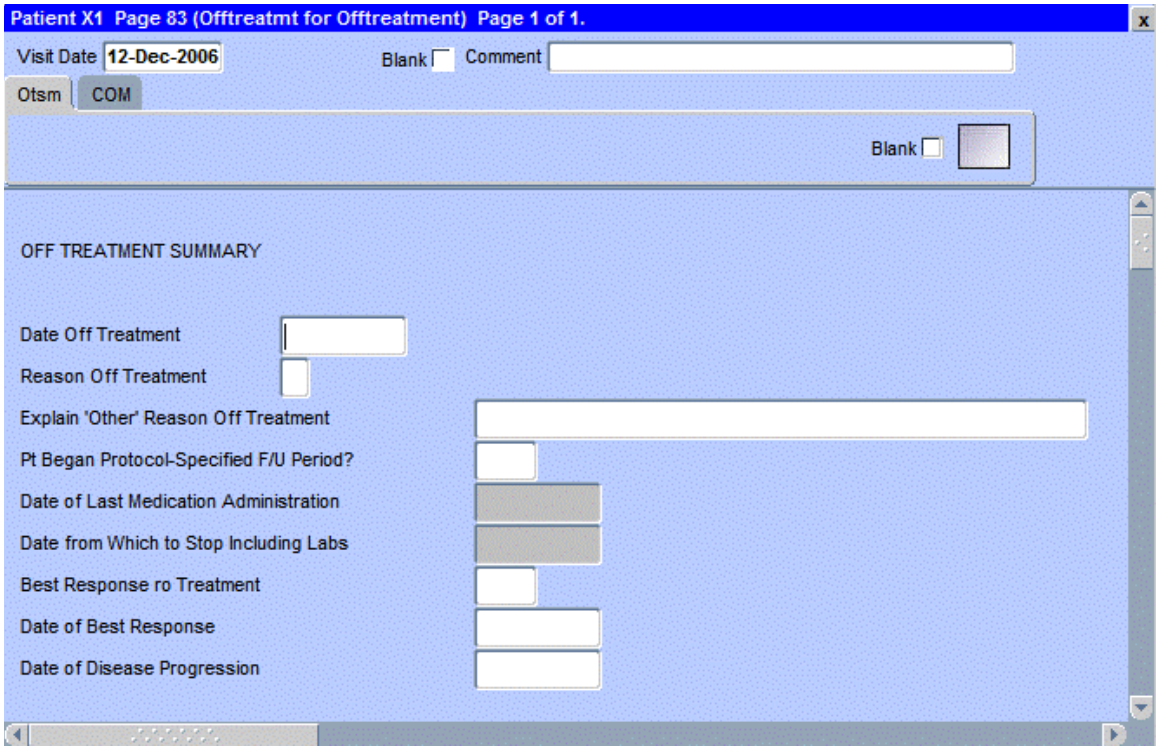
Off Treatment

Purpose

Record information concerning the patient's off treatment date, reason and best response to treatment.

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

Off Treatment eCRF



Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form is being completed.	DD-MMM-YYYY
Date Off Treatment (m)	Enter the date when all courses have been completed (including the normal observation period) or discontinued and no further treatment courses are planned. This date will correspond to the clinic visit that would have served as the pre-course visit had the patient continued on therapy. This is the date the patient has been officially taken off treatment.	DD-MMM-YYYY
Reason Off Treatment (m) ...	Select an off treatment reason from one of the following reason groups: 1) If the patient's participation has been completed as per protocol, and the protocol does not specify a follow-up observation period, select: **C- Study Completed** *Note: Option 'C' is only available for studies without a follow-up period.* 2) For patients who were evaluated for entry to the protocol and signed an informed consent form, but were not treated (never received any drugs or therapies per the protocol), select one of the following: **X- Patient Declined to Participate** (before treatment started.) **B- Disease Progression before Treatment.** **Z- No Treatment, per protocol.** **U- Not Treated - Other Reasons, explain** - Enter an explanation in the Reason Other field. 3) When the patient's participation terminated during treatment period, select one of the following:	Use pick list.

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	P- Disease Progression On Study: The patient was taken off treatment for disease progression. This must be reflected by an increase in the non-measurable or measurable disease state. (See Course Assessment and Extent of Disease Forms). This can be manifested as clinical deterioration. **A Date of Progression must be entered.** **D- Death During Treatment**: The patient has died during the treatment phase. The cause of death should be listed on the Survival case report form and, if applicable, on the Adverse Events case report form as well. **T- Adverse Events / Side Effects**: The patient experienced any toxicity that was considered related to the study medication, which prohibited further protocol treatment. Patients discontinued due to toxicity are evaluable provided the observation period has been completed per protocol. The toxicity must be listed on the Adverse Events form. **S- Complicating Disease / Intercurrent Illness:** Patient was taken off treatment due to complicating disease not related to malignancy. This should be included in the Adverse Event form by an event not considered to be related to therapy. **G- Cytogenetic Resistance.** **A- Switched to Alternative Treatment:** The patient was taken off treatment due to a decision to pursue alternative therapy (such as palliative radiation)**.** **R- Refused Further Treatment:** If at any time the patient refused further treatment. **I- Late Determination of Ineligibility:** Patient was taken off treatment	

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	following treatment because follow-up tests indicate that patient was not eligible for the study. **V- Protocol Violation:** If a major protocol violation has occurred, the reason must be stated in the Comments part of this case report form. **2- Patient Noncompliance:** If the patient did not comply with the study plan. *Note: For CTMS protocols, the actual Reason sent is 'O' and the explanation text is* - 'Patient Noncompliance'. **N- PI Discretion:** If PI made the decision. *For CTMS protocols, the actual Reason sent is 'O' and the explanation text is* - PI Discretion'. **O- Other:** Other reasons may be given for taking the patient off treatment, although they may not be included in the protocol stipulated rules. The patient's evaluability will subsequently be determined. Enter an explanation in the Reason 'Other' field. 4) When the patient completes protocol-specified treatment period, select the following: **Q- Treatment Period Completed** *Note: Option 'Q' is only available for studies with a follow-up period.*	
Explain 'Other' Reason Off Treatment	Enter an explanation for selecting "Other" for a Reason Off Treatment.	50 characters

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Patient Began Protocol Specified Follow-up (m) ▪▪▪	Indicate whether or not the patient began the protocol-specified follow-up period. Y- Yes N- No *Note: This field is only available for protocols with a specified follow-up period.*	Use pick list.
Date of Last Medication Administration (d)	Indicates date the last medication was administered.	DD-MMM-YYYY
Date from Which to Stop Including Labs (d)	Indicates when lab data stops being loaded. It is the same date as the Date Off Treatment. **Any lab data after this date must be entered manually.** *Note: If the Date Off Treatment is not provided or this form is not completed in a timely manner, lab data will continue until the Date Off Treatment is provided.*	DD-MMM-YYYY
Best Response to Treatment (m) ▪▪▪	Select the best overall response to treatment while on protocol. CR- Complete response MR- Less than partial response NA- Not assessed NE- Not evaluable NP- Not applicable per protocol PD- Progressive disease PR- Partial response SD- Stable disease TE- Too early to access, per protocol According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression.	Use pick list.

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	Ordinarily this would be the best of the responses reported on the course assessment CRFs. For example, do not enter "SD" if the patient 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 patient was assessed with a PR followed by a PD, enter the "PR". If response was not assessed at all during the protocol treatment, 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 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. A response of PD is 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 CR.	
Date of Best Response	Enter the date that a Best Response of Treatment 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 Course Assessment case report form(s) and with evaluations on the Extent of Disease Form.	DD-MMM-YYYY

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Date of Disease Progression	Enter the date that progression (or relapse) was first observed (i.e.: date of scan). **This date is required if the Reason for Off Treatment is for Disease Progression.** This date must be consistent with the date of progression entered on the Course Assessment form(s) and with evaluations on the Extent of Disease Form. Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a patient with no evaluable disease at enrollment (e.g. on an adjuvant treatment study).	DD-MMM-YYYY
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Validations		
Code	**Description**	**Resolution**
OTS10 OTS11 OTS12	Date Off Treatment, Date of Best Response and/or Date of Progression cannot be a date in the future.	Enter a date earlier than, or equals to, the current date.
OTS15	Reason Off Treatment is Protocol Violation and a comment with the date the patient ended treatment does not exist.	If patient discontinued due to Protocol Violation, then reason must be stated in the Comments tab of this form.
OTS05	Best Response to Treatment is not 'Disease Progression' and Date of Best Response is missing.	If anything other than 'Disease Progression' is checked for Best Response to Treatment, then Date of Best Response must be entered.

Off Treatment (cont'd)

Validations		
Code	**Description**	**Resolution**
OTS07	Best Response to Treatment is 'Disease Progression' and Date of Progression is missing.	If 'Disease Progression' is checked for Best Response to Treatment, then Date of Progression must be entered.
OTS08	Date of Progression is not equal to the earliest Date of Progression reported on the Course Assessment forms.	Date of Progression must be consistent with Date of Progression on Course Assessment form(s).
OTS28	Date of Disease Progression on Off Treatment is provided but there is no Date of Progression reported on the Course Assessment forms.	Make data consistent.
OTS09	Best Response to Treatment is not the same as the best response reported on Course Assessment forms.	Best response should be validated against responses on Course Assessment form(s).
OTS16	Reason Off Treatment is 'Death' and Date Off Treatment is not equal to Date of Death on Survival form.	If patient died during treatment, Date Off Treatment must the same as the Date of Death on the Survival form.
OTS17	Reason Off Treatment is 'Death' and Date Off Treatment is not equal to Date of Study on Off Study form.	If patient died during treatment, Date Off Treatment must the same as the Date Off Study on the Off Study form.
OTS26	For studies with protocol-specified follow-up period only: Answer to 'Patient Began Protocol-Specified Follow-up Period' is 'N-No' and there is no Off Study case report form or Off Study Reason is missing.	Please review the answer to 'Patient Began Protocol-Specified Follow-up Period' or enter an Off Study Reason.

Off Treatment (cont'd)

Derivations		
Code	**Field Name**	**Description**
OTS1001	Date from Which to Stop Including Labs	Indicates when lab data stops being loaded. It is the same date as the Date Off Treatment.
OTS1002	Date of Last Medication Administration	Indicates date the last medication was administered.

(OFF-TREATMENT)

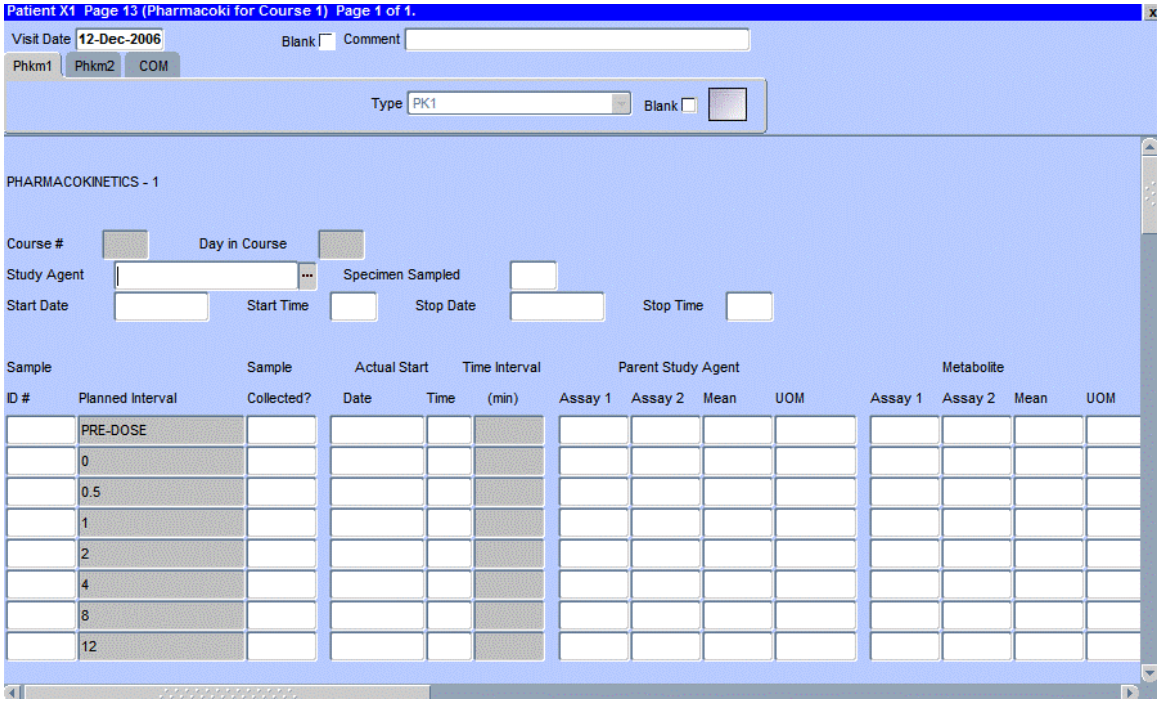
Filler Page

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.

Pharmacokinetics eCRF



Pharmacokinetics (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the study agent administration was started.	DD-MMM-YYYY
Course Number (d)	Course number derived from the study agent start date and course initiation start dates.	5 digits
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.	5 digits
Study Agent (m)	Enter the name of the study agent (investigational or commercial) which is the subject of the pharmacokinetic study. *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 (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
Stop Date	Enter the date the study agent administration was stopped. *Note: This field will be used for infusional therapies only.*	DD-MMM-YYYY
Stop Time	Enter the time the study agent administration was stopped. *Note: This field will be used for infusional therapies only.*	HH(24):MM

Pharmacokinetics (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Specimen Sampled (m) ...	Select the body fluid that is being collected for the biological samples. A- Apheresis Cells B- Whole Blood C- Cerebrospinal E- Pericardial Effusion F- Abdominal Effusion M- Peripheral Blood Mononuclear Cells P- Plasma S- Serum T- Tumor Tissue R- Pleural Effusion V- Saliva *Note: Urine sample collection will be documented on the Urinary Excretion Case Report Form.*	Use pick list.
Sample ID Number	If the specimen acquisition labeling process uses a bar code (or similar) system, enter the unique sample identification number for each of the planned interval time points samples.	10 digits
Planned Interval	Planned interval pre-determined per protocol.	80 characters
Sample Collected? (m) ...	Indicate whether or not the specimen is collected. YES- then the Sample ID (if applicable), Actual Start Date and Time should be entered NO UNKNOWN	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.	5 digits

Pharmacokinetics (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Parent Study Agent Assay 1	Enter the results of the parent assay for the study agent indicated in the study agent field. If the results are below the sensitivity threshold of the test, record the value as 0 (zero). Baseline assay values may be entered as Interval 0 (zero).	8 digits and 3 decimals
Parent Study Agent Assay 2	If the planned interval time point specimen was tested a second time, enter the results of the second parent assay for the study agent indicated in the study agent field.	8 digits and 3 decimals
Parent Study Agent Assay Mean	Enter the parent study agent assay mean concentration, if available. *Note: This will not be completed if a second assay result is not available.*	8 digits and 3 decimals
Parent Study Agent Assay UOM ▪▪▪	Select the appropriate concentration units of measurement for the parent study agent assay(s) (e.g.: mg/dL or mmol/l).	Use pick list.
Metabolite Assay 1	If applicable, enter the first metabolite assay results for the parent study agent.	8 digits and 3 decimals
Metabolite Assay 2	If applicable, enter the second metabolite assay results in the biological samples.	8 digits and 3 decimals
Metabolite Assay Mean	Enter the metabolite assay mean concentration, if available. *Note: This will not be completed if a second assay result is not available.*	8 digits and 3 decimals
Metabolite Assay UOM ▪▪▪	Select the appropriate concentration units of measurement for the metabolite assays (e.g.: mg/dL or mmol/l).	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Pharmacokinetics (cont'd)

Validations		
Code	**Description**	**Resolution**
PHM01	Start Date is less than or equal to the Enrollment Date of Registration.	Start Date must be after the Enrollment Date of Registration.
PHM02	Start Date is in the future.	Enter a date earlier than or equal to the current date.
PHM03	Sample ID number is repeated.	Sample ID number must be unique.
PHM05	Start Date / Time pair appears more than once – duplicate entry.	Remove the duplicate record or correct the Start Date / Time of one of them.
PHM06	Parent Study Agent UOM entered, but Assay 1, Assay 2 and Mean Concentration are missing.	Enter a Parent Study Agent Assay 1, Assay 2 and/or Mean Concentration.
PHM07	Parent Study Agent Assay 1, Assay 2 and/or Mean Concentration entered, but UOM is missing.	Enter the Parent Study Agent UOM.
PHM08	Metabolite UOM entered, but Assay 1, Assay 2 and Mean Concentration are missing.	Enter a Metabolite Assay 1, Assay 2 and Mean Concentration.
PHM09	Metabolite Assay 1, Assay 2 and/or Mean Concentration entered, but UOM is missing.	Enter the Metabolite UOM.
PHM10	No Parent Study Agent and Metabolite results and UOM were provided.	At least one Parent Study Agent or Metabolite results, with respective UOM, are required.
PHM15	Stop Date is in the future.	Enter a date earlier than or equal to the current date.
PHM16	A Study Medication with a Medication/Agent matching the Pharmacokinetic with the same administration Date and Time was not found.	Verify that the pharmacokinetics study agent administration is recorded on the study medication form.

Pharmacokinetics (cont'd)

Validations		
Code	**Description**	**Resolution**
PHM17	Collected Pharmacokinetics samples does not have corresponding sample ID, Date and Time.	Enter Sample ID, Actual Start Date and Time if 'Sample Collected' is 'YES'.

Derivations		
Code	**Field Name**	**Description**
PHM1001	Course #	Course Number is derived from the Study Agent Start Date and the Course Initiation Start Dates.
PHM1002	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.

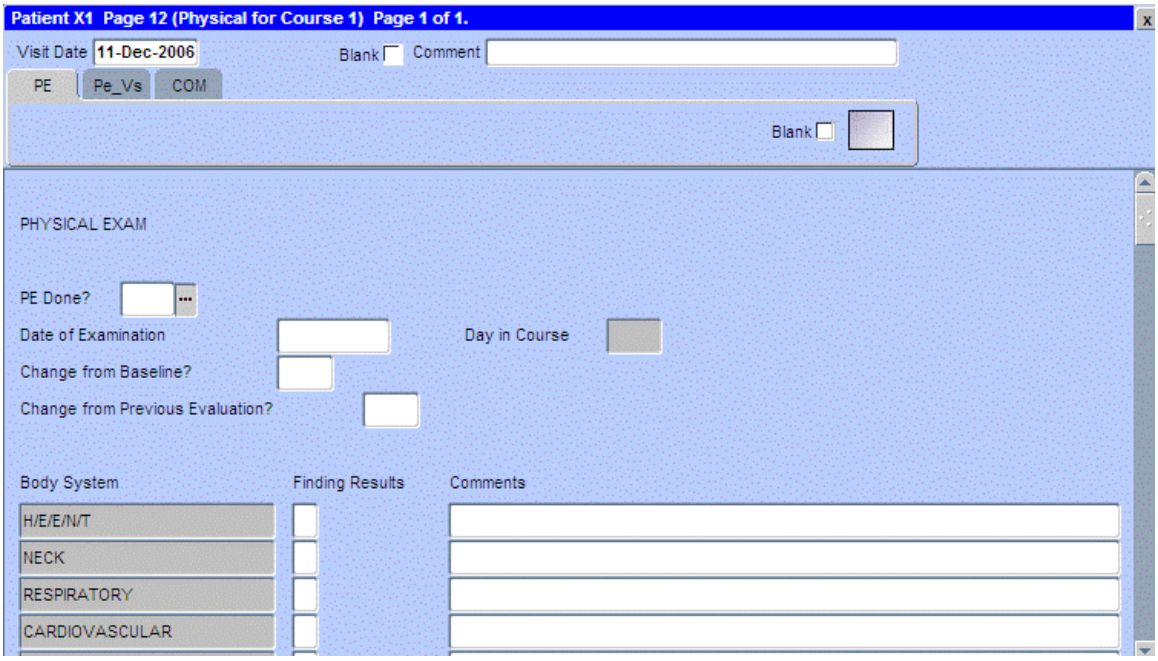
(PHARMACOKINETICS)

Physical Exams - Courses

Purpose

Record physical exam results during treatment.

Physical Exams - Courses eCRF



Physical Exams – Courses (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the physical examination took place.	DD-MM-YYYY
PE Done? (m) ▪▪▪	Indicate whether the physical examination was performed: YES- Yes NO- No *Note: not applicable for CTMS.*	Use pick list.
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 is derived from the course initiation start date and examination date.	5 digits
Change from Baseline? ▪▪▪	Indicate whether the finding results were changed compared with that of baseline: Y- Yes N- No *Note: not applicable for CTMS.*	Use pick list.
Change from Previous Evaluation? ▪▪▪	Indicate whether the finding results were changed compared with that of previous evaluation: Y- Yes N- No *Note: not applicable for CTMS.*	Use pick list.

Physical Exams – Courses (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Finding Results ▪▪▪	Indicate whether the finding results for the particular body system were either: N- Normal A- Abnormal X- Not Examined Comments are required for abnormal finding results. *Note: Do not select "Normal" if the body system was not specifically assessed during the physical exam (i.e., not mentioned in the progress note in the medical record).* Any baseline body system with "Abnormal" Finding Results that remained unchanged must be re-entered in this case report form.	Use pick list.
Comments	If the finding results of a particular body system have changed from baseline, give a brief description of the change. If choosing "Other", indicate the body or organ system missing from the list in the comment and include this for subsequent exams.	200 characters (128 reported)
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Physical Exams – Courses (cont'd)

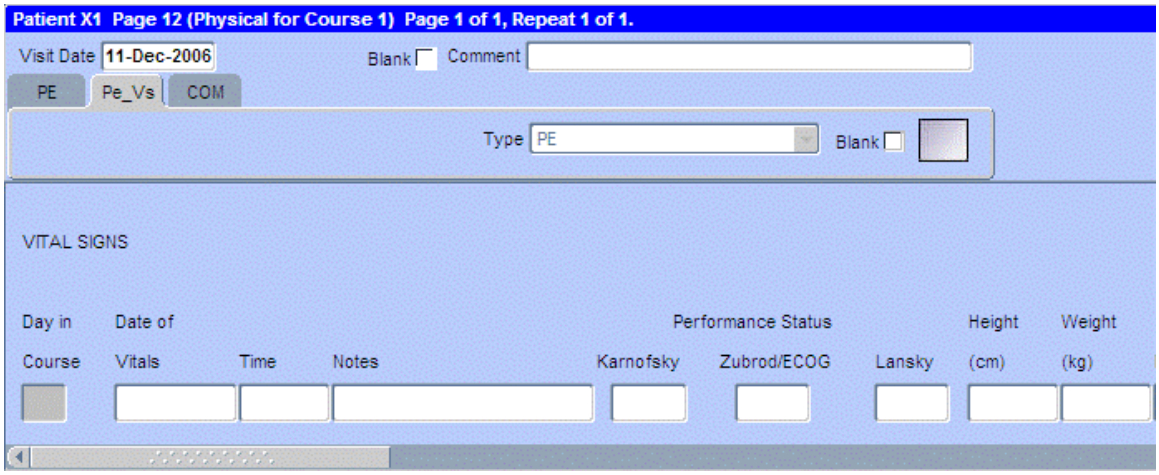
Validations		
Code	**Description**	**Resolution**
PE01	Finding Results is marked abnormal and a comment is not specified.	Enter a comment or change the Finding Results.
PE03	Finding Results has changed from baseline (either from N to A or A to N or X to A), but comment is missing.	Review the Finding Results or enter a comment.
PE04	Date of Examination is in the future.	Enter an earlier date.
PE06	CTMS study has Comment length is greater than 128.	CTMS study should have comment no longer than 128.
PE07	PE is done but the Date of Examination is not provided.	Enter the Date of Examination.
PE08	PE is done and the response(s) to the change question(s) is/are 'Y', but the response to the evaluation section is absent.	Enter the evaluation section.

Derivations		
Code	**Field Name**	**Description**
PE1001	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and examination date.

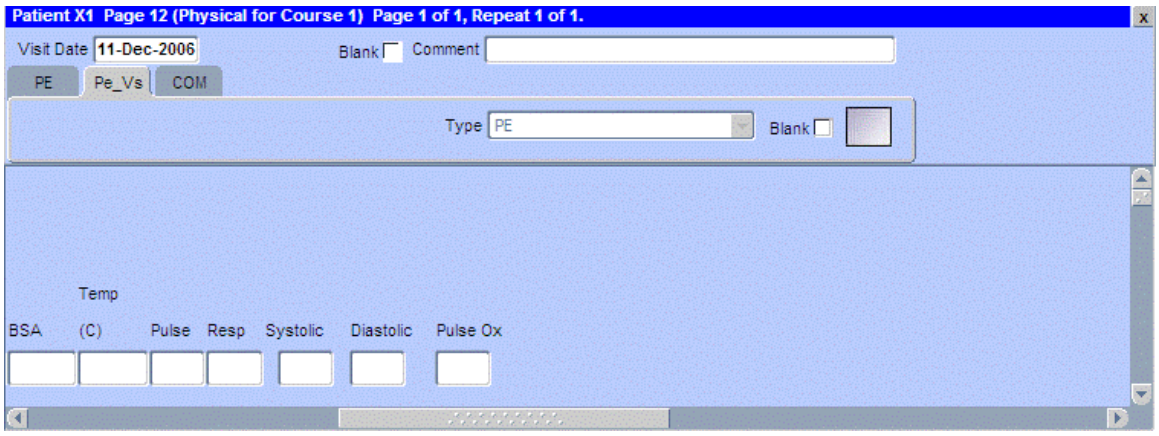
Physical Exams – Courses (cont'd)

Physical Exams - Courses eCRF

Vital Signs tab



The following screen shot is the portion to the right of the Weight field.



Physical Exams – Courses (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Vitals field.	DD-MMM-YYYY
Day in Course (d)	Indicates the day since the beginning of course the vital signs are related to based on their date and time.	5 digits
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. *Note: This information is not sent to the reporting agency.*	200 characters
Performance Status (Karnofsky) ▪▪▪	Select a value from the Karnofsky performance status scale. 0- Dead 10- Moribund 20- Very Sick 30- Hospitalized 40- Disabled 50- Frequent Assistance 60- Occasional Assistance 70- Self Care 80- Effort 90- Able 100- Normal	Use pick list.
Status (Zubrod) ▪▪▪	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.

Physical Exams – Courses (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Performance Status (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.
Height (m)	Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors.	5 digits and 2 decimals
Body Weight (m)	Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors.	5 digits and 2 decimals
BSA (m)	Enter the patient's body surface area in m^2 (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 1. The following simple approximation may be used for persons of "normal" height and weight: $BSA(m^2) = \sqrt{\frac{Height\ \ (cm)\,x\,Weight\ \ (kg)}{3600}}$	4 digit and 2 decimals

Physical Exams – Courses (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Temperature	Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors.	8 digits and 3 decimals
Pulse	Enter the patient's pulse rate.	8 digits and 3 decimals
Respiration Rate	Enter the patient's respiration rate.	8 digits and 3 decimals
Systolic Blood Pressure	Enter the patient's systolic blood pressure.	8 digits and 3 decimals
Diastolic Blood Pressure	Enter the patient's diastolic blood pressure.	8 digits and 3 decimals
Pulse Oximetry	Enter the patient's pulse oximetry reading.	3 digits and 2 decimals
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Physical Exams – Courses (cont'd)

Validations		
Code	**Description**	**Resolution**
VIT01	Systolic Blood Pressure is less than Diastolic Blood Pressure.	Systolic Blood Pressure must be greater than Diastolic Blood Pressure.
VIT02	Two Vital Signs entries have the same Date and Time.	Correct the date and/or time.
VIT03	Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula.	Correct the BSA. The MIS BSA formula is: BSA (m^2) = 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.	Correct the BSA. The Mosteller BSA formula is: BSA (m^2) = ([Height(cm) x Weight(kg)] / 3600)^½
VIT05	Vitals Date is in the future.	Enter a date that is equal to or prior to the current date.
VIT06, VIT07, VIT08, VIT09, VIT10, VIT11, VIT12, VIT13	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 Blood Pressure and Diastolic Blood Pressure must be greater than zero.
VIT14	Pulse Oximetry is out of range.	Pulse Oximetry must be an integer number between 0 and 100.
VIT15	Vitals (on cycle sections) have Date of Vitals outside the range of the cycle start and stop date.	Enter a appropriate date. Note: this does not apply for all protocol.

Physical Exams – Courses (cont'd)

Derivations		
Code	**Field Name**	**Description**
VIT1002	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.

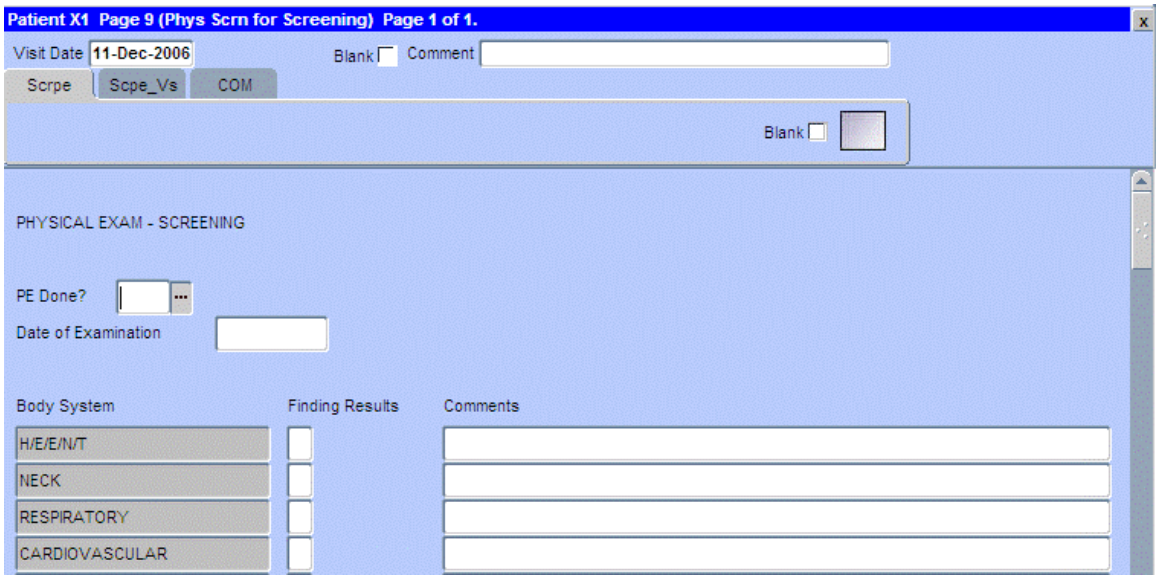
(PHYSICAL-EXAMS-COURSES)

Physical Exams - Screening

Purpose

Record baseline physical exam results.

Physical Exams - Screening eCRF



Physical Exams - Screening (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the physical examination took place.	DD-MM-YYYY
PE Done? (m) ▪▪▪	Indicate whether the physical examination was performed: YES- Yes NO- No *Note: not applicable for CTMS.*	Use pick list.
Date of Examination	Enter the date the physical examination took place.	DD-MM-YYYY
Finding Results ▪▪▪	Indicate whether the finding results for the particular body system were either: N- Normal A- Abnormal X- Not Examined Comments are required for abnormal finding results. *Note: Do not select "Normal" if the body system was not specifically assessed during the physical exam (i.e.: not mentioned in the progress note in the medical record).*	Use pick list.
Comments	Give a brief description for all abnormal finding results. If choosing "Other", indicate the body or organ system missing from the list in the comment and include this under both baseline and follow-up exams.	200 characters (128 reported)
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

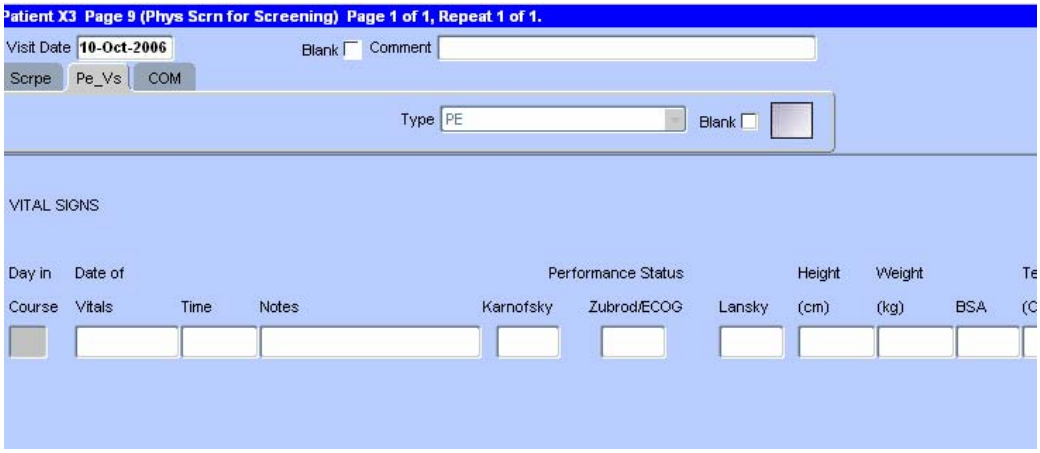
Physical Exams - Screening (cont'd)

Validations		
Code	**Description**	**Resolution**
PE01	Finding Results is marked abnormal and a comment is not specified.	Enter a comment or change the Finding Results selection.
PE04	Date of Examination is in the future.	Enter an earlier date.
PE06	CTMS study has Comment length is greater than 128.	CTMS study should have comment no longer than 128.
PE07	PE is done but the Date of Examination is not provided.	Enter the Date of Examination.

Physical Exams - Screening (cont'd)

Physical Exams - Screening eCRF

Vital Signs tab



Physical Exams - Screening (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Vitals field.	DD-MMM-YYYY
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. *Note: This information is not sent to the reporting agency.*	200 characters
Performance Status (Karnofsky) ...	Select a value from the Karnofsky performance status scale. 0- Dead 10- Moribund 20- Very Sick 30- Hospitalized 40- Disabled 50- Frequent Assistance 60- Occasional Assistance 70- Self Care 80- Effort 90- Able 100- Normal	Use pick list.
Status (Zubrod) ...	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.

Physical Exams - Screening (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Performance Status (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.
Height (m)	Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors.	5 digits and 2 decimals
Body Weight (m)	Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors.	5 digits and 2 decimals
BSA (m)	Enter the patient's body surface area in m^2 (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 1. The following simple approximation may be used for persons of "normal" height and weight: $BSA(m^2) = \sqrt{\frac{Height\ \ (cm)\,x\,Weight\ \ (kg)}{3600}}$	4 digit and 2 decimals

Physical Exams - Screening (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Temperature	Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors.	8 digits and 3 decimals
Pulse	Enter the patient's pulse rate.	8 digits and 3 decimals
Respiration Rate	Enter the patient's respiration rate.	8 digits and 3 decimals
Systolic Blood Pressure	Enter the patient's systolic blood pressure.	8 digits and 3 decimals
Diastolic Blood Pressure	Enter the patient's diastolic blood pressure.	8 digits and 3 decimals
Pulse Oximetry	Enter the patient's pulse oximetry reading.	3 digits and 2 decimals
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Physical Exams - Screening (cont'd)

Validations		
Code	**Description**	**Resolution**
VIT01	Systolic Blood Pressure is less than Diastolic Blood Pressure.	Systolic Blood Pressure must be greater than Diastolic Blood Pressure.
VIT02	Two Vital Signs entries have the same Date and Time.	Correct the date and/or time.
VIT03	Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula.	Correct the BSA. The MIS BSA formula is: BSA (m^2) = 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.	Correct the BSA. The Mosteller BSA formula is: BSA (m^2) = ([Height(cm) x Weight(kg)] / 3600)^½
VIT05	Vitals Date is in the future.	Enter a date that is equal to or prior to the current date.
VIT06, VIT07, VIT08, VIT09, VIT10, VIT11, VIT12, VIT13	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 Blood Pressure and Diastolic Blood Pressure must be greater than zero.
VIT14	Pulse Oximetry is out of range.	Pulse Oximetry must be an integer number between 0 and 100.
VIT15	Vitals (on cycle sections) have Date of Vitals outside the range of the cycle start and stop date.	Enter an appropriate date. Note: this does not apply for all protocol.

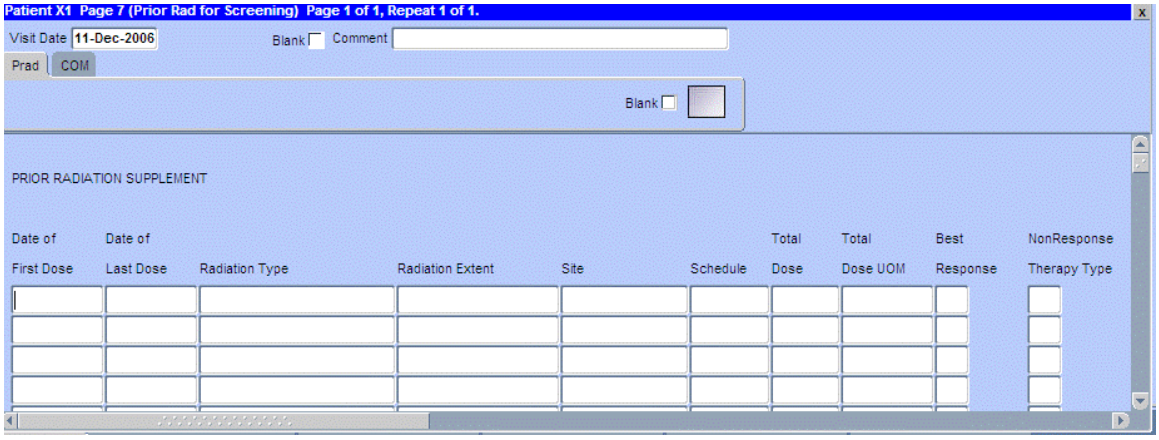
(PHYSICAL-EXAMS-SCREENING)

Prior Radiation Supplement

Purpose

Record details of prior radiation therapy when specified by the protocol or when the details would be clinically significant for the evaluation of this study.

Prior Radiation Supplement eCRF



Prior Radiation Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed. *Note: If the information was obtained at multiple visits, please enter the date the form was completed.*	DD-MMM-YYYY
Date of First Dose (m)	Enter the date of the first dose of the radiation therapy. Partial dates are acceptable when the day is not known.	DD-MMM-YYYY or 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. "Ongoing' will be reported to CTMS or CDS.	DD-MMM-YYYY, MMM-YYYY
Radiation Type (m) ...	Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant".	Use pick list.
Radiation Extent (m) ...	Select the extent of the radiation therapy as follows: LR- Limited Radiation: therapy using ionizing radiation to a limited (<50%) portion of the body. ER- Extensive Radiation: therapy using ionizing radiation to a significant portion of the body (>50%), e.g. cardiospinal, pelvic, or total-body. R- Radiation (NOS): Extent is not known.	Use pick list.
Site (m) ...	Select the site of the radiation therapy.	Use pick list.
Schedule	Select the radiation therapy schedule on which it was given.	24 characters
Total Dose	State the total radiation dose the patient received during the treatment period. **Leave this field as well as the Total Dose UOM blank if the radiation therapy is ongoing.**	8 characters

Prior Radiation Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Total Dose UOM ▪▪▪	Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem).	Use pick list.
Best Response ▪▪▪	Select the best response for the irradiated lesion. It applies to the type of therapy/intervation 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.
NonResponse Therapy Type ▪▪▪	Select the therapy type for which the conventional response calls are not appropriate. AJ- Adjuvant Therapy PA- Palliative Therapy NJ- Neoadjuvant Therapy	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Prior Radiation Supplement (cont'd)

Validations		
Code	**Description**	**Resolution**
PRD01	Date of First Dose is greater than Date of Last Dose.	Enter a Date of First Dose that is equal to or earlier than the Date of Last Dose.
PRD02, PRD03	Date of First Dose and Date of Last Dose are in the future.	Enter a date that is equal to or earlier than the current date.
PRD04	Both Best Response and Nonresponse Therapy Type are present/absent.	One and only one fields should be entered.

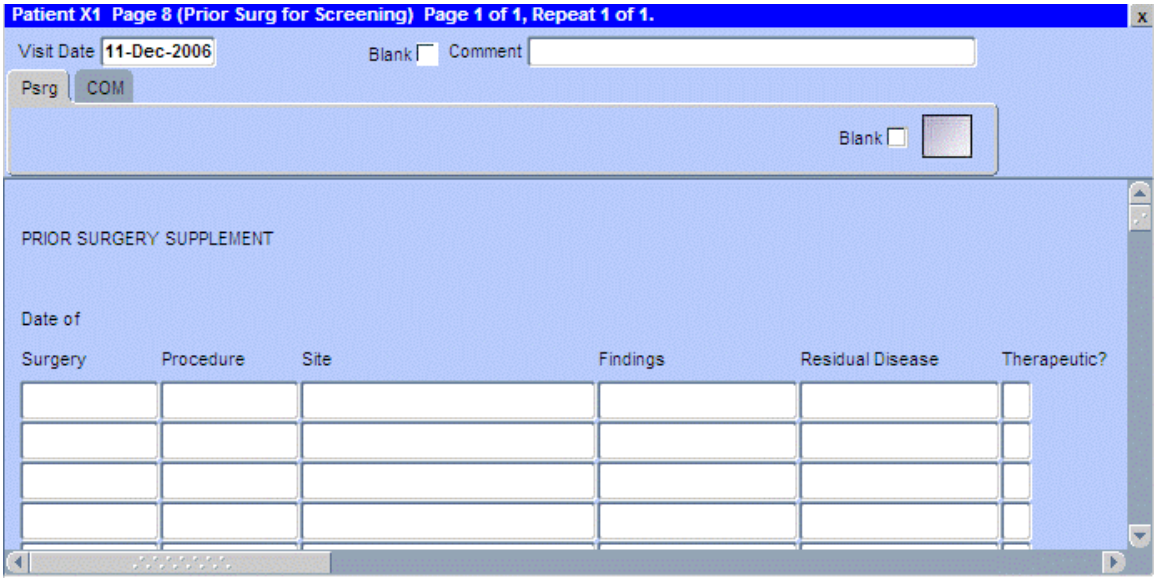
(PRIOR-RADIATION-SUPPLEMENT)

Prior Surgery Supplement

Purpose

Record details of prior surgery when required by the protocol or when the details would be clinically significant for the evaluation of this study.

Prior Surgery Supplement eCRF



Prior Surgery Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed. *Note: If the information was obtained at multiple visits, please enter the date the form was completed.*	DD-MMM-YYYY
Date of Surgery (m)	Enter the date of the surgical procedure. Partial dates are acceptable when the day and/or month are not known.	DD-MMM-YYYY, MMM-YYYY or YYYY
Procedure (m)	Enter the type of procedure performed to diagnose / to treat the patient's disease. Examples include, but not limited too: biopsy, node dissection, cytology, bone marrow biopsy, FNA (fine needle aspiration).	50 characters
Site (m) ▪▪▪	Select the anatomical site of the procedure.	Use pick list.
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).	24 characters
Therapeutic? ▪▪▪	Select if the surgical procedure was performed with curative intent: Y- Yes N- No	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Prior Surgery Supplement (cont'd)

Validations		
Code	**Description**	**Resolution**
PSG01	Date of Surgery is in the future.	Enter a date that is equal to or earlier than the current date.

(PRIOR-SURGERY-SUPPLEMENT)

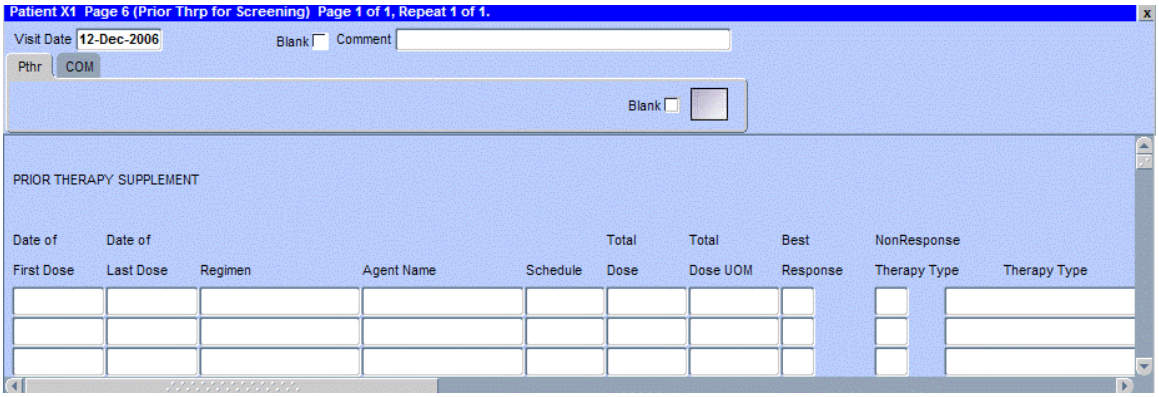
Filler Page

Prior Therapy Supplement

Purpose

Record details of prior therapies when specified 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.

Prior Therapy Supplement eCRF



Prior Therapy Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Date of First Dose (m)	Enter the date of the first dose of the prior therapy. Partial dates are acceptable when the day is not known.	DD-MMM-YYYY or MMM-YYYY
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. "Ongoing' will be reported to CTMS or CDS.	DD-MMM-YYYY, MMM-YYYY
Regimen ...	In the case of a standard combination regimen of multiple agents, the conventional abbreviation for the regimen (i.e., MOPP, CHOP, CAF, etc.) should be used.	Use pick list.
Agent Name ...	Select the generic name of the agent that was used. For standard regimen, enter one record for each agent.	Use pick list.
Schedule	Select the schedule on which the agent (or combination) was given.	24 characters
Total Dose	Enter the total dose of the agent.	8 characters
Total Dose UOM ...	Enter the total dose units of measurement.	12 digits

Prior Therapy Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Best Response ▪▪▪	Select the best response encountered: CR- Complete Response MR- Minimal/Marginal Response NA- Not Assessed NE- Not Evaluable PD- Progressive Disease PR- Partial Response SD- Stable Disease UK- Unknown **Leave this field blank if the treatment is ongoing.**	Use pick list.
NonResponse Therapy Type ▪▪▪	Select the therapy type for which the conventional response calls are not appropriate. AJ- Adjuvant Therapy PA- Palliative Therapy NJ- Neoadjuvant Therapy	Use pick list.

Prior Therapy Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Therapy Type (m) ▪▪▪	Select the appropriate type of prior therapy: Anti-Retroviral Therapy Antisense Bone Marrow Transplant Chemotherapy (NOS) Chemotherapy multiple agents systemic Chemotherapy non-cytotoxic Chemotherapy single agent systemic Gene Transfer Hormonal Therapy Drug and/or Immunotherapy Oncolytic Virotherapy Vaccine Prior Therapy (NOS) Hematopoietic Stem Cell Transplantation Image Directed Local Therapy No prior Therapy	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Prior Therapy Supplement (cont'd)

Validations		
Code	**Description**	**Resolution**
PTS01	Date of First Dose is greater than Date of Last Dose.	Enter a Date of First Dose that is equal to or earlier than the Date of Last Dose.
PTS02, PTS03	Date of First Dose and Date of Last Dose are in the future.	Enter a date that is equal to or earlier than the current date.
PTS04	Both Best Response and Nonresponse Therapy Type are present/absent.	One and only one fields should be entered.
PTS05	Regimen and agent have both absent.	Should have at least one of them present.

(PRIOR-THERAPY-SUPPLEMENT)

Filler Page

Prior Treatment Summary

Purpose

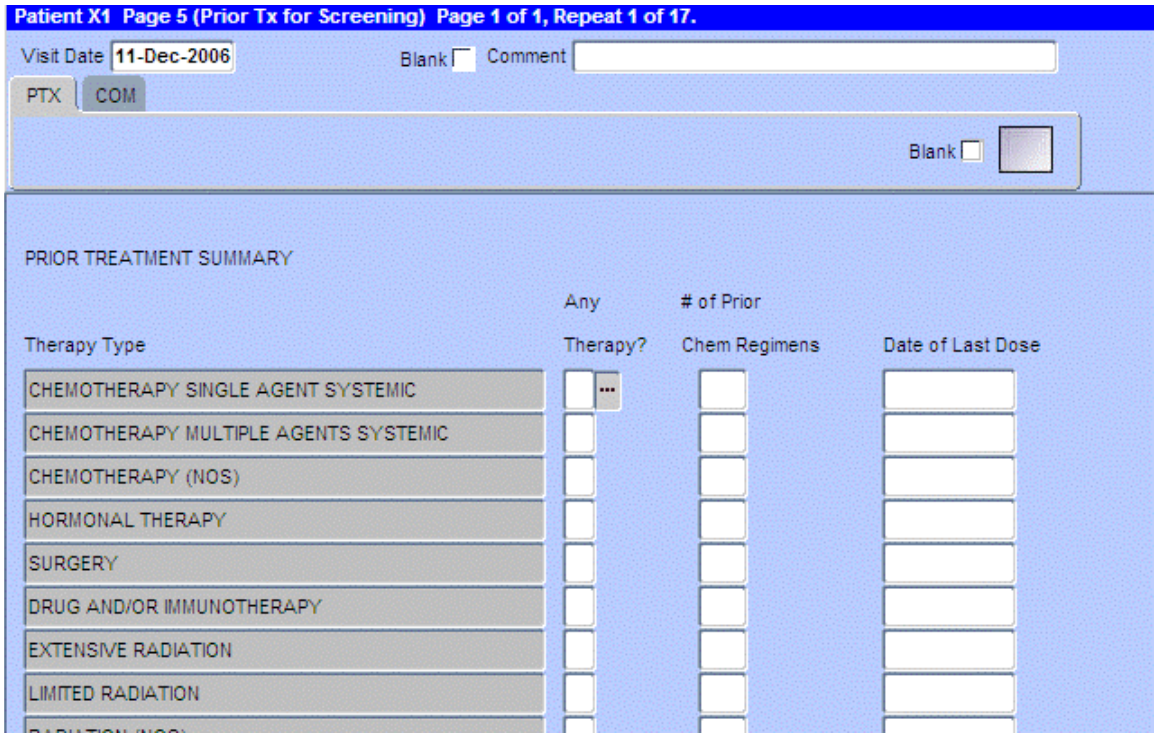
Record whether or not the patient has received any treatments for each of the prior therapy types listed.

Note: This CRF is only for CTEP-sponsored studies.

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.

Prior Treatment Summary eCRF



Prior Treatment Summary (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Therapy Type	Name of the type of therapy. The appropriate list of therapy types is provided by CTMS. *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.* *Note: "Chemotherapy (NOS)" should be used only when it is not possible to determine whether the treatment was "single agent" or "multiple agent".*	Not applicable.
Any Therapy? (m) ▪▪▪	Indicate whether or not the patient has received any prior treatment for the type of therapy listed. Y- Yes - then Date of Last Dose must be provided. N- No	Use pick list.
Number of Prior Regimens (u) (m)	Enter the number of prior regimes received for the type of therapy. *Note: This field is only mandatory for studies that report data to CDUS.*	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 and/or month are not known. Leave it blank if the treatment is currently being received and "Ongoing" will be reported to CTMS or CDUS. For combination therapies, record the date of the last dose of medication for the combination.	DD-MMM-YYYY, MMM-YYYY, YYYY
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only, (u) for CDUS reporting only.		

Prior Treatment Summary (cont'd)

Validations		
Code	**Description**	**Resolution**
PTX02	Date of Last Dose is specified for a therapy type but the respective "Any Therapy?" is not checked 'Yes'.	Verify Date of Last Dose and/or "Any Therapy?".
PTX03	Date of Last Dose, which could be partial, is in the future.	Enter a Date of Last Dose that is equal to or earlier than the current date.
PTX04	Number of Prior Regimens is negative or not a number. (Note: only for studies reporting data to CDUS)	Enter a number between 0 and 99 when applicable.
PTX05	Some of the 'Any Therapy?' answers were not provided.	Answer 'Y' or 'N' for all the 'Any Therapy?' questions.

(PRIOR-TREATMENT-SUMMARY)

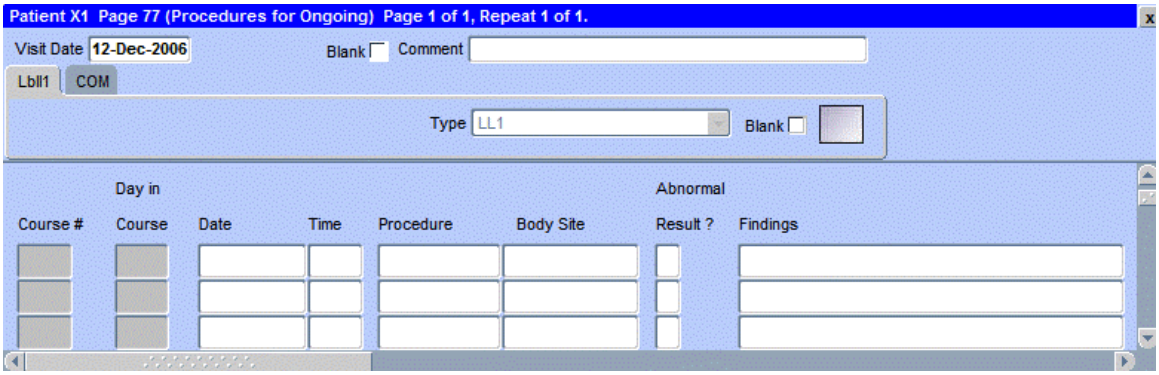
Filler Page

Procedures

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

Procedures eCRF



Procedures (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date field.	DD-MMM-YYYY
Course # (d)	Indicates the course number the procedure is related to based on their date and time.	5 digits
Day in Course (d)	Indicates the day since the beginning of course the procedure is related to based on their date and time.	5 digits
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. *Note: For CTMS monitored protocols, these are the only Procedures sent:* EKG Electrocardiogram CXR Chest X-ray BRNCHGRM Bronchogram UPGISER Upper GI Series LOGISER Lower GI Series SKELSURV Skeletal Survey HOLTMON Holter Monitor BONESCAN Bone Scan EEG Electroencephalogram BMCELLUTY Bone Marrow Cellularity UCASTS Urine Casts MUGASCAN Muga Scan ULTRASND Ultrasound CATSCAN CAT Scan MRI MRI X-RAY X-ray PETSCAN PET Scan CULTURE Culture	Use pick list.

Procedures (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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.	Use pick list.
Abnormal Result ? (m) ...	Select whether the finding results for the particular procedure / body site were either: A- Abnormal N- Normal	Use pick list.
Findings	If abnormal, enter as summary of the abnormal findings.	128 characters 200 characters for non-CTEP sponsored studies.
Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Procedures (cont'd)

Validations		
Code	**Description**	**Resolution**
LBLL01	Procedure date is in the future.	Enter a date that is equal to or prior to the current date.
LBLL02, LBLL03	Findings were entered and Abnormal is not "A-Abnormal" or Abnormal is "A-Abnormal" and no brief description was entered in the Findings.	Abnormal Findings must have a brief description.

Derivations		
Code	**Field Name**	**Description**
LL1001	Course #	Course number is derived based on the course initiation start dates and the procedure date.
LL1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the procedure date.

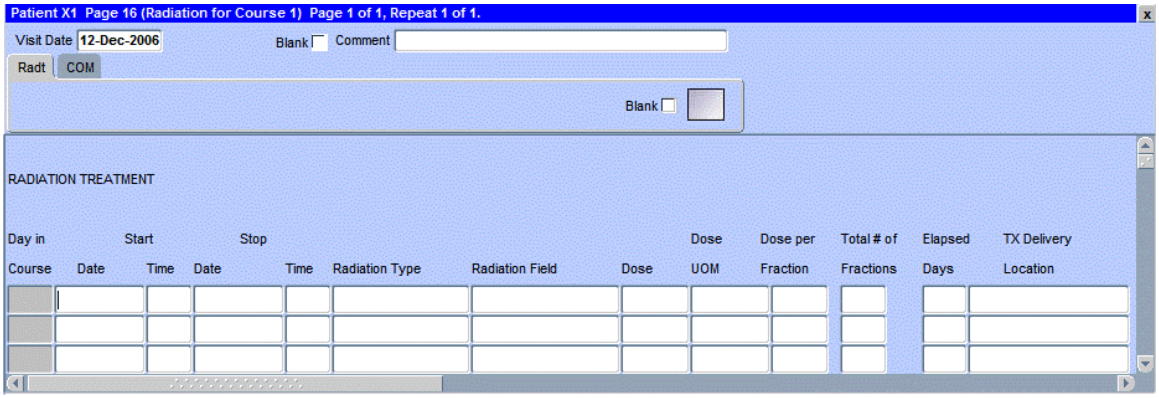
(PROCEDURES)

Radiation

Purpose

Record details of radiation therapy when specified by the protocol.

Radiation eCRF



Radiation (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Vitals field.	DD-MMM-YYYY
Day in Course (d)	Indicates the day since the beginning of course initiation. Derived from the course initiation start date.	5 digits
Start Date (m)	Enter the start date of the radiation therapy.	DD-MMM-YYYY
Start Time	Enter the start time of the radiation therapy.	HH(24):MM
Stop Date (m)	Enter the date of the last dose of the radiation therapy.	DD-MMM-YYYY
Stop Time	Enter the stop time of the radiation therapy.	HH(24):MM
Radiation Type (m) ...	Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant".	Use pick list.
Radiation Field ...	Select the site of the radiation therapy.	Use pick list.
Dose (m)	State the total radiation dose the patient received during the treatment period.	8 characters
Dose UOM (m) ...	Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem).	Use pick list.
Dose per Fraction	Enter the fractionated dose of radiation therapy administered to a treatment field or site according to protocol.	5 digits
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.	30 digits
Tx Delivery Location ...	Select the institute where the radiation therapy was administered.	Use pick list.

Radiation (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Radiation (cont'd)

Validations		
Code	**Description**	**Resolution**
RAD01 RAD02	Date is in the future.	Enter a date that is equal to or earlier than the current date.
RAD03	Stop Date/Time is greater than Start Date/Time.	Correct the Start Date/Time or Stop Date/Time.

Derivations		
Code	**Field Name**	**Description**
RAD1002	Day in Course	Derived from the respective course initiation start date.

(RADIATION)

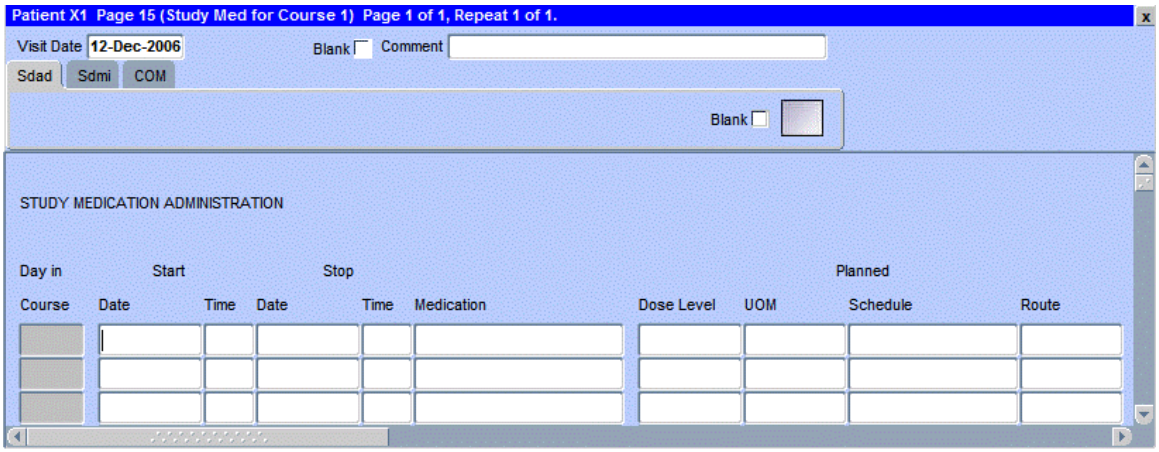
Study Medication Administration

Purpose

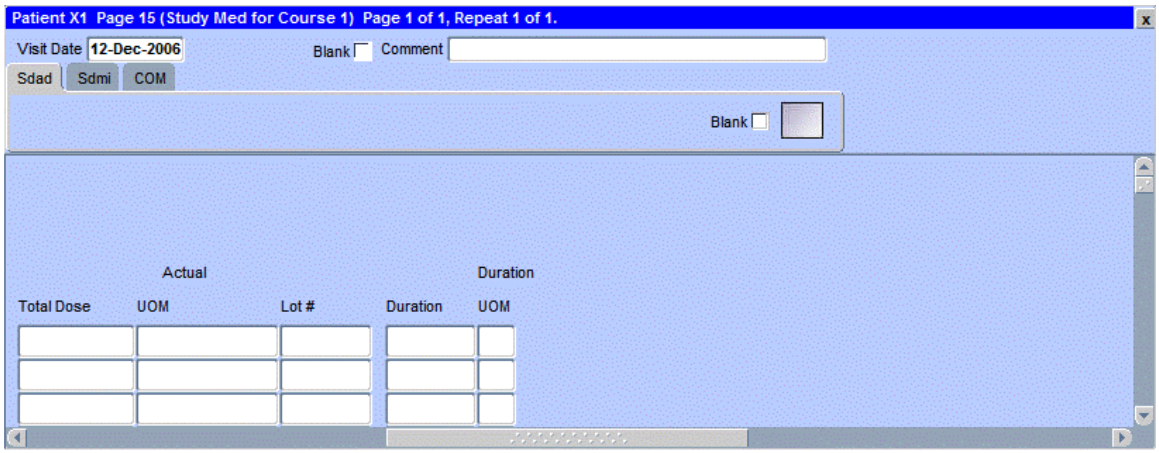
Record medication administration. Use a separate line for each medication.

Study Medication Administration eCRF

Study Medication Administration Tab



The following screen shot is the portion to the right of the Planned Route field.



Study Medication Administration (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date (m)	Enter the date the course started.	DD-MMM-YYYY
Day in Course (d)	Indicates the day since the beginning of course initiation. Derived from the course initiation start date.	5 digits
Start Date (m)	Enter the date the medication was administered.	DD-MMM-YYYY
Start Time	For IV infusions only: Enter the start time of the infusion.	HH(24):MM
Stop Date	Enter the date the medication was discontinued.	DD-MMM-YYYY
Stop Time	For IV infusions only: Enter the stop time of the infusion.	HH(24):MM
Medication (m) ▪▪▪	Select a medication from the list. *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.

Study Medication Administration (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Planned Dose Level (m) (c)	Enter the amount of medication (a number) that was planned to be given for the dose level. It is not appropriate to record the dose level number such as "dose level 1". If the dose level is 100 mg/m^2, then enter 100 for the dose level. The mg/m^2 will be captured in the Planned UOM field. For dose levels that are expressed with scientific exponential units using powers of 10 such as vaccines and viral particles, enter as x10E. For example, dose level description is 2×10^6 PFUs, the dose level would be 2x10E6 and the PFUs would be noted in the Planned UOM (Units of Measurement) field. *Note: for non-CTEP studies, this field may be removed.*	8 characters
Planned UOM (m) (c) ▪▪▪	Select the Planned Dose Level unit of measurement. *Note: for non-CTEP studies, this field may be removed.*	Use pick list.
Planned Schedule (m) (c) ▪▪▪	Select the schedule of medication administration as indicated in the protocol. *Note: for non-CTEP studies, this field may be removed.*	Use pick list.
Planned Route (m) ▪▪▪	Select the route from the list.	Use pick list.
Actual Total Dose (m)	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. 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) 10^6 as 1X10E6.	8 characters

Study Medication Administration (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Actual Dose UOM (m) ▪▪▪	Select the Actual Dose Level unit of measurement.	Use pick list.
Lot #	Enter the Lot Number for the medication supply.	24 characters
Duration (m)	Enter the duration calculated from the start date/time and stop date/time. *Note: for non-CTEP studies, this field is not mandatory.*	6 digits & 2 decimals
Duration UOM (m) ▪▪▪	Select the units of measurement so that the duration can be derived. **DY**- Days **HR**- Hours **MN**- Minutes **MO**- Months **Wk**- Weeks	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Study Medication Administration (cont'd)

Validations		
Code	**Description**	**Resolution**
SD01, SD03	Start Date and/or Stop Dare are/is in the future.	Enter a date earlier than or equals to the current date.
SD04	Stop Date/Time is prior to Start Date/Time.	Correct the Start Date/Time or Stop Date/Time.
SD05	Duplicate Medication records exist.	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.	Review the medications in question and their respective start and stop dates/times.
SD10	Start Time or Stop Time is missing.	Both Start and Stop Time are required or optional.

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

Study Medication Administration (cont'd)

Purpose

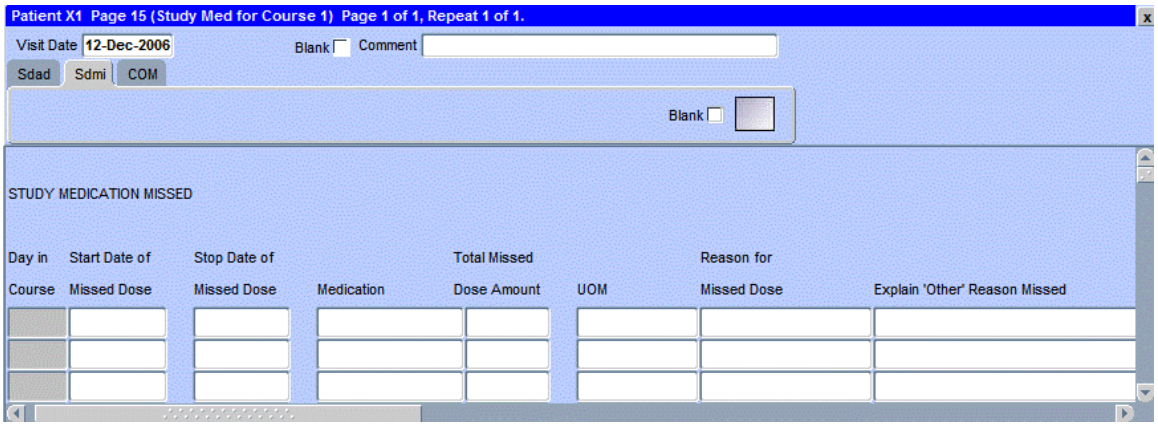
To record study medications that were intended to be taken by the patient, but were missed.

Note: Please be aware that missed dose and partial dose are different. A missed dose means a dose was missed entirely.

This DOES NOT include dose held as per the protocol for toxicity.

Study Medication Administration eCRF

Study Medication Missed tab



Study Medication Administration (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Day in Course (d)	Indicates the day since the beginning of course initiation. Derived from the course initiation start date.	5 digits
Start Date of Missed Dose (m)	Enter the start date the medication was not administered.	DD-MMM-YYYY
Stop Date of Missed Dose (m)	Enter the stop date the medication was not administered.	DD-MMM-YYYY
Medication (m)	Select the name of the missed medication.	Use pick list.
Total Missed Dose Amount (m) ▪▪▪	Enter the actual amount of medication missed for the date entered above. *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.*	8 characters
UOM (m) ▪▪▪	Select the Missed Dose Amount unit of measurement.	Use pick list.
Reason for Missed Dose (m) ▪▪▪	Select the reason the medication was missed.	Use pick list.
Explain 'Other' Reason Missed	Enter an explanation for selecting "Other" for Reason for Missed Dose	30 characters
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Study Medication Administration (cont'd)

Validations		
Code	**Description**	**Resolution**
SD11	Missed medication does not have a respective planned medication administration record.	Verify the selected Medication.
SD13	Stop Date/Time for Study Medication Missed is before Start Date/Time.	Verify that Start Date/Time is before Stop Date/Time.
SD14	Actual Total Dose is not valid numeric value.	Enter valid numeric value.
SD15	Dose Level is not valid numeric value.	Enter valid numeric value.

Derivations		
Code	**Field Name**	**Description**
SM1001	Day in Course	Derived from the respective course initiation start date.

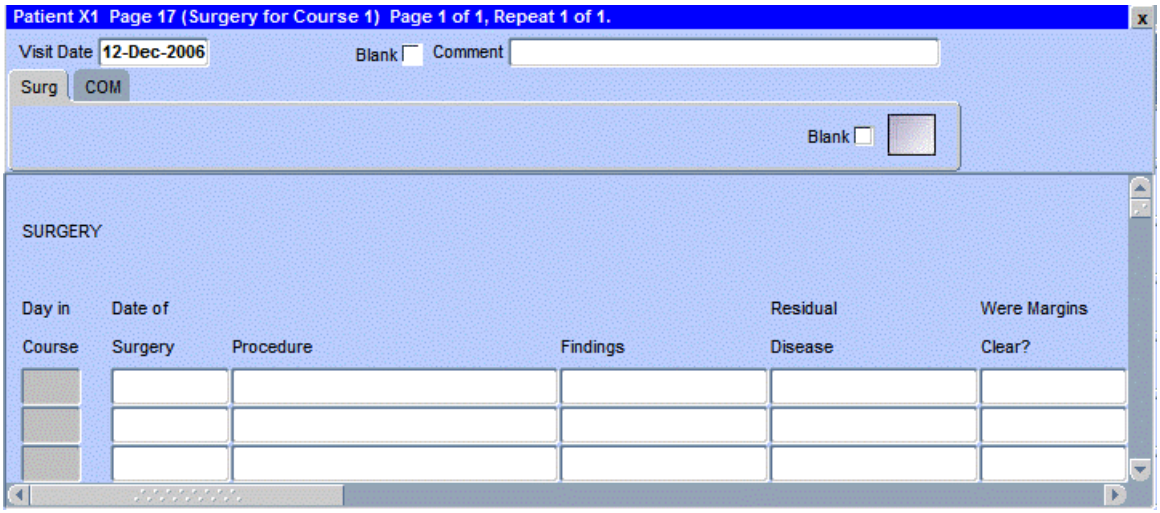
(STUDY-MEDICATION-ADMINISTRATION)

Surgery

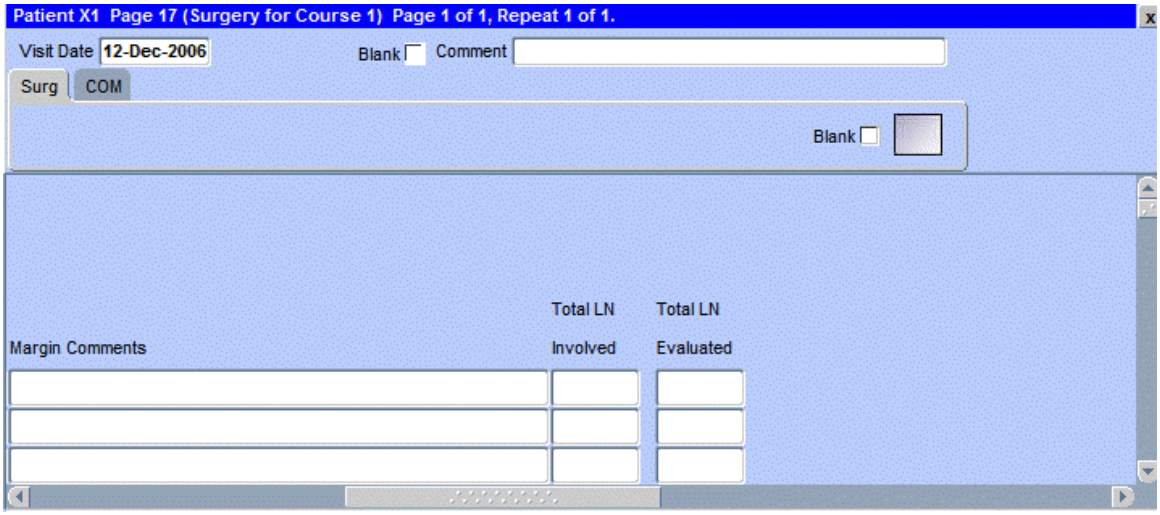
Purpose

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

Surgery eCRF



The following screen shot is the portion to the right of the Were Margins Clear field.



Surgery (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Vitals field.	DD-MMM-YYYY
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.	5 digits
Date of Surgery (m)	Enter the date of the surgical procedure.	DD-MMM-YYYY
Procedure (m)	Enter the type of procedure performed to diagnose / to treat the patient's disease. Examples include, but not limited too: 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).	24 characters
Were Margin Clear?	Select the results of tissue margin examination.	Use pick list.
Margin Comments	Enter the comment for margin examination.	200 characters
Total Lymph Nodes Involved	Enter the number of lymph nodes involved with disease as determined by pathologic examination.	5 digits
Total Lymph Nodes Evaluated	Enter the total number of lymph nodes removed and pathologically assessed for disease.	5 digits
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Surgery (cont'd)

Validations		
Code	**Description**	**Resolution**
SUG01	Date of Surgery is in the future.	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.

(SURGERY)

Filler Page

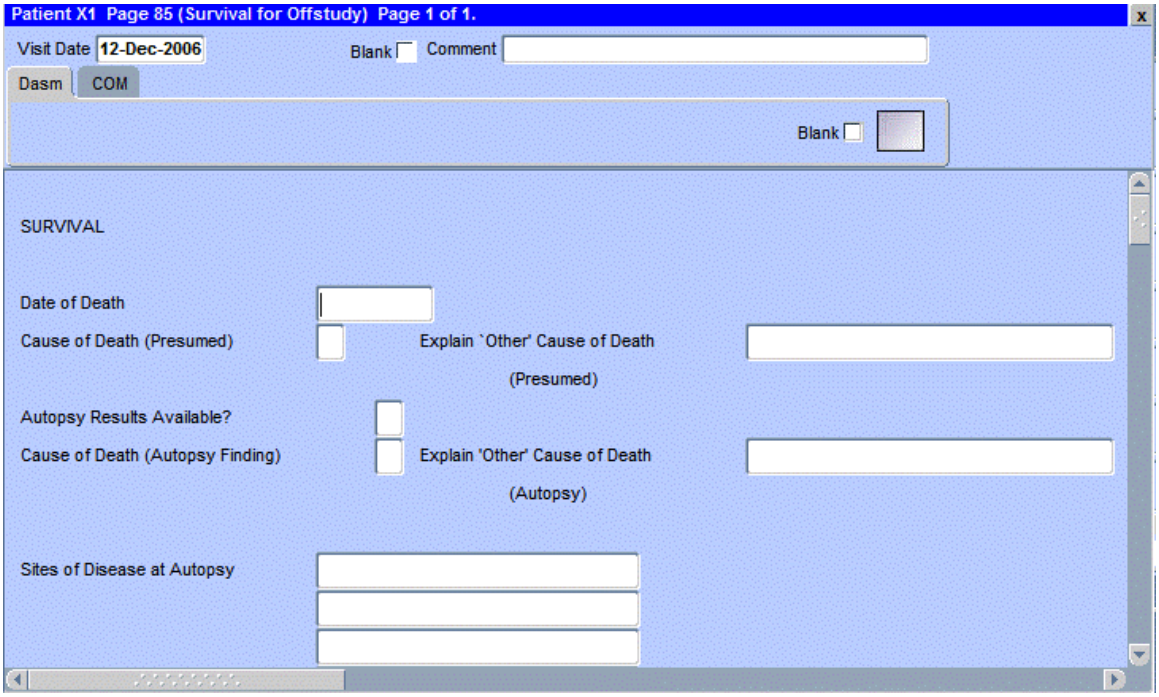
Survival

Purpose

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

Note: Only the Date of Death is sent to CTMS if there is an indication, on the Follow-up case report form, that the patient has received further treatment. All the fields still need to be entered though.

Survival eCRF



Survival (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Last Contact field.	DD-MMM-YYYY
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: M- Malignant Disease T- Toxicity from Protocol Treatment I- Infection O- Other (Explain) If "Other" is checked, enter a succinct description of the presumed cause of death on the field "Explain 'Other' Presumed Cause of Death".	Use pick list.
Explain 'Other' Cause of Death (Presumed)	Enter a succinct description if option "Other" is selected as presumed cause of death. For example: Concurrent illness/MI".	24 characters
Autopsy Results Available? ... (m)	Select an option indicating whether the results of an autopsy are available. Y- **Yes** - Autopsy done and results available. N- **No** - Autopsy not done or autopsy done, but results not yet available. U- **Unknown** - Do not know if an autopsy was done. If the autopsy results are still pending, select "No" and update this CRF when the results are available.	Use pick list.

Survival (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Cause of Death (Autopsy Finding) ▪▪▪	If an autopsy was performed and a cause of death was determined at autopsy, it should be categorized according to: M- Malignant Disease T- Toxicity from Protocol Treatment I- Infection O- Other Only one category should be checked. If "Other" is checked, enter a succinct description of the autopsy finding cause of death on the field "Explain 'Other' Autopsy Finding Cause of Death".	Use pick list.
Explain 'Other' Cause of Death (Autopsy Finding)	If option "Other" is selected as autopsy finding cause of death, enter a succinct description, i.e., MI.	24 characters
Sites of Disease (Autopsy Finding) ▪▪▪	Select the major sites of malignant disease involvement found at the autopsy, i.e., heart, brain, lungs, etc.	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Survival (cont'd)

Validations		
Code	**Description**	**Resolution**
SUR01	Date of Death is in the Future.	Enter a Date of Death that is earlier than or equal to the current date.
SUR02	Autopsy Results Available is set to "Yes", but Cause of Death (Autopsy Finding) is not specified.	Cause of Death (Autopsy Finding) must be provided when the Autopsy Results Available is set to "Yes".
SUR03	Autopsy Results Available is not set to "Yes" and some, or all, of the other autopsy fields have been entered.	Verify Autopsy Results Available and the other autopsy fields.
SUR04	Cause of Death (Autopsy Finding) is "Other" and Explain 'Other' Cause of Death (Autopsy Finding) is not specified.	Verify Cause of Death (Autopsy Finding) and Explain 'Other' Cause of Death (Autopsy Finding) fields.
SUR05	Explanation provided in Explain 'Other' Cause of Death (Autopsy Finding), but Cause of Death (Autopsy Finding) is not "Other".	Cause of Death (Autopsy Finding) must be 'Other' when an explanation is provided in the Explain 'Other' Cause of Death (Autopsy Finding) field.
SUR06	Cause of Death (Presumed) is "Other" and Explain 'Other' Cause of Death (Presumed) is missing.	An 'Other' Cause of Death (Presumed) requires an explanation in the Explain 'Other' Presumed Cause of Death field.
SUR07	Explanation provided in Explain 'Other' Cause of Death (Presumed), but Cause of Death (Presumed) is not "Other".	Cause of Death (Presumed) must be 'Other' when an explanation is provided in the Explain 'Other' Presumed Cause of Death field.

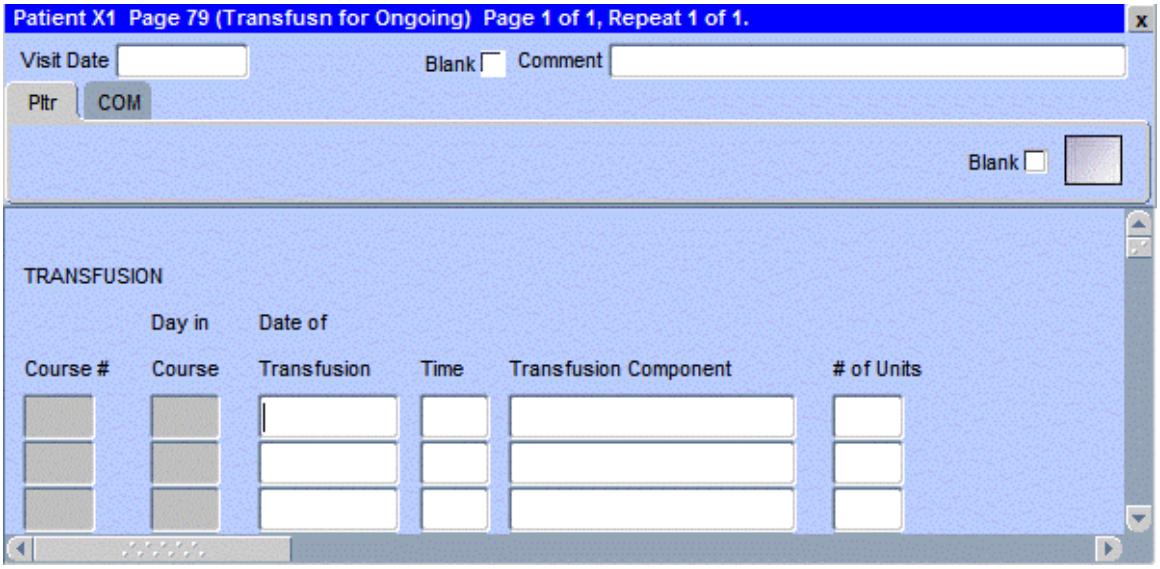
(SURVIVAL)

Transfusions

Purpose

Record the patient's received transfusions.

Transfusions eCRF



Transfusions (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date field.	DD-MMM-YYYY
Course # (d)	Indicates the course number the transfusion is related to based on their date and the Course Initiation start dates.	5 digits
Day in Course (d)	Indicates the day since the beginning of course the transfusion is related to based on their date and the Course Initiation start dates.	5 digits
Date (m)	Enter the date that the transfusion was done.	DD-MMM-YYYY
Time (m)	Enter the time the transfusion was done.	HH(24):MM
Transfusion Component (m) ...	Select the transfusion component from the pick list.	Use pick list.
# of Units (m)	Enter the blood component number of units transfused (in Units)	3 digits
Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Transfusions (cont'd)

Validations		
Code	**Description**	**Resolution**
TF01	Transfusion date is in the future.	Enter a date that is equal to or prior to the current date.
TF02	Two or more transfusions with the same date and time.	There can only be one transfusion for a date and time.

Derivations		
Code	**Field Name**	**Description**
TF1001	Course #	Course number is derived based on the course initiation start dates and the transfusion date.
TF1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the transfusion date.

(TRANSFUSIONS)

Filler Page

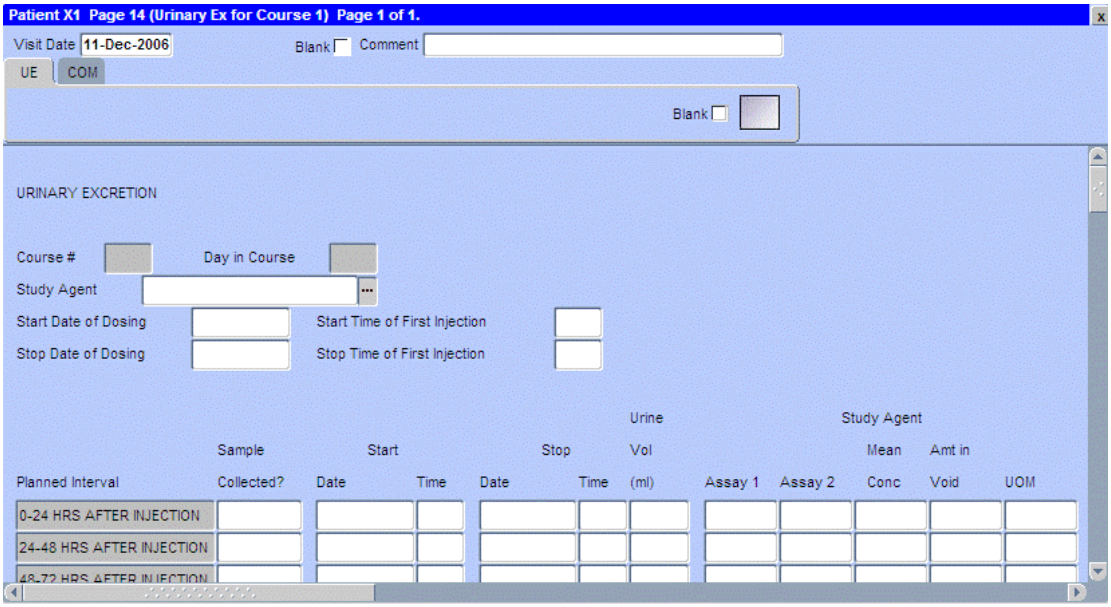
Urinary Excretions

Purpose

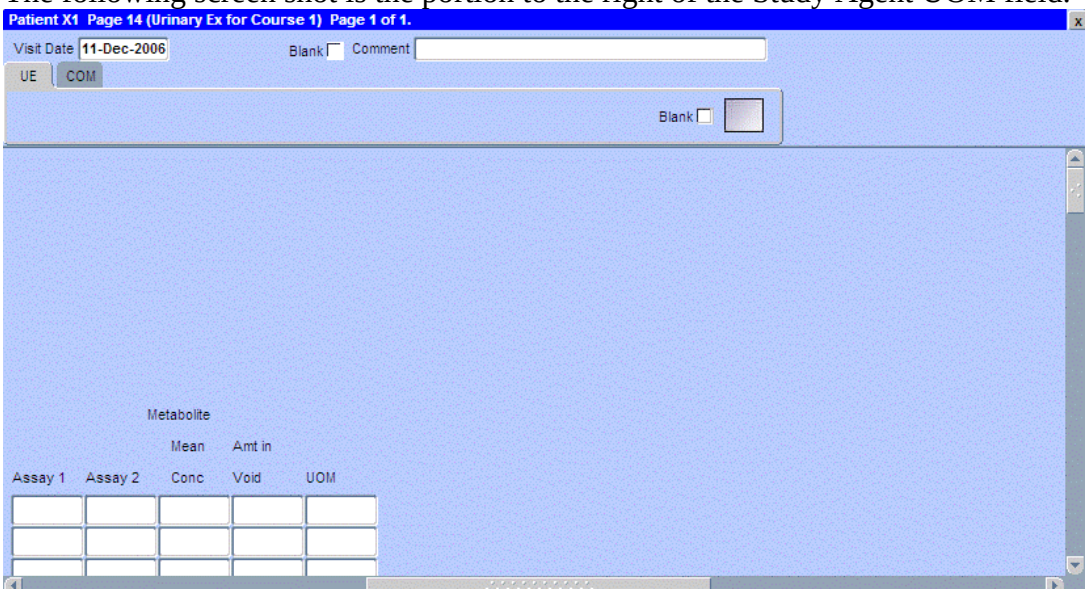
Record detailed information about the collection of urine samples for analysis of the presence and quantity of the study medication and/or its metabolites.

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

Urinary Excretion eCRF



The following screen shot is the portion to the right of the Study Agent UOM field.



Urinary Excretions (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Dosing field.	DD-MMM-YYYY
Course Number (d)	Indicates the course number that this urinary excretion sample is related to as derived from the course initiation start date.	5 digits
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.	5 digits
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
Study Agent (m) ...	Enter the name of the study agent (investigational or commercial) which is the subject of the urinary excretion study. *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.
Stop Date of Dosing	Enter the date the study agent administration was stopped. *Note: This field will be used for infusional therapies only.*	DD-MMM-YYYY

Urinary Excretions (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Stop Time of First Injection	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). *Note: This field will be used for infusional therapies only.*	HH(24):MM
Planned Interval	Planned interval pre-determined per protocol.	80 characters
Sample Collected? (m)	Indicate whether or not the specimen is collected. YES- then the Start Date, Time and Urine Volume should be entered NO UNKNOWN	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	Enter the urine volume collected in milliliters.	4 digits.
Parent Study Agent Assay 1	Enter the first parent study agent assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Parent Study Agent Assay 2	Enter the second parent study agent assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals

Urinary Excretions (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Parent Study Agent Assay Mean Concentration	Enter the parent study agent assay mean concentration, if available.	8 digits and 3 decimals
Parent Study Agent in Void	Enter the parent study agent assay in void results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Parent Study Agent UOM ▪▪▪	Select the appropriate Study Agent units of measurement (e.g.: mg/dL or mmol/l).	Use pick list.
Metabolite Assay 1	Enter the first metabolite assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite Assay 2	Enter the second metabolite assay results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite Mean Concentration	Enter the metabolite mean concentration, if available.	8 digits and 3 decimals
Metabolite in Void	Enter the metabolite in void results in the biological samples. If results are not available, record at least the collection times on the case report form.	8 digits and 3 decimals
Metabolite UOM ▪▪▪	Enter the appropriate Metabolite units of measurement (e.g.: mg/dL or mmol/l).	Use pick list.
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Urinary Excretions (cont'd)

Validations		
Code	**Description**	**Resolution**
UE01, UE02, UE07, UE15	Urinary excretion dates are in the future.	Enter dates that are equal to or prior to the current date.
UE06	Collection End Date/Time is prior to the collection Start Date/Time.	Collection End Date/Time must be after the collection Start Date/Time.
UE08	Start Date / Time and Stop Date / Time pair appears more than once – duplicate entry.	Remove the duplicate record or correct the Start Date / Time and Stop Date / Time of one of them.
UE10	No Study Agent and Metabolite results and UOM were provided.	At least one Study Agent or Metabolite results, with respective UOM, are required.
UE11	Study Agent UOM entered, but Assay 1, Assay 2, Mean Concentration and Amount in Void are missing.	Enter a Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void.
UE12	Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void entered, but UOM is missing.	Enter the Study Agent UOM.
UE13	Metabolite UOM entered, but Assay 1, Assay 2, Mean Concentration and Amount in Void are missing.	Enter a Metabolite Assay 1, Assay 2, Mean Concentration and/or Amount in Void.
UE14	Metabolite Assay 1, Assay 2, Mean Concentration and/or Amount in Void entered, but UOM is missing.	Enter the Metabolite UOM.
UE16	Collected Urinary Excretion sample does not have corresponding Start Date, Time and Urine volume.	Enter Start Date, Time and Urine Volume if 'Sample Collected' is 'YES'.

Urinary Excretions (cont'd)

Derivations		
Code	**Field Name**	**Description**
UE1001	Course #	Course number is derived based on the course initiation start dates and the infection episode onset date.
UE1002	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.

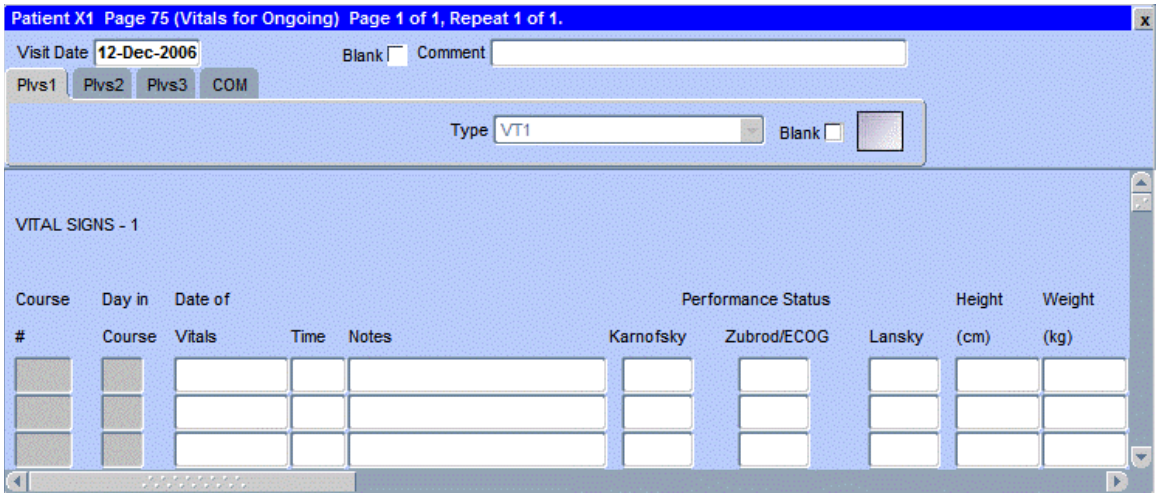
(URINARY-EXCRETIONS)

Vital Signs

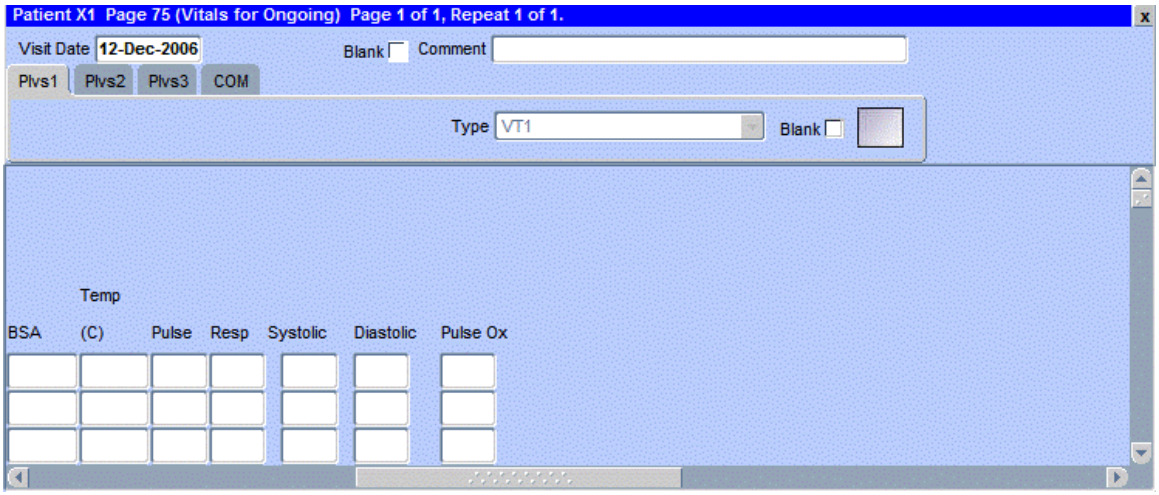
Purpose

Record the patient's vital signs during treatment.

Vital Signs eCRF



The following screen shot is the portion to the right of the Weight.



Vital Signs (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Vitals field.	DD-MMM-YYYY
Course # (d)	Indicates the course number the vital signs are related to based on their date and time.	5 digits
Day in Course (d)	Indicates the day since the beginning of course the vital signs are related to based on their date and time.	5 digits
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. *Note: This information is not sent to the reporting agency.*	200 characters
Performance Status (Karnofsky)	Select a value from the Karnofsky performance status scale. 0- Dead 10- Moribund 20- Very Sick 30- Hospitalized 40- Disabled 50- Frequent Assistance 60- Occasional Assistance 70- Self Care 80- Effort 90- Able 100- Normal	Use pick list.

Vital Signs (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Status (Zubrod) ▪▪▪	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) ▪▪▪	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.
Height (m)	Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors.	5 digits and 2 decimals
Body Weight (m)	Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors.	5 digits and 2 decimals

Vital Signs (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
BSA (m)	Enter the patient's body surface area in m^2 (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 1. The following simple approximation may be used for persons of "normal" height and weight: $BSA(m^2) = \sqrt{\frac{Height\ \ (cm)\ x\ Weight\ \ (kg)}{3600}}$	4 digit and 2 decimals
Temperature	Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors.	8 digits and 3 decimals
Pulse	Enter the patient's pulse rate.	8 digits and 3 decimals
Respiration Rate	Enter the patient's respiration rate.	8 digits and 3 decimals
Systolic Blood Pressure	Enter the patient's systolic blood pressure.	8 digits and 3 decimals
Diastolic Blood Pressure	Enter the patient's diastolic blood pressure.	8 digits and 3 decimals
Pulse Oximetry	Enter the patient's pulse oximetry reading.	3 digits and 2 decimals
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.		

Vital Signs (cont'd)

Validations		
Code	**Description**	**Resolution**
VIT01	Systolic Blood Pressure is less than Diastolic Blood Pressure.	Systolic Blood Pressure must be greater than Diastolic Blood Pressure.
VIT02	Two Vital Signs entries have the same Date and Time.	Correct the date and/or time.
VIT03	Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula.	Correct the BSA. The MIS BSA formula is: BSA (m^2) = 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.	Correct the BSA. The Mosteller BSA formula is: BSA (m^2) = ([Height(cm) x Weight(kg)] / 3600)^½
VIT05	Vitals Date is in the future.	Enter a date that is equal to or prior to the current date.
VIT06, VIT07, VIT08, VIT09, VIT10, VIT11, VIT12, VIT13	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 Blood Pressure and Diastolic Blood Pressure must be greater than zero.
VIT14	Pulse Oximetry is out of range.	Pulse Oximetry must be an integer number between 0 and 100.
VIT15	Vitals (on cycle sections) have Date of Vitals outside the range of the cycle start and stop date.	Enter an appropriate date. Note: this does not apply for all protocol.

Vital Signs (cont'd)

Derivations		
Code	**Field Name**	**Description**
VIT1001	Course #	Course number is derived based on the course initiation start dates and the vital signs date.
VIT1002	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)

Appendices

Appendix I

Conversion Tables

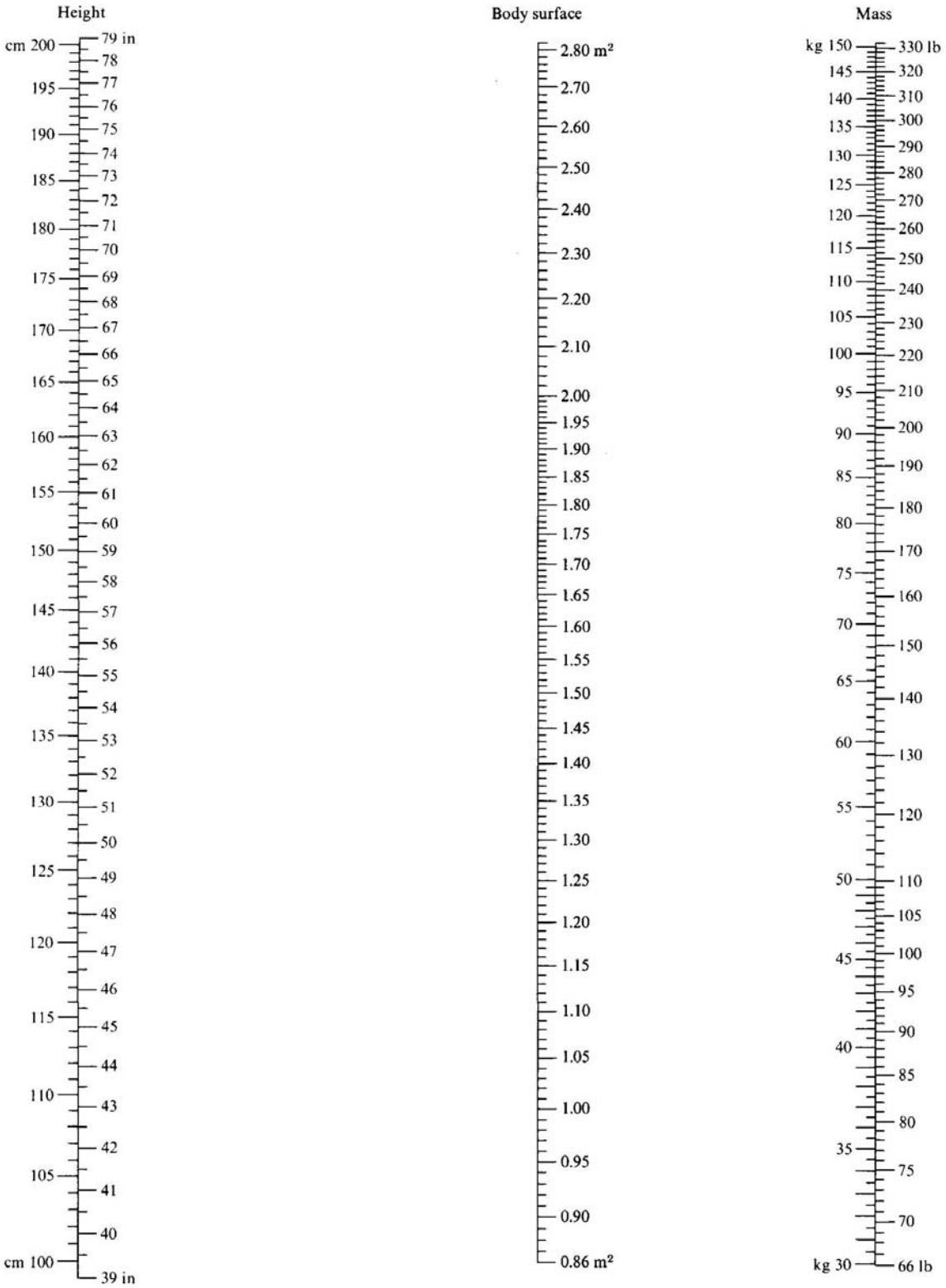
Appendix I - Conversion Tables (cont'd)

Conversion Factors

Height	**Weight**	**Temperature**
Ht (in) x 2.54=Ht (cm)	Wt (lb) ÷ 2.2=Wt (kg)	(T (F)-32) * 5 ÷ 9=T (C)
60 in = 152.4 cm	100 lb = 45.5 kg	105.0 F = 40.6 C
61 in = 154.9 cm	105 lb = 47.7 kg	104.5 F = 40.3 C
62 in = 157.5 cm	110 lb = 50.0 kg	104.0 F = 40.0 C
63 in = 160.0 cm	115 lb = 52.3 kg	103.5 F = 39.7 C
64 in = 162.6 cm	120 lb = 54.5 kg	103.0 F = 39.4 C
65 in = 165.1 cm	125 lb = 56.8 kg	102.5 F = 39.2 C
66 in = 167.6 cm	130 lb = 59.1 kg	102.0 F = 38.9 C
67 in = 170.2 cm	135 lb = 61.4 kg	101.5 F = 38.6 C
68 in = 172.7 cm	140 lb = 63.6 kg	101.0 F = 38.3 C
69 in = 175.3 cm	145 lb = 65.9 kg	100.5 F = 38.1 C
70 in = 177.8 cm	150 lb = 68.2 kg	100.0 F = 37.8 C
71 in = 180.3 cm	155 lb = 70.5 kg	99.5 F = 37.5 C
72 in = 182.9 cm	160 lb = 72.7 kg	99.0 F = 37.2 C
73 in = 185.4 cm	165 lb = 75.0 kg	98.5 F = 36.9 C
74 in = 188.00 cm	170 lb = 77.3 kg	98.0 F = 36.7 C
75 in = 190.5 cm	175 lb = 79.5 kg	97.5 F = 36.4 C
These examples are intended as a guide only. Please use the formula provided for a precise conversion.		

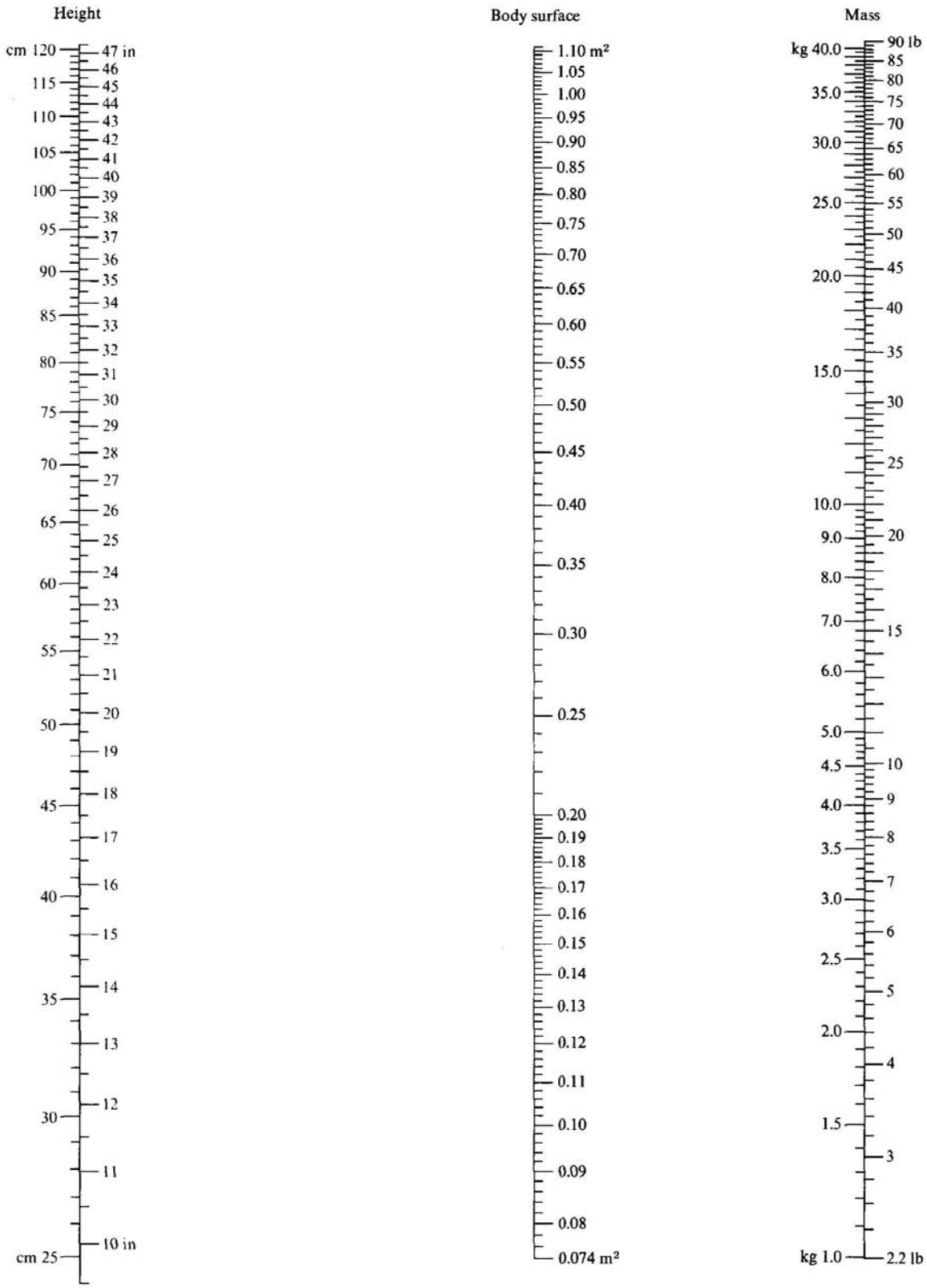
Appendix I - Conversion Tables (cont'd)

Nomogram for determining Body Surface of Adults from the formula of Du Bois and Du Bois, Arch. intern. Med., 17, 863 (1916)



Appendix I - Conversion Tables (cont'd)

Nomogram for determining Body Surface of Children from the formula of Du Bois and Du Bois, Arch. intern. Med., 17, 863 (1916)



Appendix I - Conversion Tables (cont'd)

Performance Status Scale Equivalences

ECOG (Zubrod)	Karnofsky	Definitions
0	100	Asymptomatic
1	80 – 90	Symptomatic, fully ambulatory
2	60 – 70	Symptomatic, in bed less than 50% of day
3	40 – 50	Symptomatic, in bed more than 50% of the day, but not bedridden
4	20 – 30	Bedridden

Appendix II

Useful References

Appendix II - Useful References (cont'd)

NIH	
National Institutes of Health	http://www.nih.gov/
Protomechanics Guide to Preparing and Conducting a Clinical Research Study	http://www.cc.nih.gov/ccc/protomechanics/index.html
NIH Clinical Center	
Drug Information Generic and Brand Names	http://www.nlm.nih.gov/medlineplus/druginformation.html
Laboratory Medicine	http://intranet.cc.nih.gov/dlm/index.html
Medical Abbreviations	http://intranet.cc.nih.gov/medbrd/abbreviations/
Micromedex Healthcare Series	http://druginfo.cc.nih.gov/
Medical Record Handbook	http://intranet.cc.nih.gov/ccc/mrh/Default.htm
NCI	
National Cancer Institute	http://www.cancer.gov/
Clinical Trials	http://www.cancer.gov/clinicaltrials
Glossary of Clinical Trials Terms	http://clinicaltrials.gov/ct/gui/info/glossary
Dictionary of Cancer Terms	http://cancer.gov/dictionary/
Metathesaurus	http://ncievs.nci.nih.gov/indexMetaphrase.html
CTEP Cancer Therapy Evaluation Program	http://ctep.info.nih.gov/

Appendix II - Useful References (cont'd)

CTCAE Common Terminology Criteria for Adverse Events	http://ctep.cancer.gov/reporting/ctc.html
AdEERs Adverse Event Expedited Reporting System	http://ctep.info.nih.gov/reporting/adeers.html
CDUS Clinical Data Update Systems	http://ctep.cancer.gov/reporting/cdus.html
CTMS Clinical Trials Monitoring Service	http://www.theradex.com/CTMS/ctmsmenu.htm
CCR	
Center for Cancer Research	http://ccr.cancer.gov/default.asp
Intranet	http://ccrintra.cancer.gov/default.asp
C3D Cancer Central Clinical Database	http://ccrtrials.nci.nih.gov/CCR_trials/C3DS/C3D
C3D RDC Login	http://octrials.nci.nih.gov/opa45/rdclaunch.htm
C3D Support	http://ncicbsupport.nci.nih.gov/sw/content/C3D.html
C3D eCRFs Instructions	http://ccrintra.cancer.gov/clin_ops/C3D/ecrf_instructions.asp
FDA	
Food and Drug Administration	http://www.fda.gov/
Code of Federal Regulation **Title 21 CRF Part 11**	http://www.fda.gov/cdrh/aboutcfr.html http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1 http://www.21cfrpart11.com/