Manual for the Completion

of the

NCI / CCR / C^3D

Case Report Forms

Prepared by:

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

Disclaimer:

This manual was developed by Harris IT Services 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.

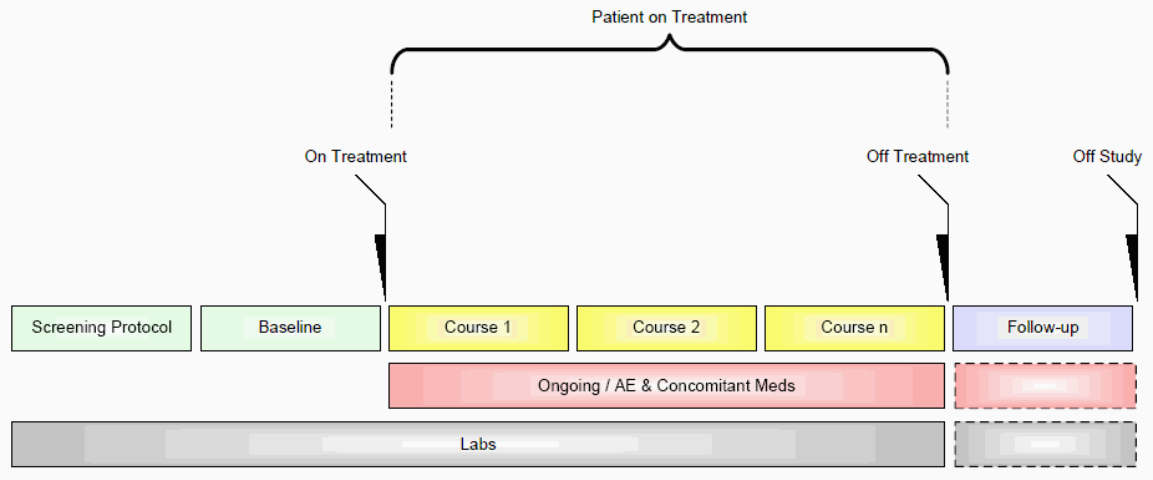
The eCRF instruction manual is preceeded by a General Instructions section which describes topics applicable to all eCRFs.This is followed by instuctions for each form which include how to complete each field, what the validation rules are for the CRF, and what fields will be derived by the database.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

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.

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.

Currently there are four pick lists that over one thousand items. C3D only lists the first thousand items. If the item need cannot be found because it is beyond the one thousand item, a search criterion must be specified before the pick list is displayed.

Ex: type in %odiu% and then display the pick list. This criteria searches for items that contain the lower characters odiu. Please note that the search is case sensitive and upper and lower cases will make a difference.

The four pick lists are:

1. Institutions – present in Enrollment and Course Initiation CRF;
2. Disease Term – present in the Enrollment CRF;
3. CTCAE Term – present in the Baseline Symptoms and Adverse Events CRFs;
4. Agents – present in the Concomitant Measures and Medications CRFs.

General Instructions

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.: $^{(m)}$)

Inserting Unplanned Visits

In a C3D Study, all the necessary visits and CRFs are planned according to the Protocol Schema. Each CRF has a limited amount of data that can be entered. If this limit is reached, a new CRF needs to be used. This is done by inserting an unplanned visit which creates placeholders for all CRFs in that visit. Here are the steps:

1. Select the visit which has the CRF
2. From the C3D menubar, select the menu option 'Insert'
3. Then select the menu option 'Visit'

A new unplanned visit is added to the right of the existing one and includes all CRFs planned for such visit. Enter data in the new CRFs as usual.

When unplanned visit have been added, the right most column in a visit is 'Show unplanned pages'. Clicking on it will reveal the unplanned CRFs.

Each Lab Panel has its own visit, but only one CRF is planned. Any additional CRF must be manually created by inserting an unplanned visit. That is common when entering outside labs. Labs electronically loaded into C3D automatically insert the necessary unplanned visits.

The Ongoing visit is another one where, over time, an unplanned visit might be necessary to capture additional data on Adverse Events, Concomitant Measures and Medications.

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

Record all adverse events experienced by the 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 recorded using the appropriate adverse event term and the appropriate codes for "grade", "attribution(s)", "serious", "action", "therapy", and "outcome" in the respective column for each event.

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

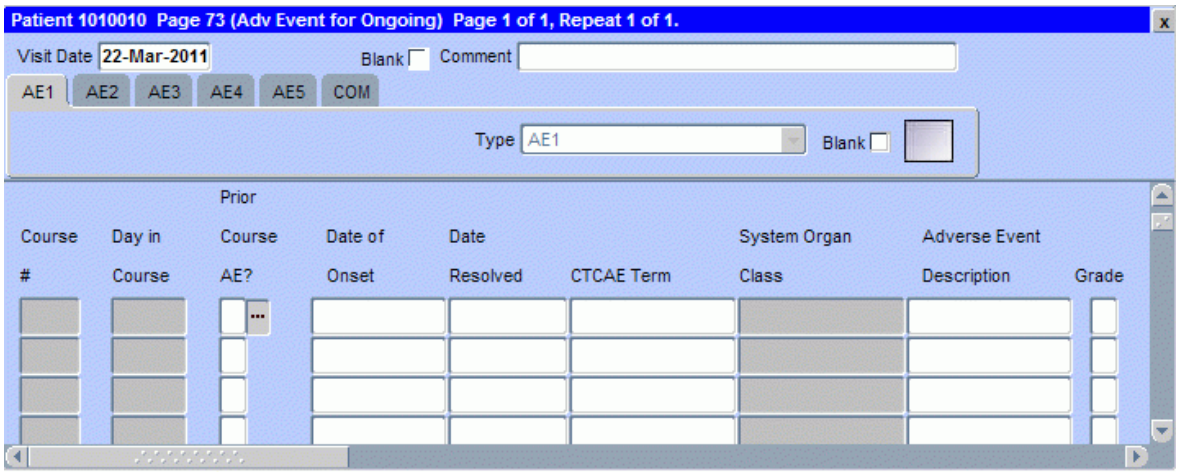
If a patient died on study then the death adverse event onset and resolved dates should be the same.

How to record baseline symptoms:

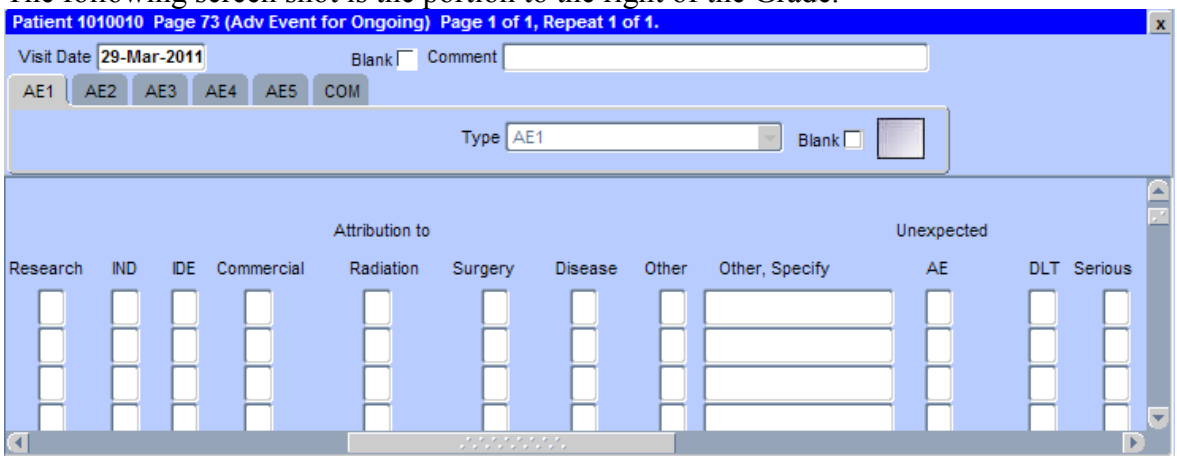
- If a pre-existing condition improves, no entry is made on the AE eCRF. See Baseline Symptoms eCRF for instructions.
- If a pre-existing condition worsens (i.e.: the grade of the baseline symptom increases), that constitutes an adverse event entry.

Adverse Events (cont'd)

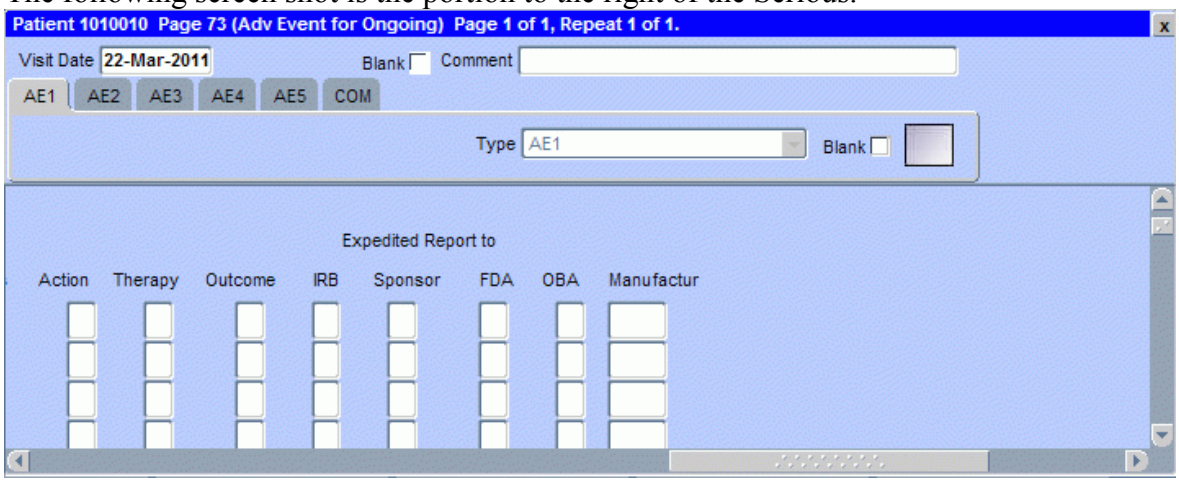
Adverse Events eCRF



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



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



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.	DD-MMM-YYYY
CTCAE Term (m) ...	Using the pick list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term. 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. *Note: This pick list does not show all the CTCAE Terms. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched CTCAE Terms. Ex: type %ypo% to list all the terms that include the lower characters 'yop' somewhere in the CTCAE Term.* *Note: Visit CTEP's CTCAE webpage for latest version.*	Use pick list.
System Organ Class (d)	Broad classification of adverse events based on anatomy and/or pathophysiology. Within each class there is the adverse event term/description. *Note: For studies using CTCAE version 3.0, this field is ' CTC category'. This field is derived from the selected CTCAE Term.*	40 Characters
Adverse Event Description	Enter a **succinct clinical description** of the adverse event. *Note: This field is mandatory, unless the CTCAE term is the same as the description (e.g. nausea, diarrhea).*	100 characters (Only 33 characters are reported for CTMS monitored studies.)

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	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.	
Grade (m)	Grade adverse events using CTCAE version indicated in the protocol. *Note: Some grades are disallowed for some categories in the CTCAE. In the CTCAE tables this will be noted by the use of an em-dash "—". For example, Hair loss/Alopecia can only be graded as a 1 or 2, so grade 3, 4, and 5 do not exist and will be noted in the table with a "—" verses a description.* If the protocol does not use 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 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.**	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Attribution to Research ...	Evaluate the adverse event's relationship to the subject's participation in the study, including study-related therapy and procedures. Select one of the following codes to record this evaluation: 1. Unrelated – clearly not related 2. Unlikely – doubtfully related 3. Possible – may be related 4. Probable – likely related 5. Definite – clearly related *Note: Attribution to Research must be the same as the highest Attribution to IND, IDE, Commercial, Surgery and Radiation.*	Use pick list.
Attribution to IND (m) ...	Evaluate the adverse event'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 IDE ...	Evaluate the adverse event's relationship to the investigational device exemption. 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 Commercial …	Evaluate the adverse event'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 adverse event'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.
Attribution to Surgery …	Evaluate the adverse event'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.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Attribution to Disease ...	Evaluate the adverse event'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.
Attribution to Other ...	Evaluate the adverse event'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
Unexpected ? (m) ...	Indicate if the adverse event is unexpected as defined by the NCI IRB, by entering: Y- Yes N- No	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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.
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. 4. persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions 5. Hospitalized or prolonged hospitalization (not including emergency room visits). 6. Caused congenital anomaly in child of patient. 7. Important medical event that jeopardizes patient / requires intervention to prevent permanent impairment or damage to patient.	Use pick list.

Adverse Events (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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: Regimen interrupted also means therapy was delayed.*	Use pick list.
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 (m) ▪▪▪	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 (m) ▪▪▪	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.
Expedited Report to Manufacturer (m) ▪▪▪	Indicate if an expedited adverse event report was sent to the Manufacturer 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.		

Adverse Events (cont'd)

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.
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.

Adverse Events (cont'd)

Validations		
Code	**Description**	**Resolutions**
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.
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)

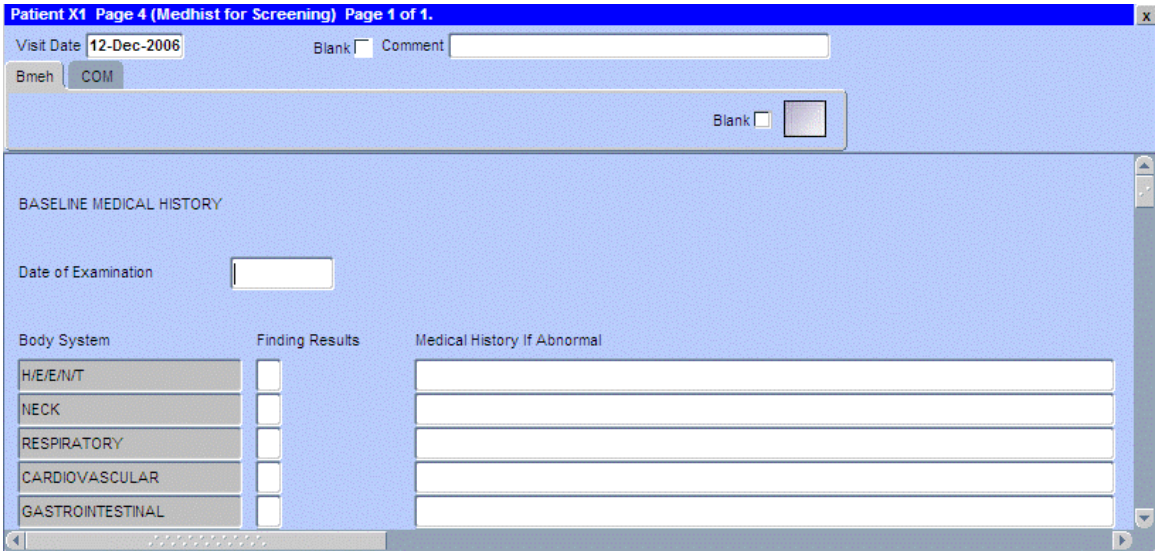
Baseline Medical History

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)

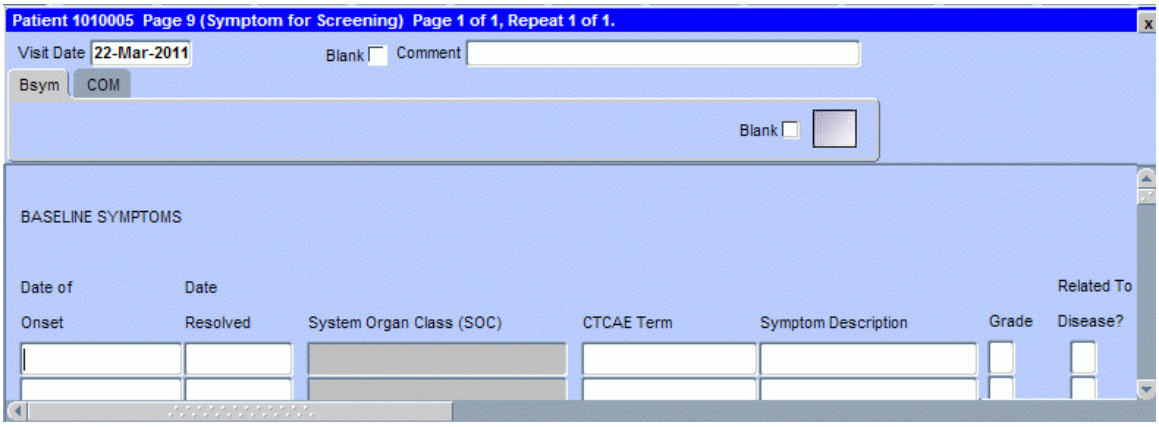
Baseline Symptoms

Purpose

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

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

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 initiated. *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. (i.e.: no longer exists at any grade).	DD-MMM-YYYY
CTCAE Term (m) ...	Use the pick list to select a CTCAE (Common Terminology Criteria for Adverse Events) Term. *Note: This pick list does not show all the CTCAE Terms. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched CTCAE Terms. Ex: type %ypo% to list all the terms that include the lower characters 'yop' somewhere in the CTCAE Term.* *Note: Visit CTEP's CTCAE webpage for latest version.*	Use pick list.
System Organ Class (d)	Broad classification of adverse events based on anatomy and/or pathophysiology. Within each class there is the adverse event term/description. *Note: For studies using CTCAE version 3.0, this field is ' CTC category'. This field is derived from the selected CTCAE Term.*	40 Characters
Symptom Description	Enter a **succinct clinical description** of the symptom. *Note: This field is mandatory for 'Other, Specify…' CTCAE terms. For example: Immune system disorders - Other (Specify, __).*	100 characters (Only 33 characters are reported for CTMS monitored studies.)

Baseline Symptoms (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	It might be also used to further describe symptom such as "Eye pain" by entering "Left eye".	
Grade (m) ▪▪▪	Enter the severity of the symptom by using the protocol's specified CTCAE Version. If the symptom is not explicitly mentioned it should be coded in the appropriate "other" category and graded according to the general criteria: 1. Mild – 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.

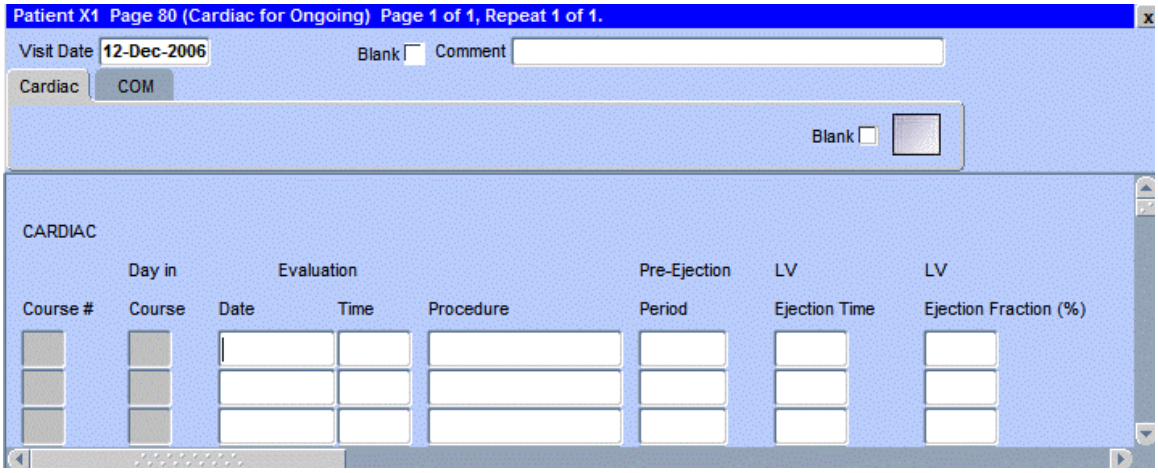
(BASELINE-SYMPTOMS)

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.	4 digits
LV Ejection Fraction (%) (m)	Enter the Left Ventricular Fraction percentage.	3 digits
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.

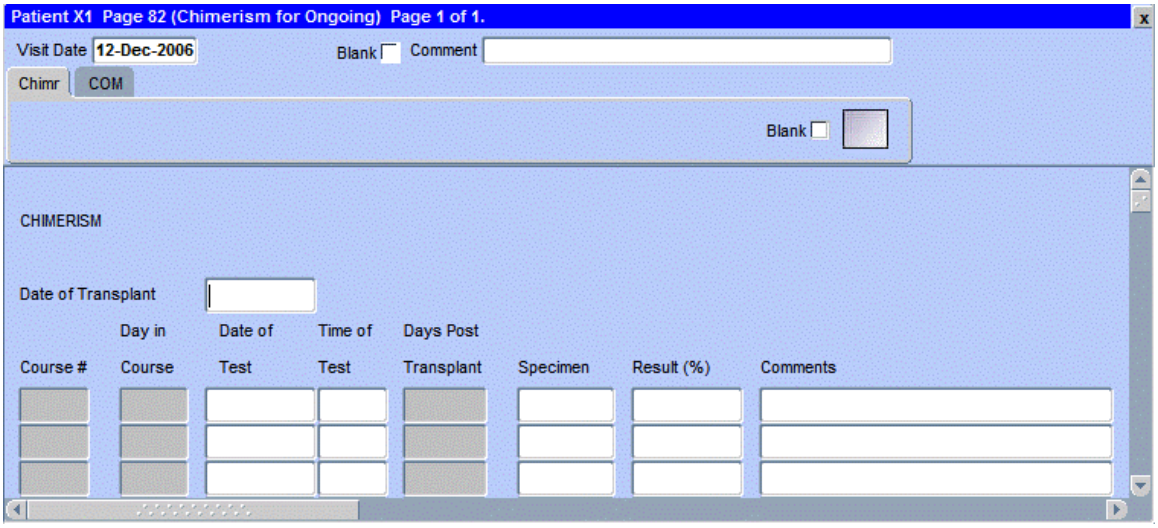
(CARDIAC)

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)

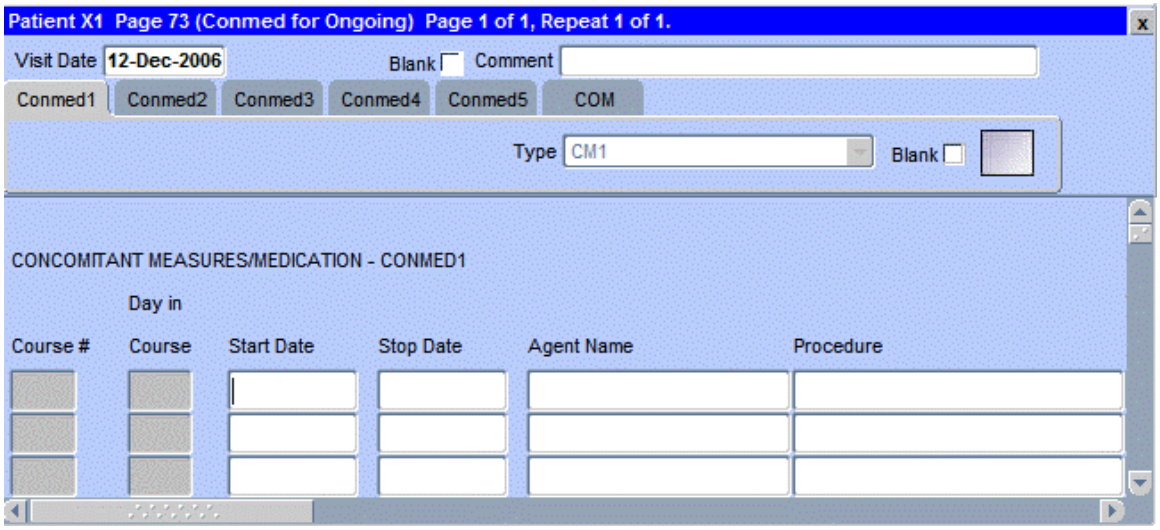
Concomitant Measures / Medications

Purpose

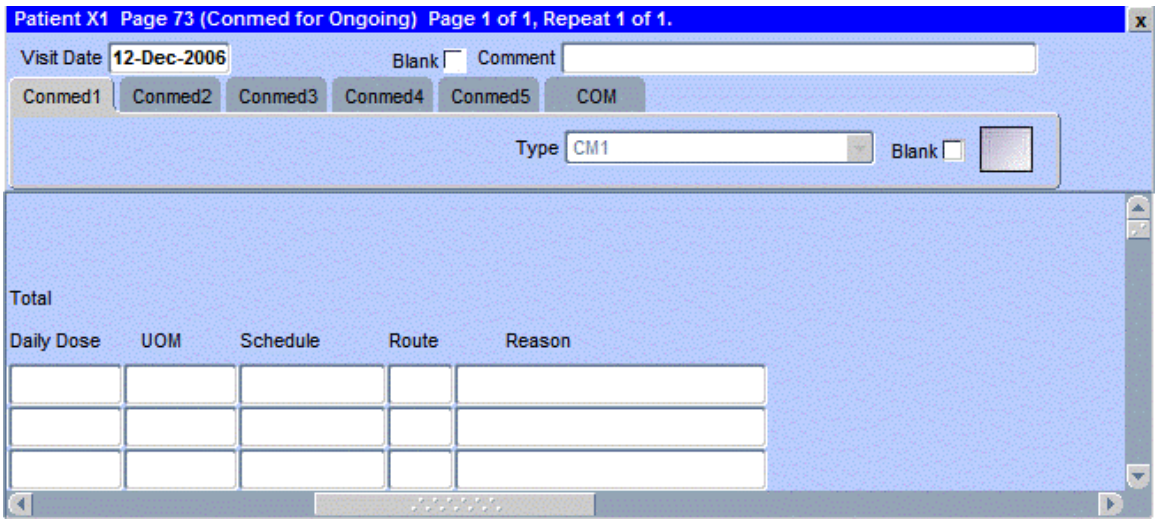
Record all concomitant medications, including therapies given to treat adverse events.

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

Concomitant Measures / Medications (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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: This pick list does not show all the Agents. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched Agents. Ex: type %ydro% to list all the agents that include the lower characters 'ydro' somewhere in the agent's name.* *Note: Pre and post medications specified in the protocol and administered as part of the 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 / Measure ...	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.
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.*	100 characters

Concomitant Measures / Medications (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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 ▪▪▪	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.
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.

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.

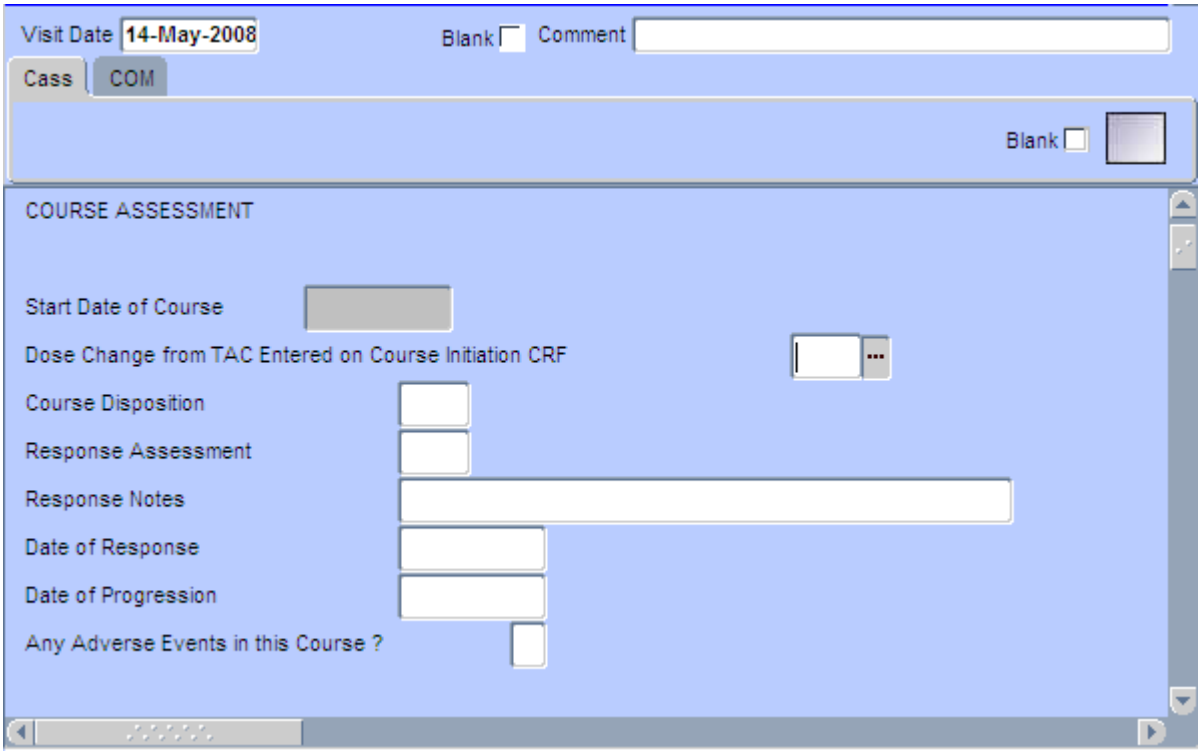
(CONCOMITANT-MEASURES-MEDICATIONS)

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
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. CRU- Complete Response Unconfirmed – Complete response assessed but not confirmed as per protocol timeframe. Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed: CR- Complete Response - There is a disappearance of all evidence of disease as assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments to demonstrate a disappearance of all evidence of disease.	Use pick list.

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
	PR or MR- Partial Response or Marginal Response - Response is assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR. 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 be used in assessing response. Please use the following selections when assessing response using RECIST criteria only. *Note: CTEP's link to an article in the European Journal of Cancer: New response evaluation criteria in solid tumors: Revised RECIST*	

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
	guideline (version 1.1) Evaluation of target lesions: CR- Complete Response - Disappearance of all target lesions. PR- Partial Response At least a 30% decrease in the sum of the LD (longest dimension) of target lesions, taking as reference the baseline sum LD. 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 on study (this includes the baseline sum if that is the smallest on study) or the appearance of one or more new lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. 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. Evaluation of non-target lesions: CR- Complete Response - Disappearance of all non-target lesions and normalization of tumor marker level. NON-CR/NON-PD- Non Complete Response and Non Progressive Disease - Persistence of one or more non-target lesion(s) and/or maintenance of tumour marker level above the normal limits. Non-CR/Non-PD is preferred over 'Stable Disease' for non-target disease since SD is increasingly used as endpoint for assessment of efficacy in some trials so to assign this category when	

Course Assessment (cont'd)

Field Descriptions / Instructions		
Field Name	**Description / Instructions**	**Format**
	no lesions can be measured is not advised. 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
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.

Course Assessment (cont'd)

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

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, or DU.	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.

Course Assessment (cont'd)

Validations		
Code	**Description**	**Resolution**
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.

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.

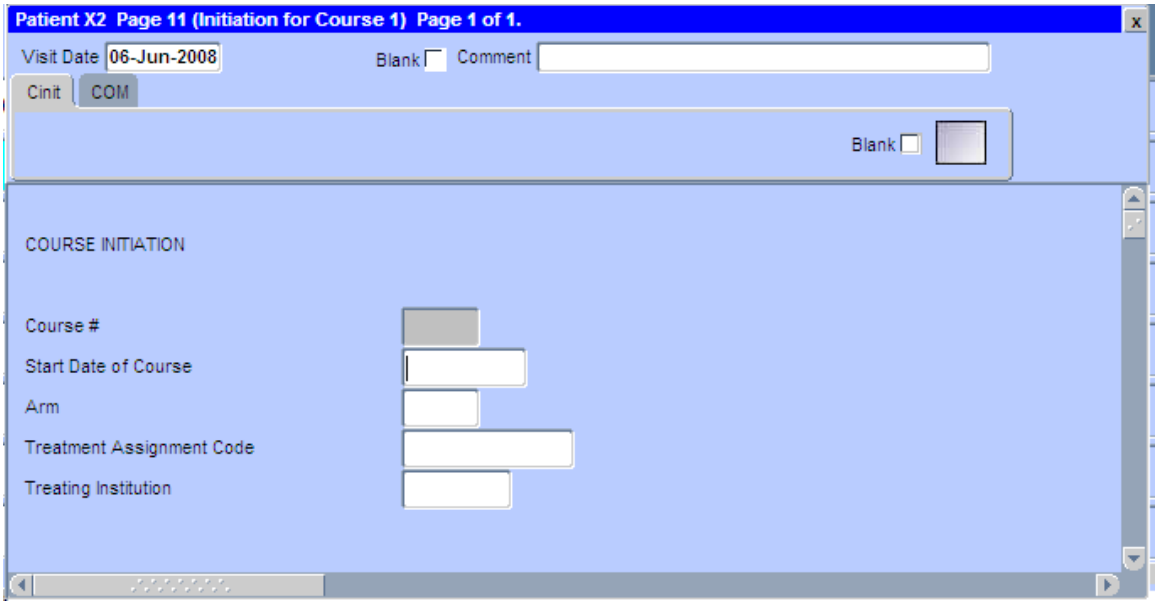
(COURSE-ASSESSMENT)

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.
Treatment Assignment Code (m) (c) ...	Select the appropriate code for the patient's treatment assignment as specified. For non-CTEP studies, "Treatment Assignment" codes are based on the treatment schedules described in the protocol. Please contact the Informatics team for advice on TAC formulation and modification. For CTEP sponsored studies, "Treatment Assignment" codes are provided by CTEP to the investigator, in the form of a coding letter, 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.

Course Initiation (cont'd)

Treating Institution (m) ▪▪▪	Select the unique CTEP institution code where the patient actually receives this course of treatment. *Note: This pick list does not show all the Institutes. User must type in a search criterion and then click on the ellipsis perform the search and display the resulting matched Institutes. Ex: type %NCI% to list all the Institutes that include the upper characters 'NCI' somewhere in the Institute code.* *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.

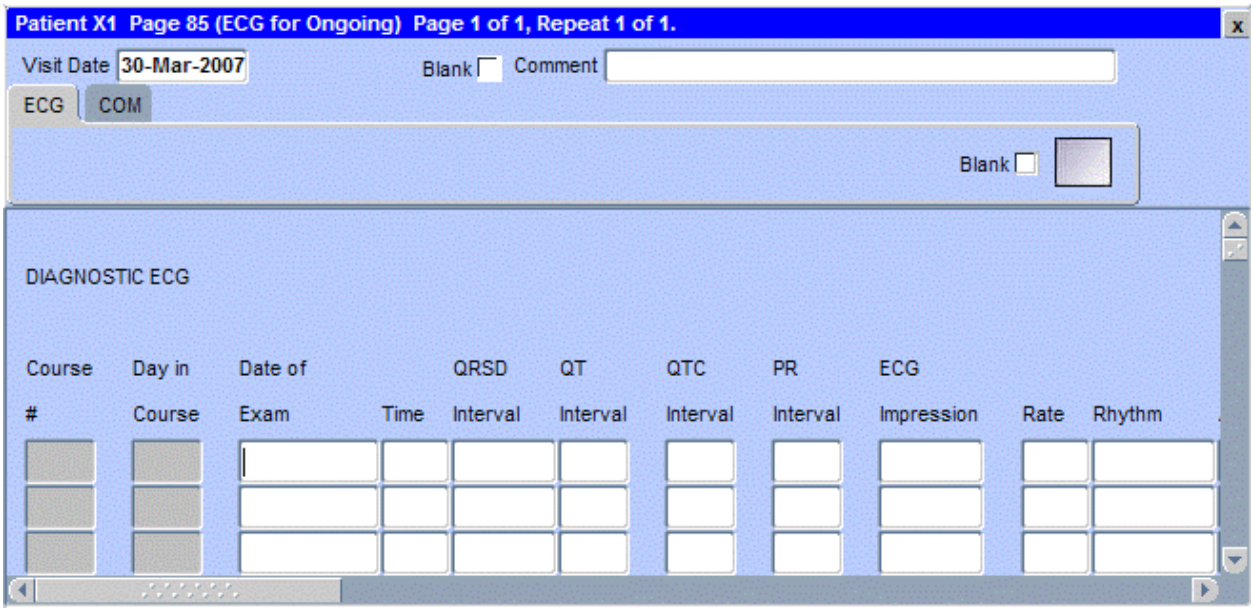
(COURSE-INITIATION)

ECG

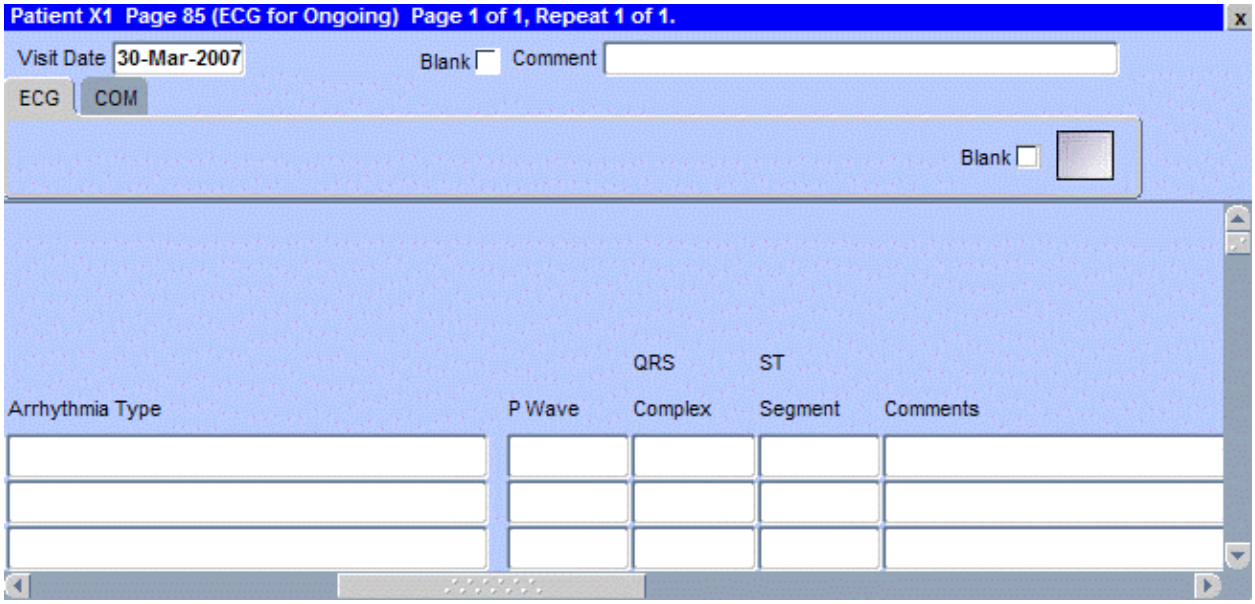
Purpose

Record the patient's ECG.

ECG eCRF



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



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**
Arrhythmia Type ▪▪▪	Select the patient's arrhythmia type.	Use pick list.
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.
Comments	Enter comments applicable to the ECG.	200 characters
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

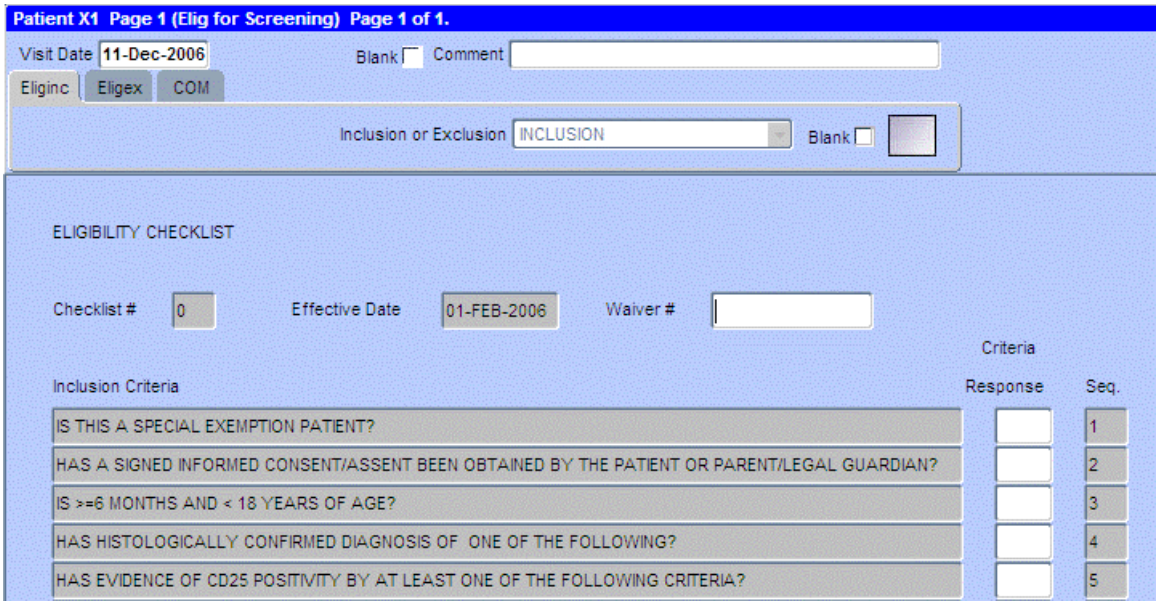
Purpose

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)



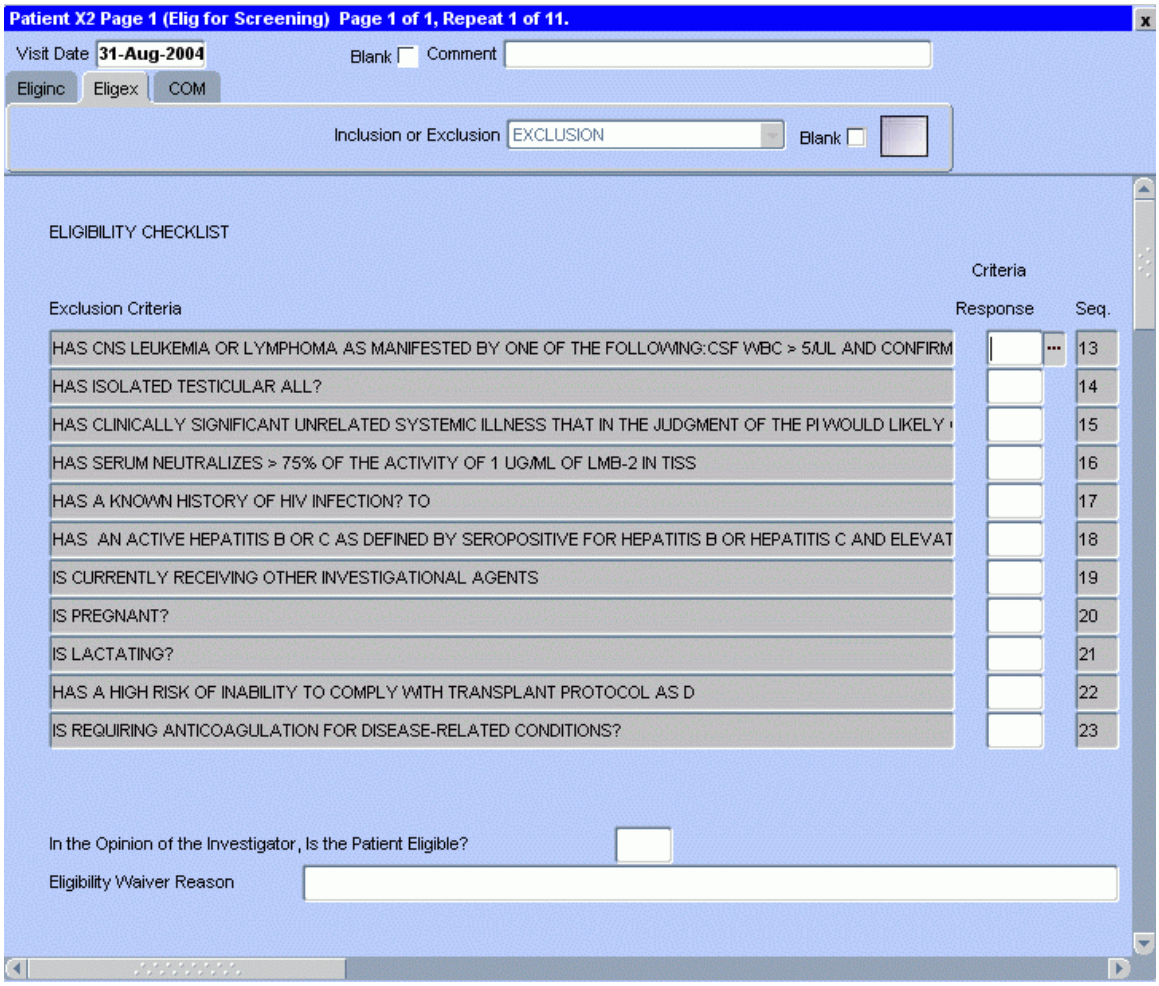
Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Visit Date [(m)]	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Checklist Number	Checklists are numbered sequentially based on NCI approval of amendments that change 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

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)

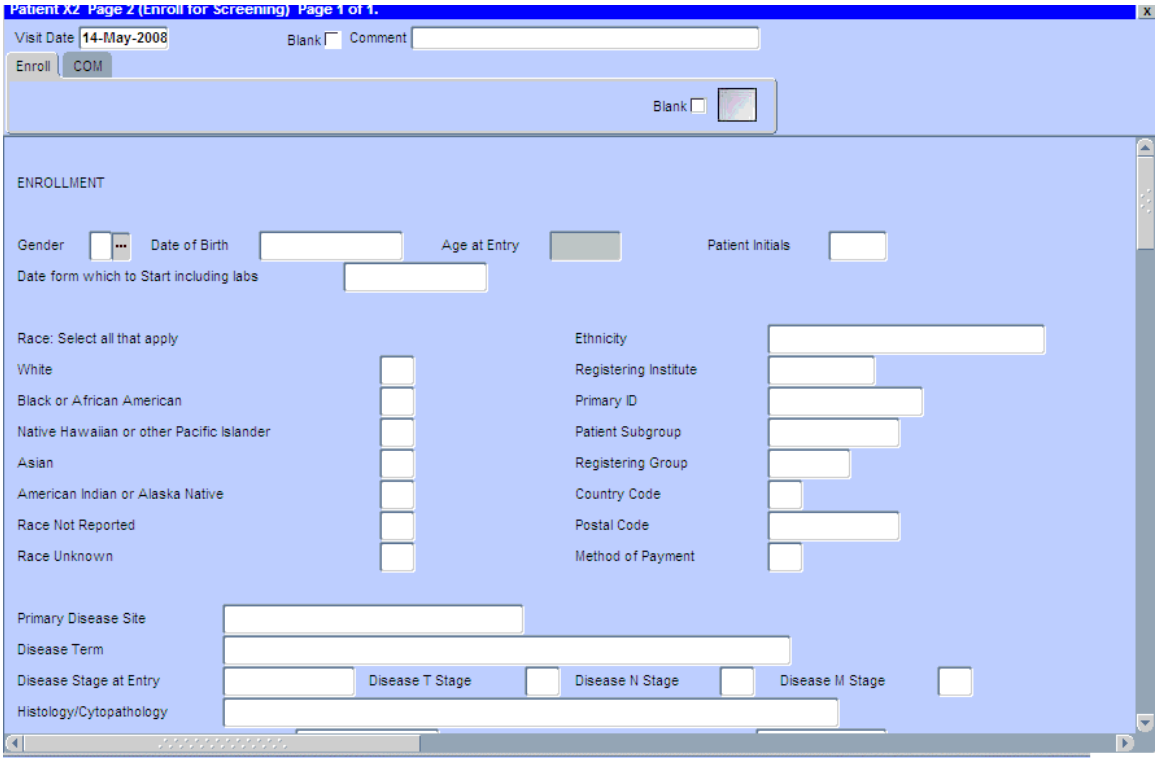
Enrollment

Purpose

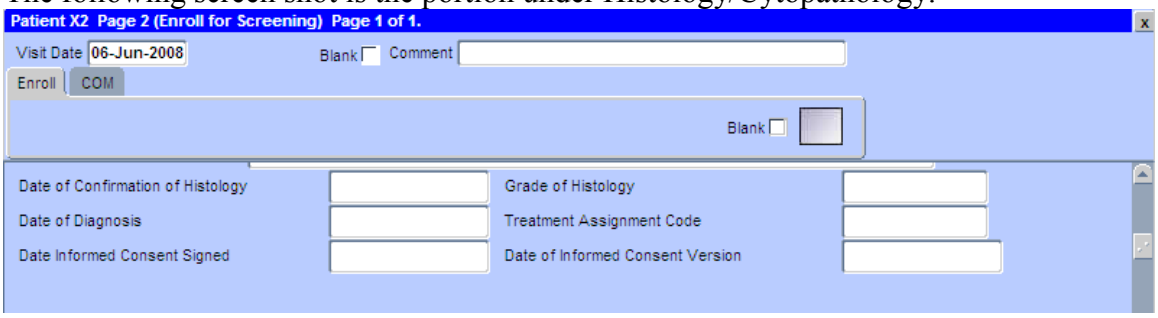
Record the patient's enrollment information at the time of study entry.

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 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 Unique Identification number provided by the Central Registration Office. This number is a combination of a site code and patient position code. 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.	Use pick list.
Disease Term (m) ▪▪▪	Select a disease term. Use the list of Disease Terms ("MedDRA") as listed on the CTEP Web site.	Use pick list.
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.

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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. *Note: Grade of Histology is the Gleason Score for Prostate Patient.*	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
Treatment Assignment Code (m) (c)	Select the appropriate code for the patient's treatment assignment as specified. For non-CTEP studies, "Treatment Assignment" codes are based on the treatment schedules described in the protocol. Please contact the Informatics team for advice on TAC formulation and modification. For CTEP sponsored studies, "Treatment Assignment" codes are provided by CTEP to the investigator, in the form of a coding letter, 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.
Date Informed Consent Signed (m)	Enter the date the patient signed the informed consent form.	DD-MMM-YYYY

Enrollment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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, ENR04, ENR05, ENR06, ENR17	Date of Birth, 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.
ENR09, ENR10, ENR11, ENR12	Birth Date is after the 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.
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.
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.

Enrollment (cont'd)

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

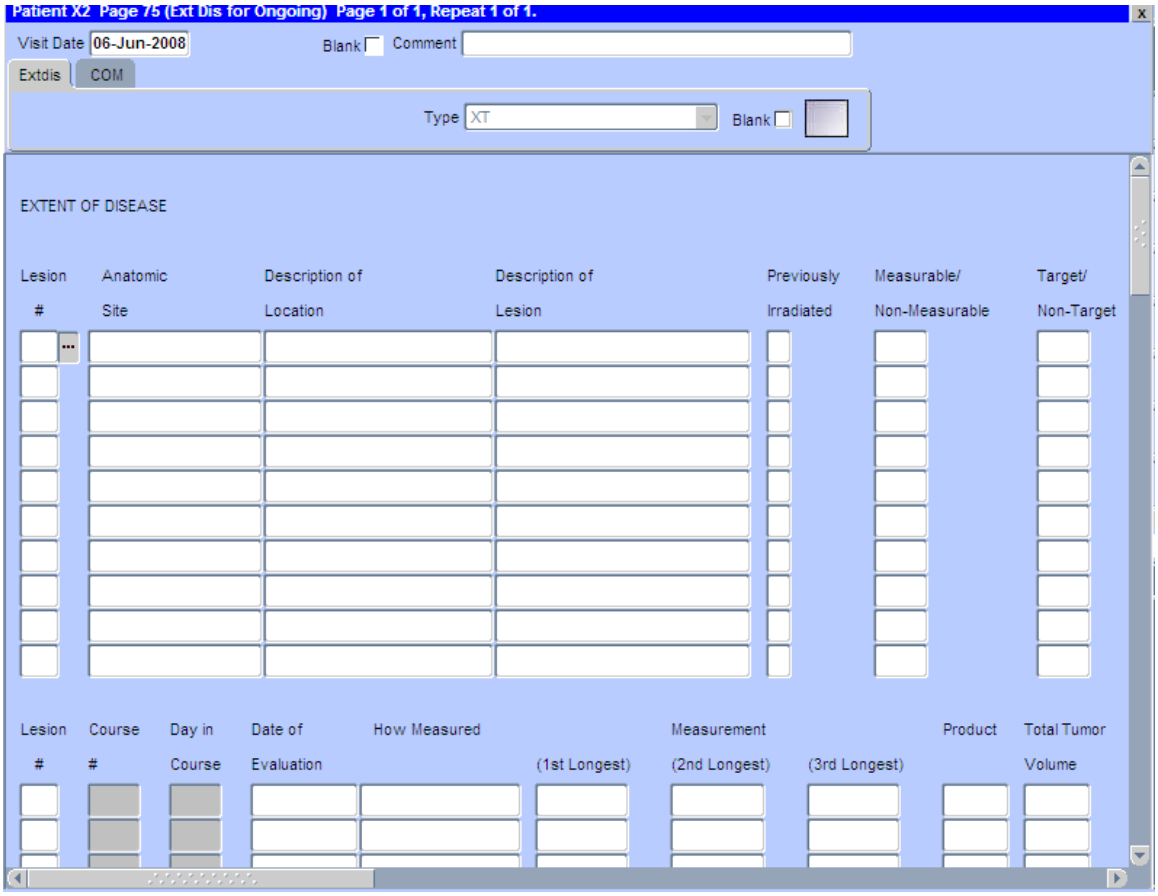
(ENROLLMENT)

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.
Anatomic Site (m) ▪▪▪	Select the anatomic position where the lesion is located, i.e. Lung, Skull, etc.	Use pick list.
Description of Location (m) ▪▪▪	Select a brief description of the lesion location.	Use pick list.
Description of Lesion	If applicable, enter a brief description of each lesion, e.g. cystic, well-defined, encapsulated, necrotic appearing center.	32 characters
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	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 which is the multiplication of the First and Second Longest Measurements.	8 digits and 2 decimals
Total Tumor Volume	Enter the total tumor volume which is the multiplication of all three measurements.	8 digits and 2 decimals
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)

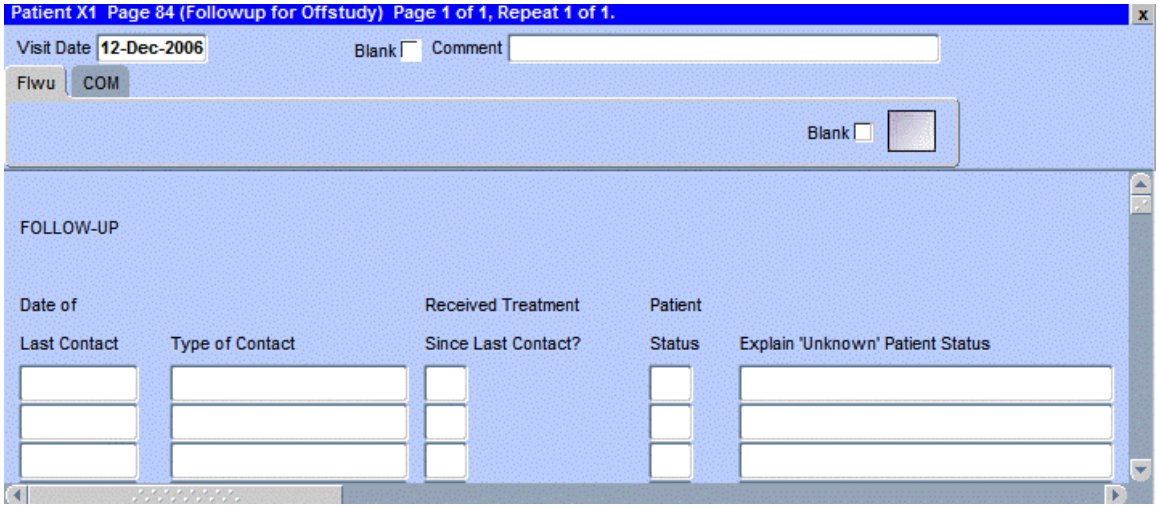
Follow-up

Purpose

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

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

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.

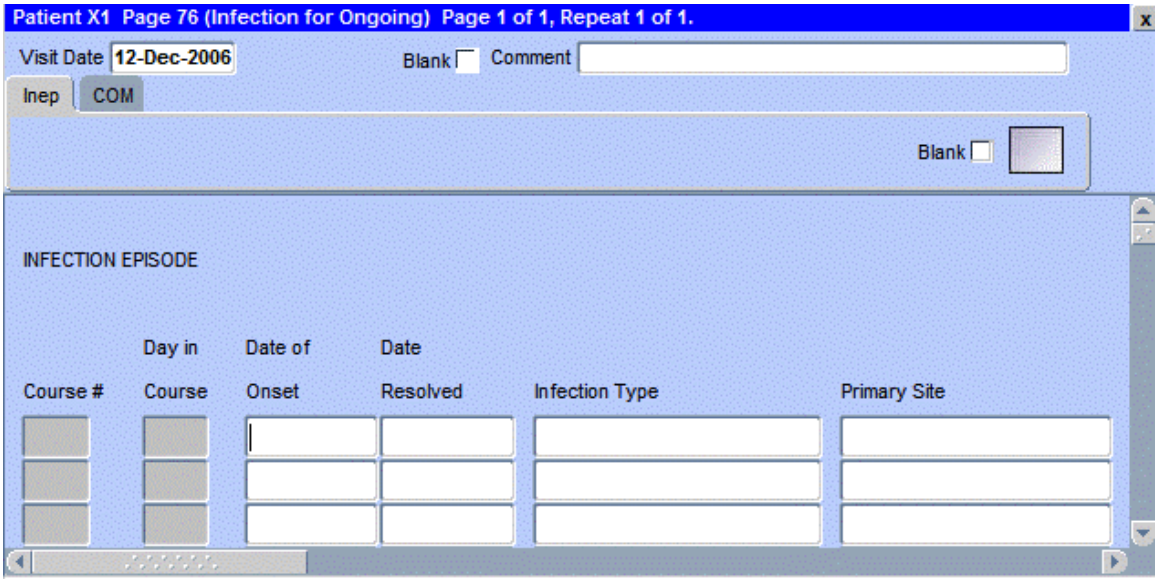
(FOLLOW-UP)

Infection Episode

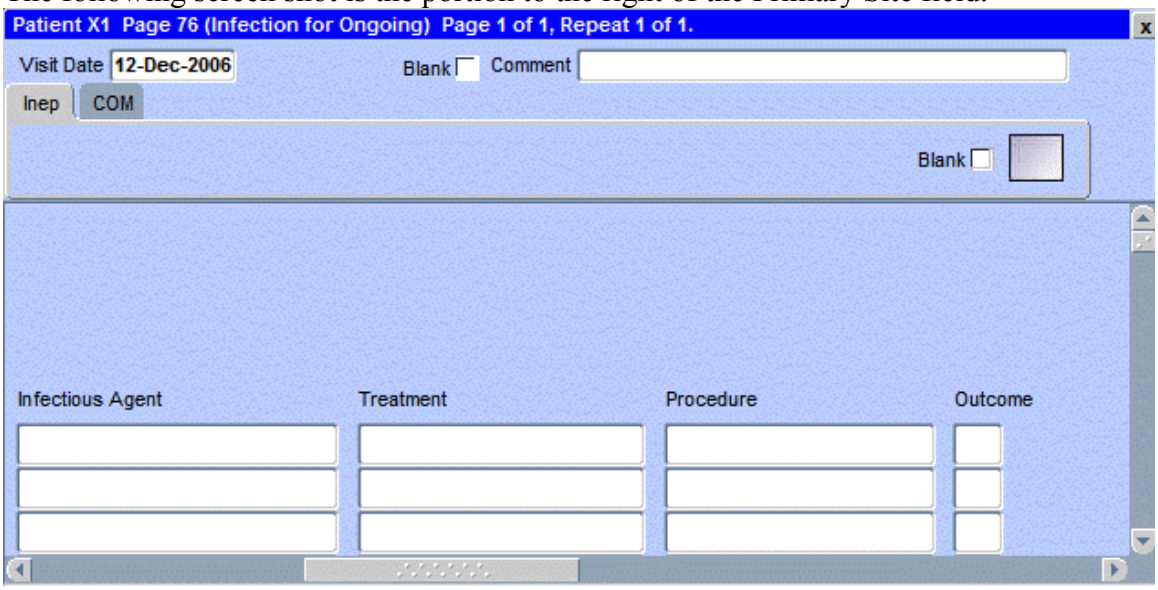
Purpose

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 NCI/CCR's intramural studies who have their labs drawn at the Clinical Center will use the Lab Load Interface (LLI) tool to select which labs results to electronically transfer into C3D. The selected results are then loaded onto the appropriate Lab Panel CRFs overnight. Instructions on how to use the LLI tool are in appendix IV.

2007 and earlier C3D Studies, in general, do not use the LLI tool and labs done in the Clinical Center are automatically loaded directly in C3D.

It takes at least 48 to 72 hours for Clinical Center Labs to become available to C3D.

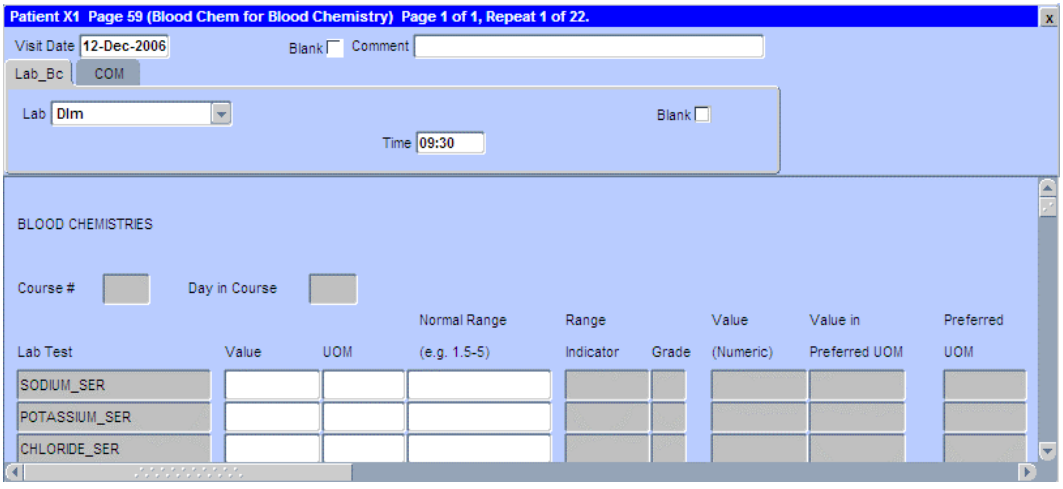
Outside labs need to be manually entered in C3D. Refer to the 'Inserting Unplanned Visits' section of the General Instructions of this manual.

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 table lists the standard lab CRFs and appendix III the tests in each of them. The C3D Study will have only the appropriate lab CRFs as specified by the Protocol.

• Blood Chemistries • Blood Gases • Bone Marrow • Chimerism Lab • Coagulation	• CSF • Hematology • Lymphocyte Phenotype • Other Serum Chemistries • Other Urinary Results	• Respiratory Functions • 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 panel has a different set of tests which are listed at the appendix III.	20 characters
Value	Enter the lab test result value as reported.	20 characters.
UOM ...	Select the appropriate lab test value unit of measurement.	Use pick list.
Normal Range	For labs loaded from the MIS/CRIS system, the range is automatically populated. For labs obtained outside the NCI Clinical Center, enter the appropriate normal range.	30 characters

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 version of the NCI Common Terminology Criteria for Adverse Events (CTCAE) specified by the Protocol. *Note: The age and gender are also factors 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 is pre-defined by the institute.	12 characters
Preferred UOM (d)	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 grade higher than zero or than the most recent 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.

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).
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)

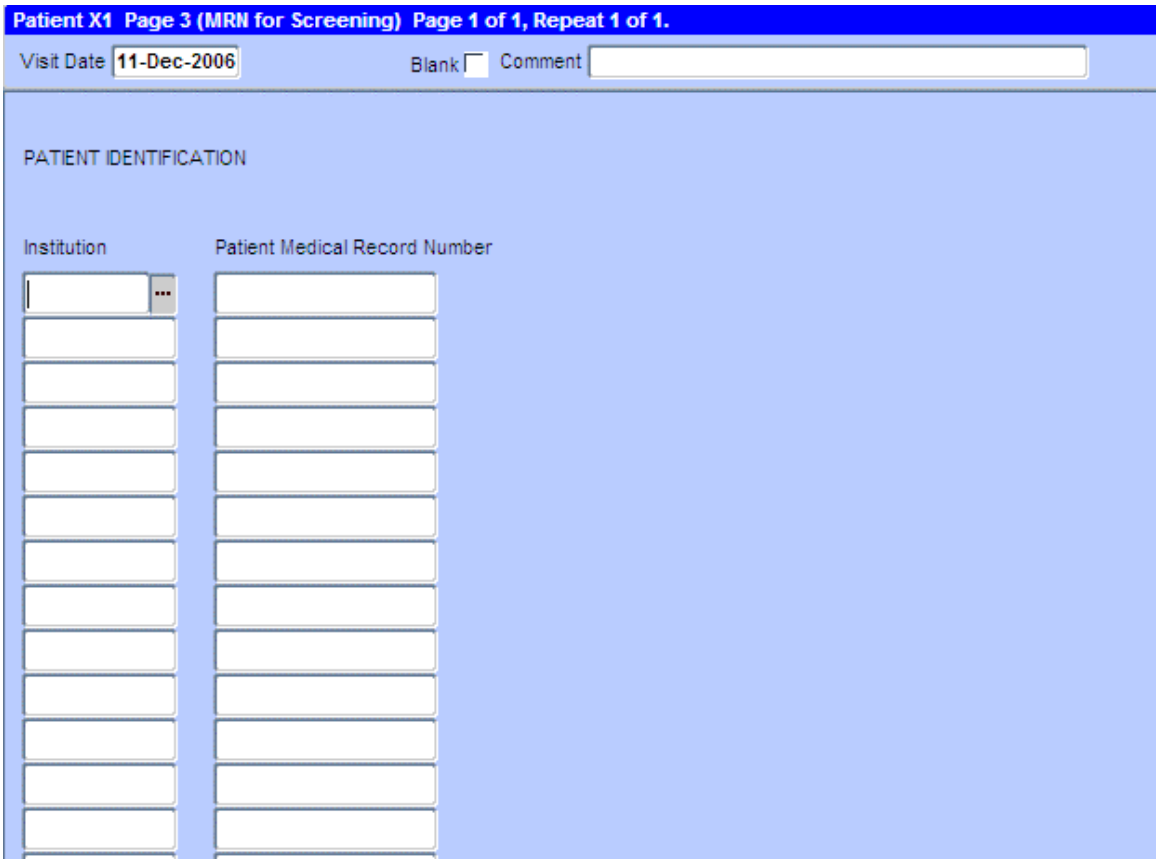
Medical Record Numbers

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

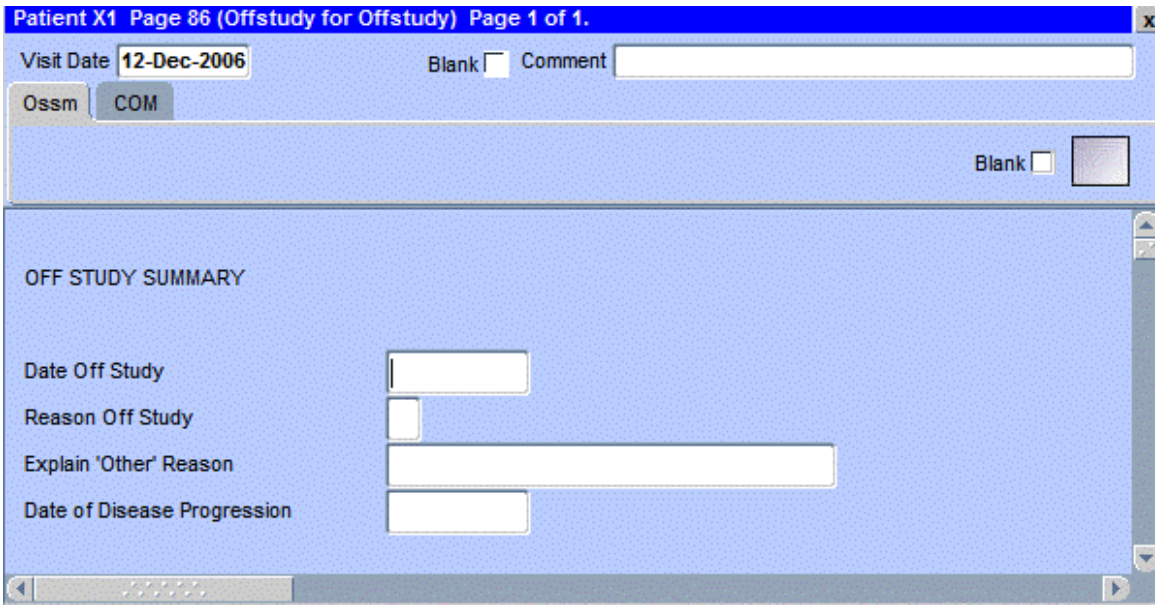
Record information concerning the patient's off study date and reason. Complete this form after the patient has been taken off study.

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)

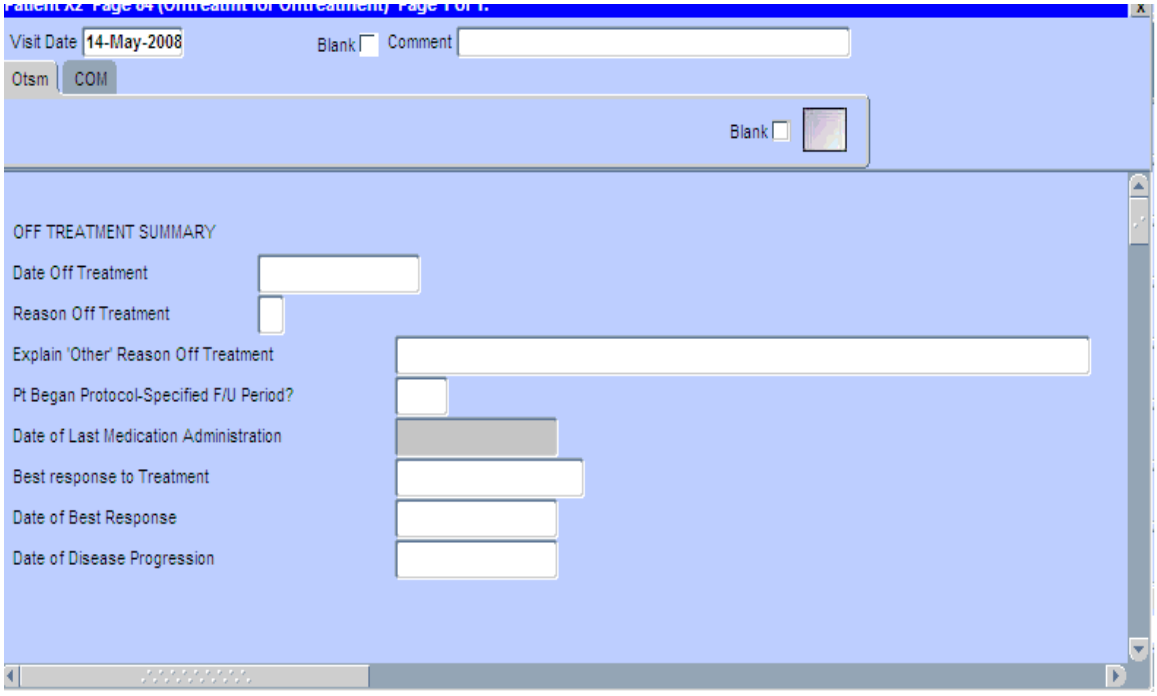
Off Treatment

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
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 CRU- Complete Response Unconfirmed NON-CR/NON-PD- Non Complete Response and Non Progressive Disease DU- Disease Unchanged According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression. 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.	Use pick list.

Off Treatment (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
	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 'PD/NA/NE/NP/TE' and Date of Best Response is missing.	If anything other than 'PD/NA/NE/NP/TE' 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).
OTS18	Best Response date to Treatment is not same as the Best Response reported on Course Assessment forms	Best response date should be validated against response date on Course Assessment form.
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**
OTS1002	Date of Last Medication Administration	Indicates date the last medication was administered.

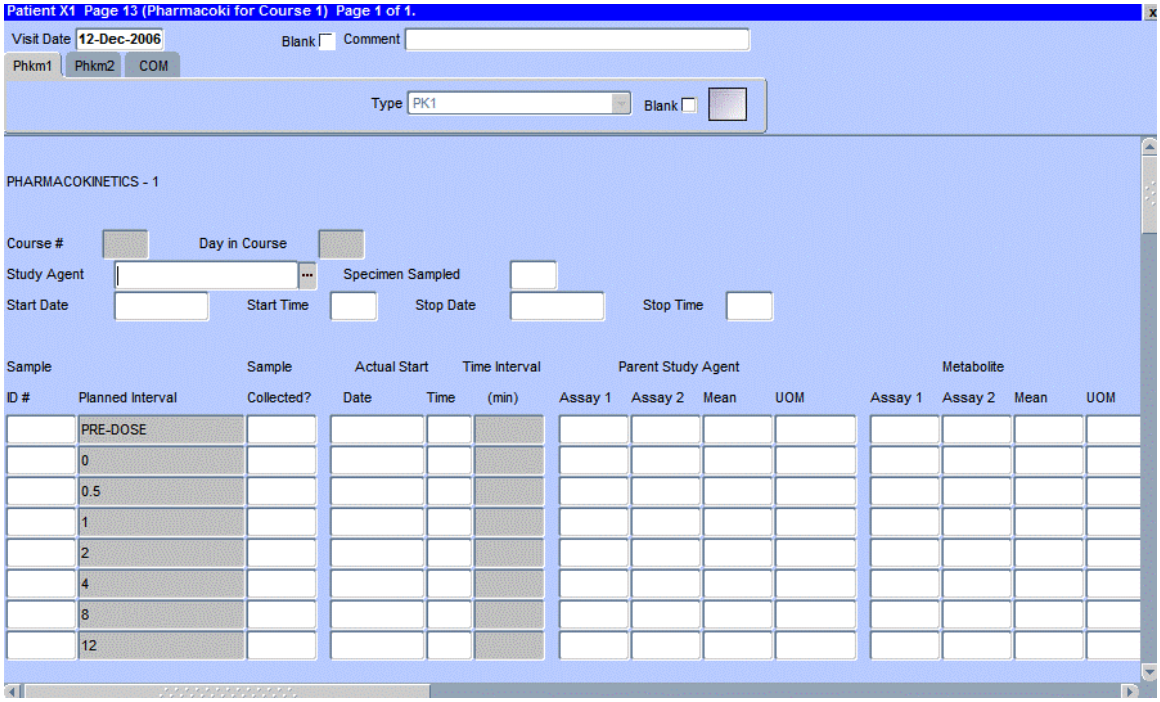
(OFF-TREATMENT)

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.	6 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 informed consent signed.	Start Date must be after the Enrollment Date of informed consent signed.
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.
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. Note: Study Medications with the following routes are ignored: PO, CIV and Topical.	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.

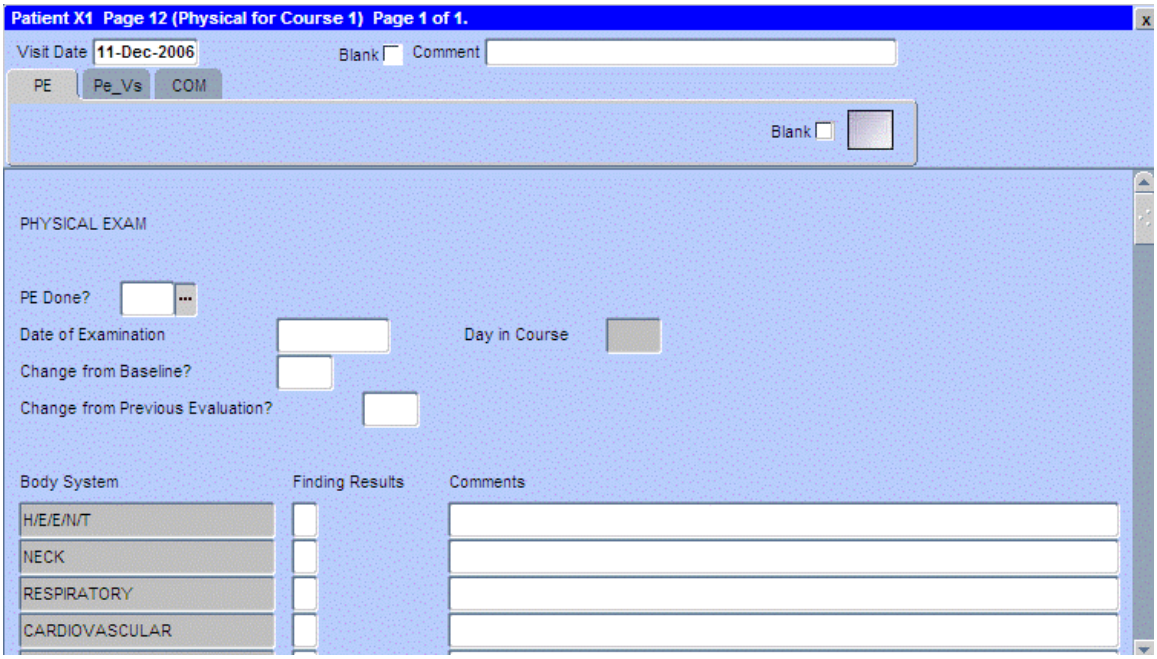
(PHARMACOKINETICS)

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)

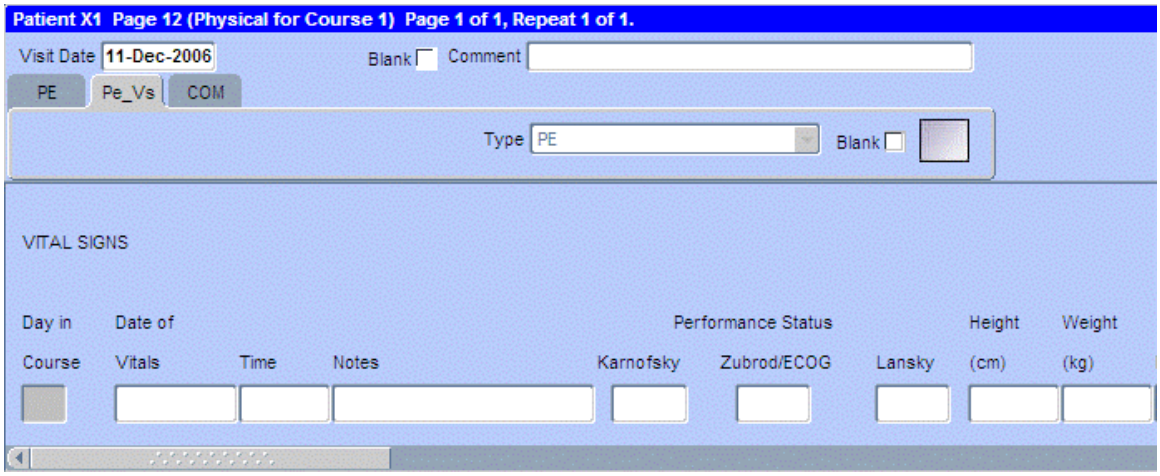
Validations		
Code	**Description**	**Resolution**
PE01	Finding Results is marked abnormal and a comment is not specified.	Enter a comment or change the Finding Results.
PE03	Finding Results has changed from baseline (either from N to A or A to N or X to A), but comment is missing.	Review the Finding 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.

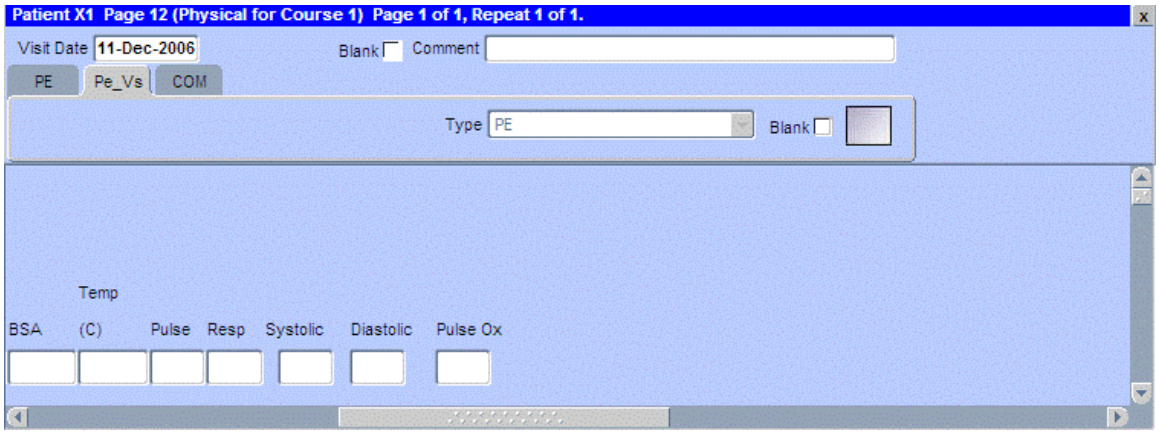
Physical Exams – Courses (cont'd)

Physical Exams - Courses eCRF

Vital Signs tab



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

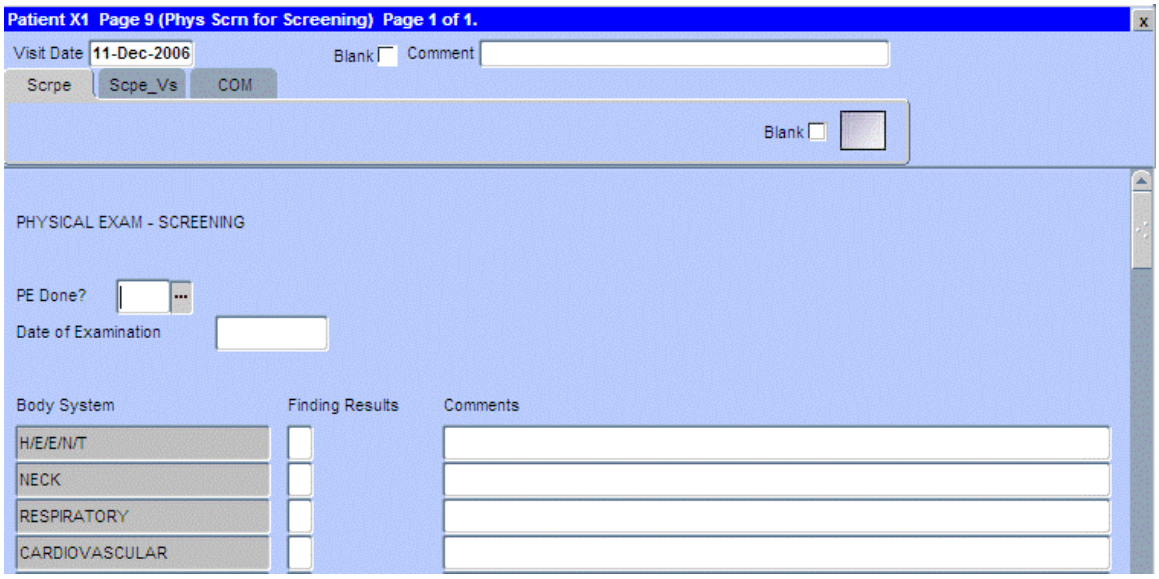
(PHYSICAL-EXAMS-COURSES)

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.		

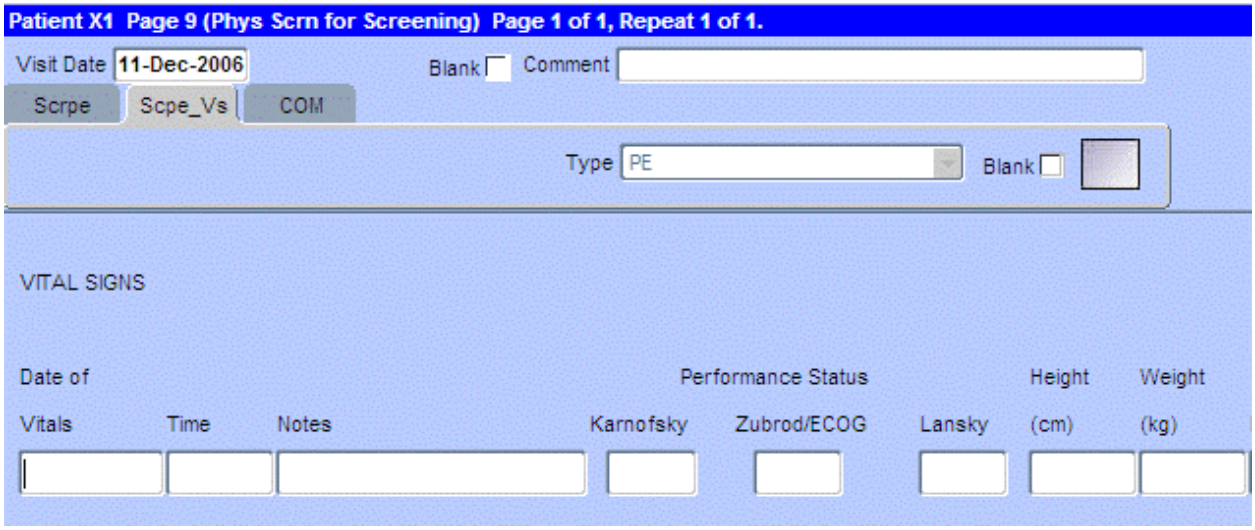
Physical Exams - Screening (cont'd)

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.

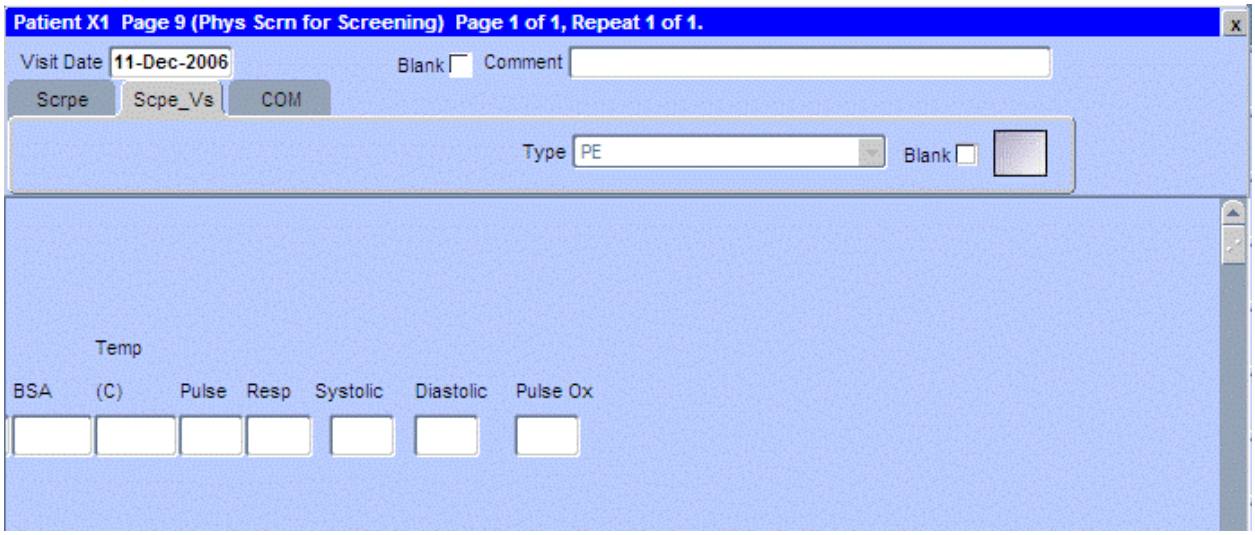
Physical Exams - Screening (cont'd)

Physical Exams - Screening eCRF

Vital Signs tab



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



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.
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
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
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.

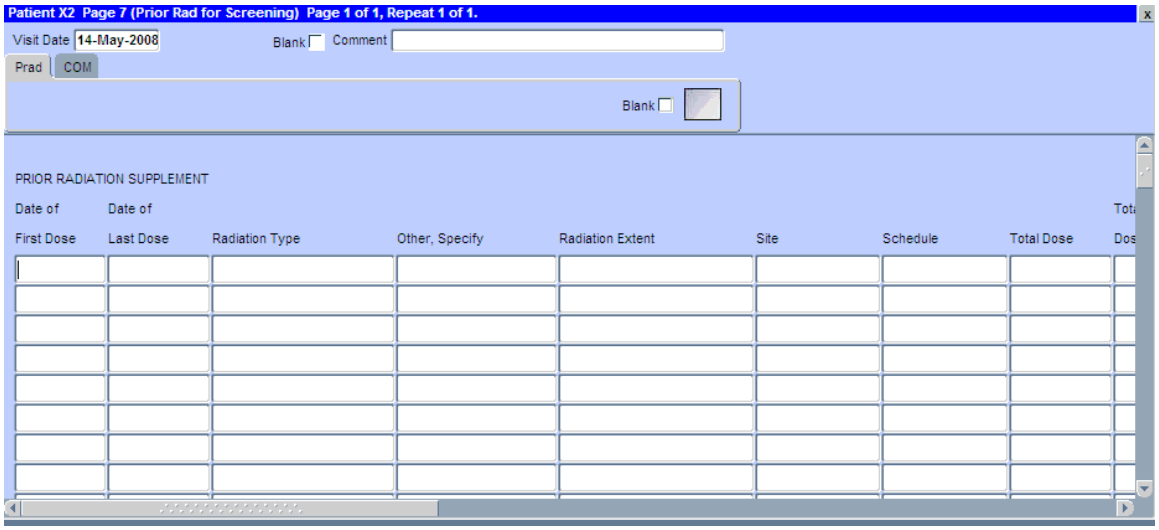
(PHYSICAL-EXAMS-SCREENING)

Prior Radiation Supplement

Purpose

Record details of prior radiation therapy related to the disease being studies 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.
Other, Specify	Enter an explanation when 'Other, Specify' is selected as a 'Radiation Type'	100 Characters
Radiation Extent (m) ...	Select the extent of the radiation therapy as follows: 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

Prior Radiation Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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
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.
PRD05	Prior Radiation Type 'Other Specify' and 'Other, Specify' field are not present together.	Enter 'Other Specify' if 'Other Specify' is selected as Prior Radiation Type.

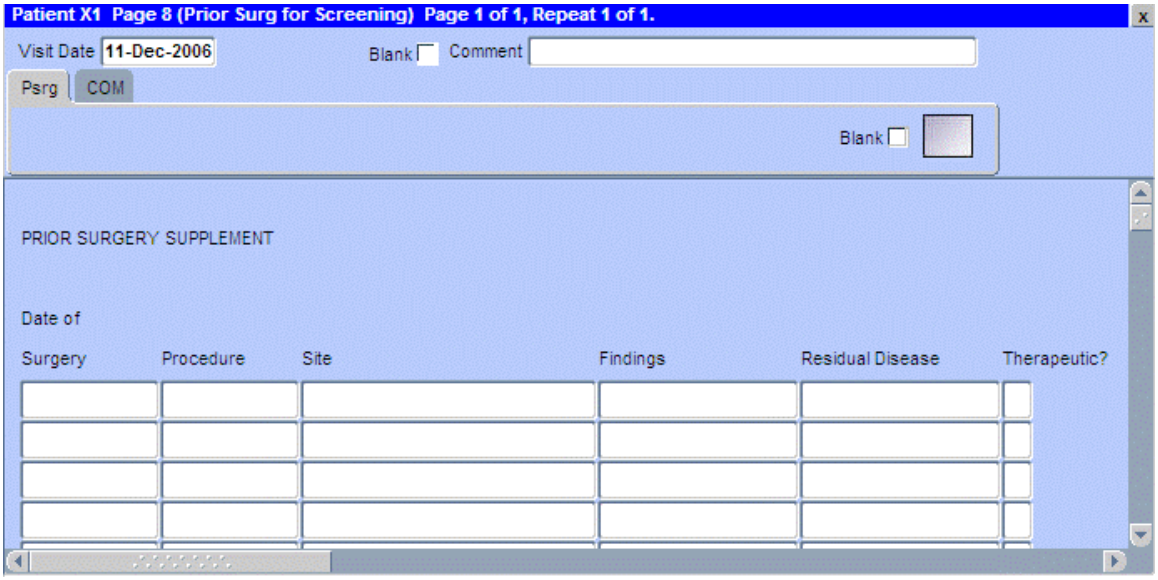
(PRIOR-RADIATION-SUPPLEMENT)

Prior Surgery Supplement

Purpose

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

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 is not known.	DD-MMM-YYYY or 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).	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.		

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.

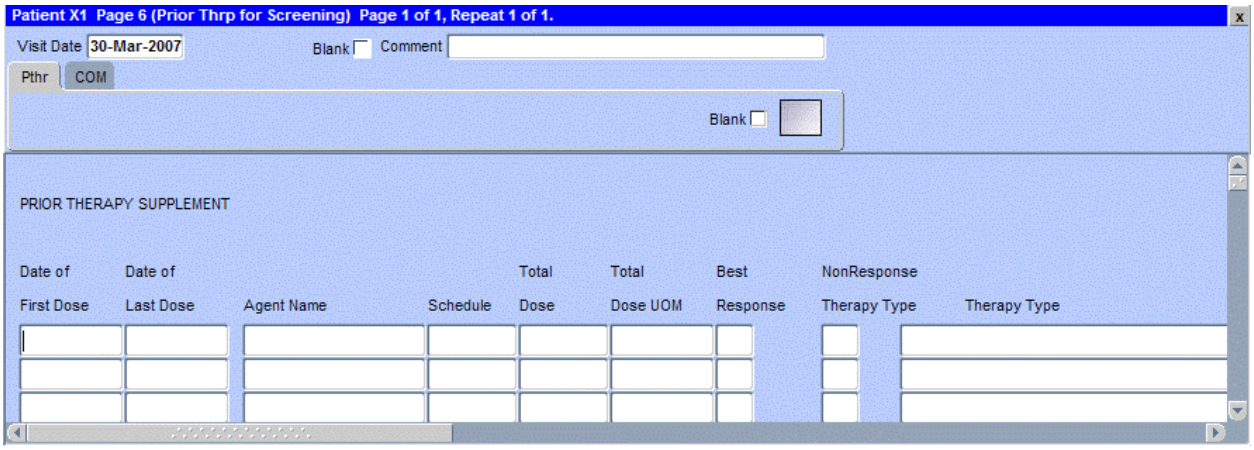
(PRIOR-SURGERY-SUPPLEMENT)

Prior Therapy Supplement

Purpose

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

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
Agent Name ▪▪▪	Select the generic name of the agent that was used. *Note: For standard regimen (multiple agents given as one regimen), enter one record for each agent.*	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
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.

Prior Therapy Supplement (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
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.
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.

(PRIOR-THERAPY-SUPPLEMENT)

Prior Treatment Summary

Purpose

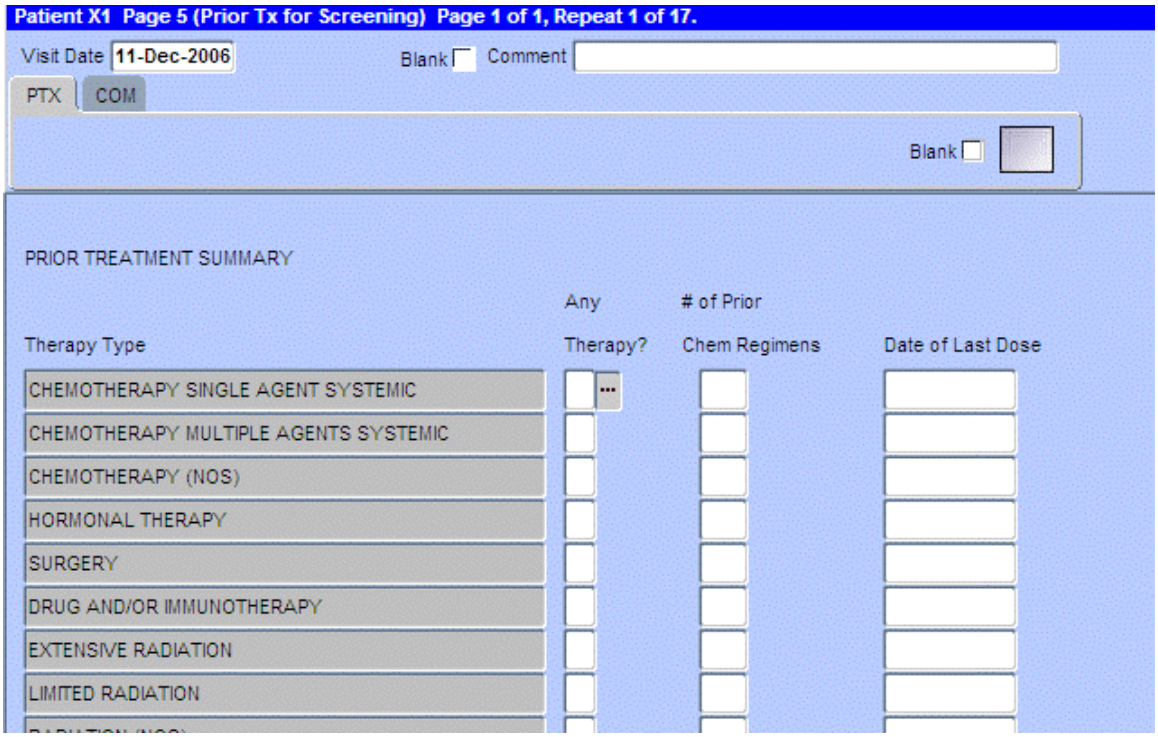
Record whether or not the patient has received any treatments for each of the prior therapy types listed that are related to the disease being studies by the protocol.

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 Chemotherapy Regimens (u) (m)	Enter the number of prior regimes received for chemotherapies types of therapy. Do not use for other types of therapy.. *Note: This field is only mandatory for studies that report data to CDS.*	2 digits

Prior Treatment Summary (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Date of Last Dose	Enter the date of the last dose of the most recent prior treatment regimen for each therapy type. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received and "Ongoing" will be reported to CTMS or CDS. For combination therapies, record the date of the last dose of medication for the combination.	DD-MMM-YYYY or MMM-YYYY
Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only, (u) for CDS reporting only.		

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 CDS)	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.

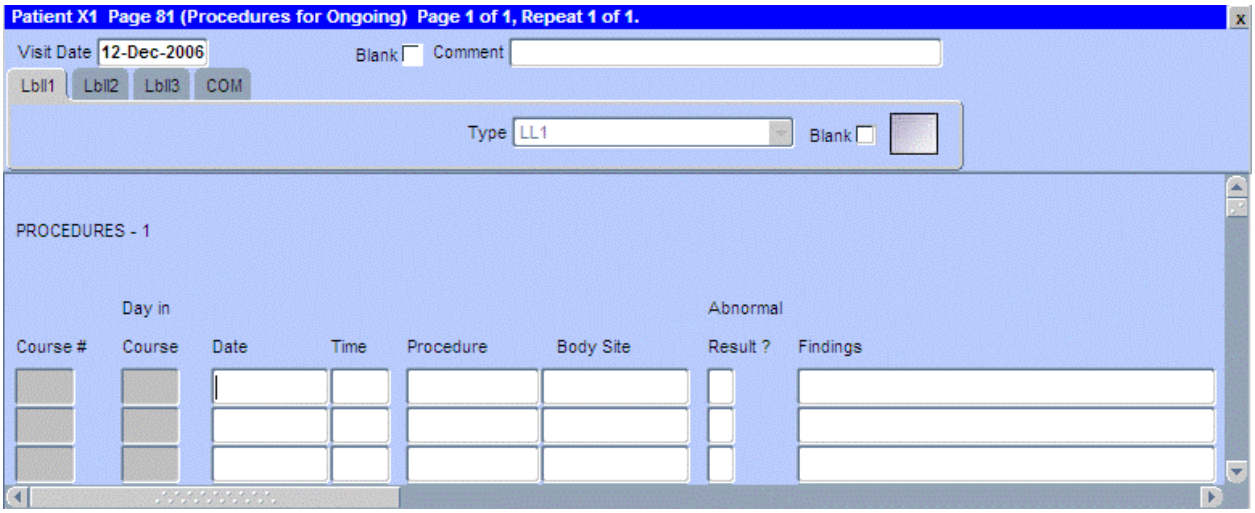
(PRIOR-TREATMENT-SUMMARY)

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.

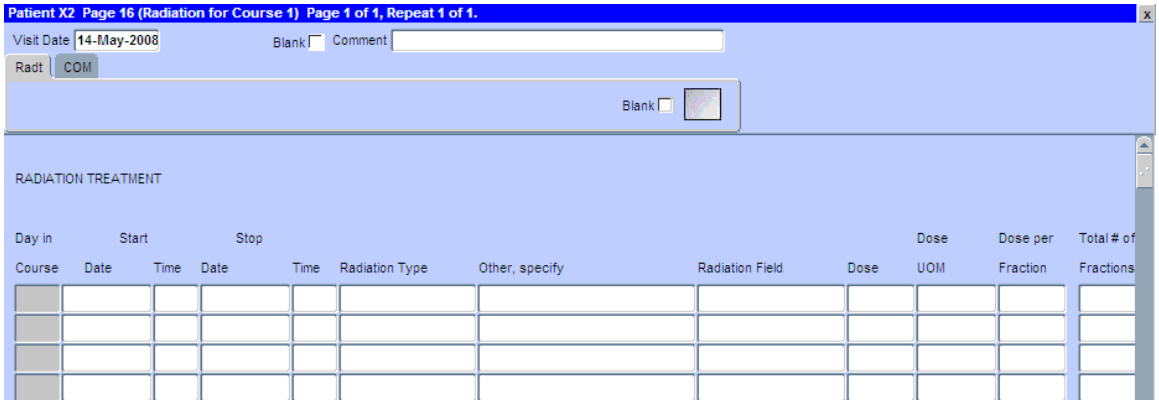
(PROCEDURES)

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.
Other, Specify	Enter an explanation when 'Other, Specify' is selected as a 'Radiation Type'	100 character
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

Radiation (cont'd)

Field Descriptions and Instructions		
Field Name	**Description / Instructions**	**Format**
Tx Delivery Location ...	Select the institute where the radiation therapy was administered.	Use pick list.
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.
RAD04	Radiation Type 'Other Specify' and 'Other, Specify' field are not present together.	Enter 'Other Specify' if 'Other Specify' is selected as Radiation Type.

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

(RADIATION)

Study Medication Administration

Purpose

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

Oral daily agent:
Enter the start date of the cycle and then enter the date of last dose in the stop date field of the cycle. Note: start and stop times are not necessary for oral agents.

If the daily dosing is interrupted, enter the stop date, and on another line enter the start date if resumed during the same cycle. Enter the missed doses on the Missed Dose eCRF.

Agent administers on Days 1-5 weekly every 28 days
Enter four lines, one for each consecutive weekly doing.

If the daily dosing is interrupted, enter the stop date, and on another line enter the start date if resumed during the same cycle. Enter the missed doses on the Missed Dose eCRF.

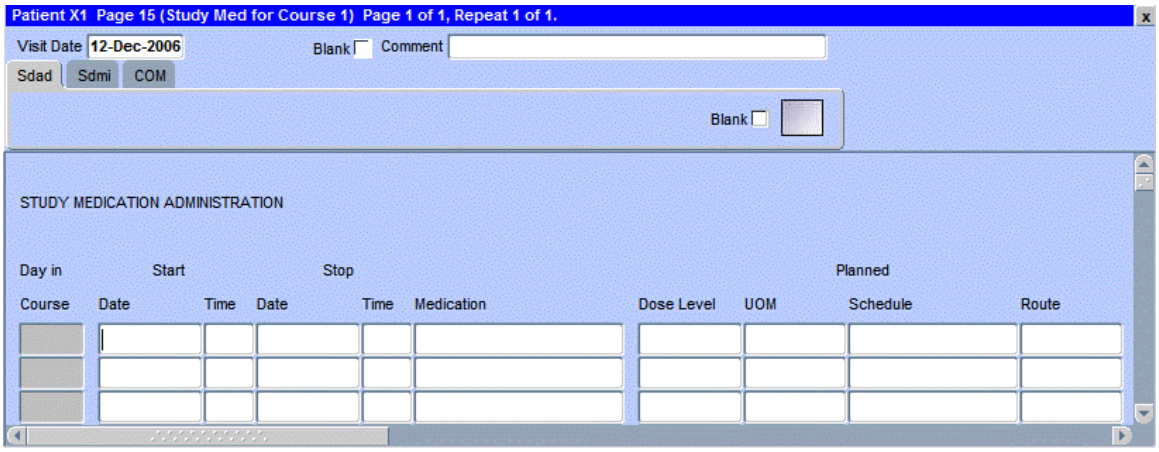
Agent administer on Days 1, 3, 5 every 21 days
Three line entries are required

Continuous IV administration >24 hours
Enter start date and time of the infusion and when the infusion is completed (e.g., after 72 hours), enter the stop date and time.

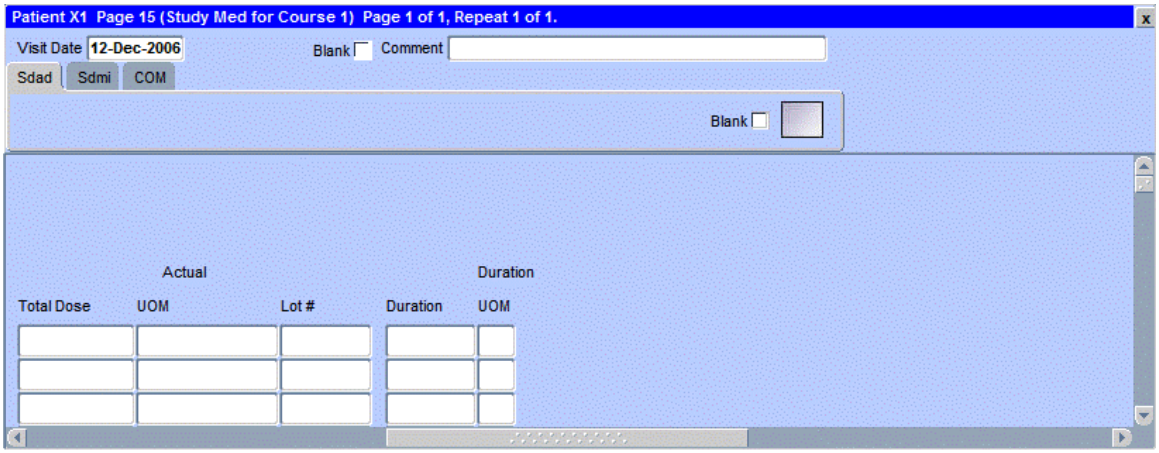
Two IV agents are administer, one on Day 1 and the other on Days 1 and 15
Enter the two agents on separate lines for Day 1 and then on the third line, enter the Day 15 administration of the second drug.

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 x 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 digits & 3 decimals
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 digits & 3 decimals

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

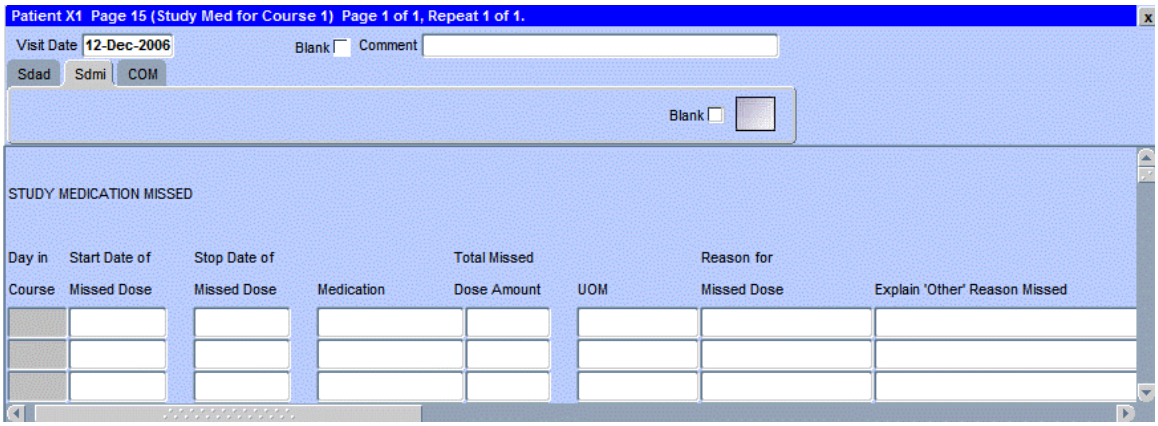
To record study medications that were intended to be taken by the patient, but were missed.

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**
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.

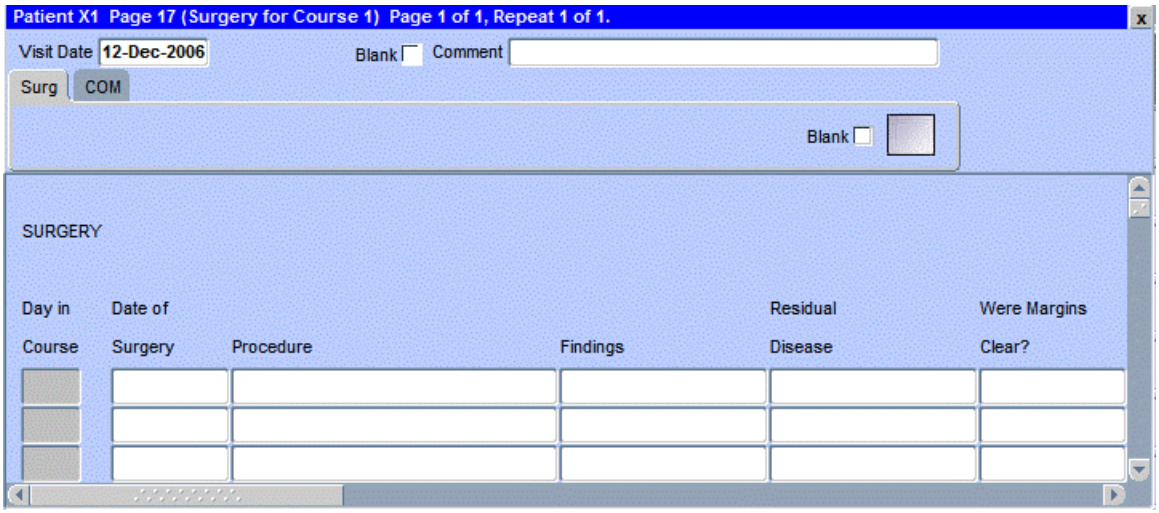
(STUDY-MEDICATION-ADMINISTRATION)

Surgery

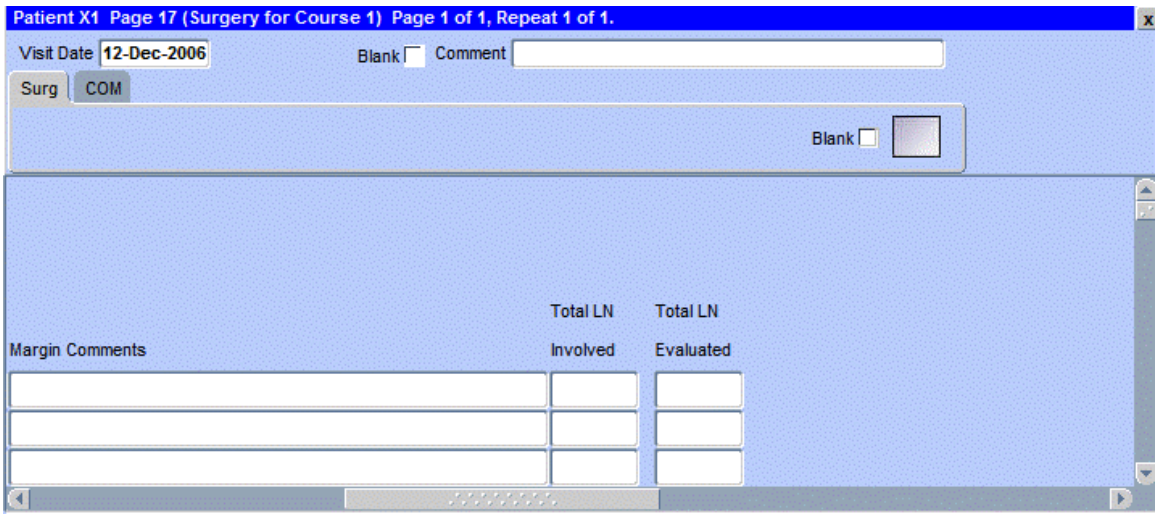
Purpose

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)

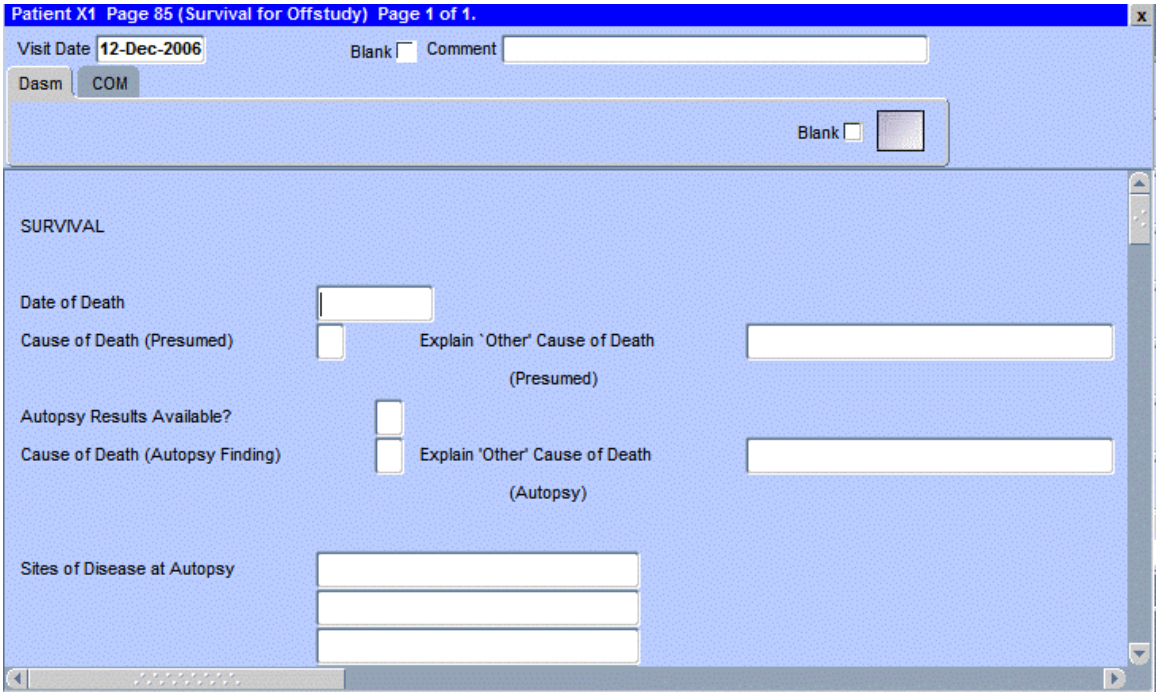
Survival

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.
SUR08	Date of Death is greater than 30 days past Off Study Date.	Survival eCRF is not applicable as patient is off study.

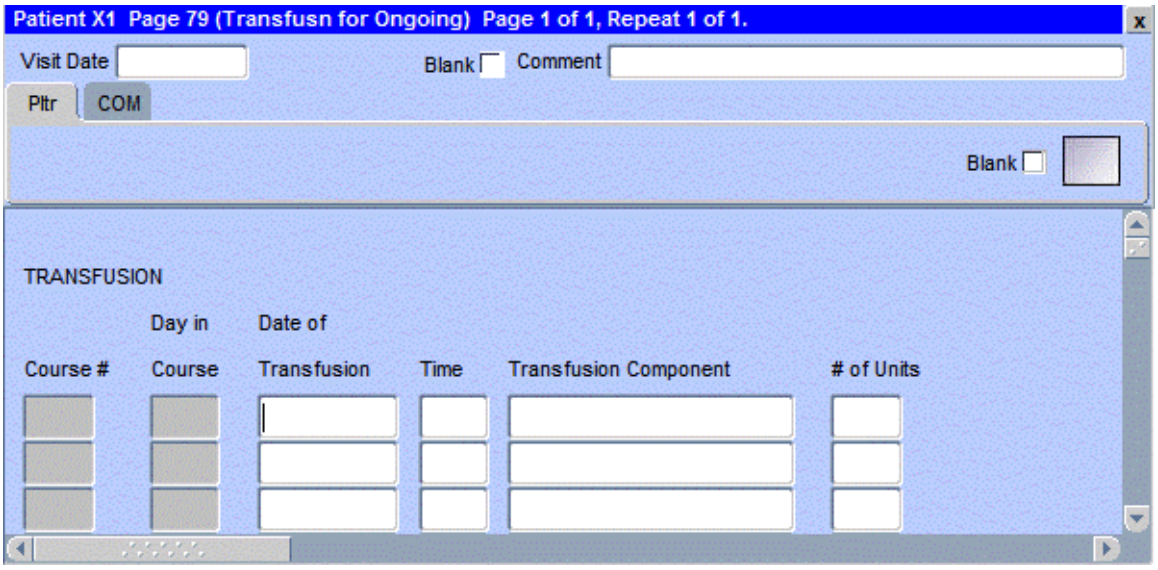
(SURVIVAL)

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)

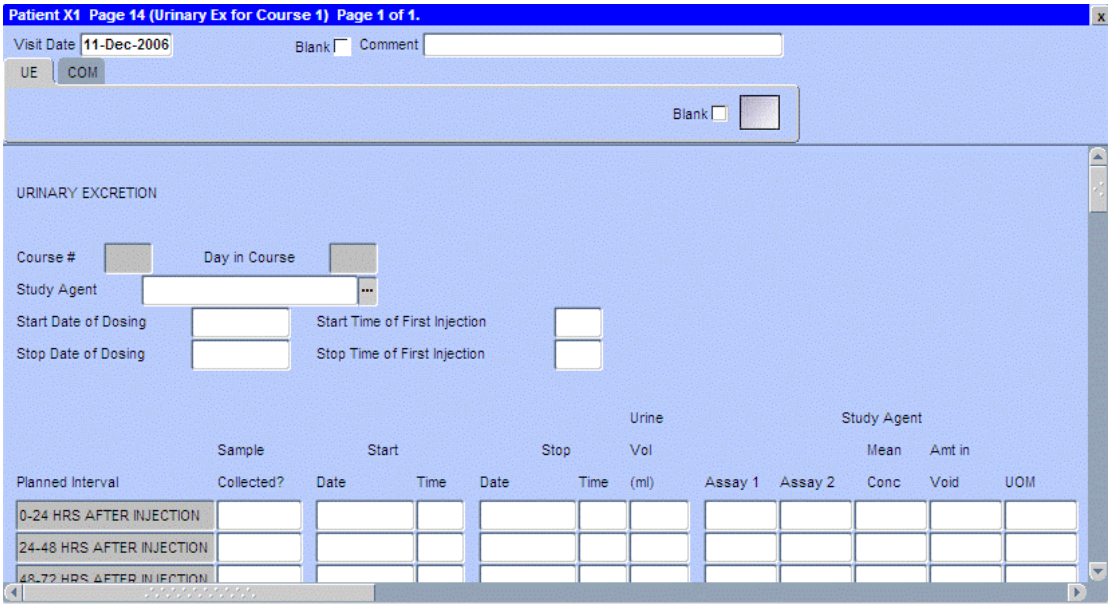
Urinary Excretions

Purpose

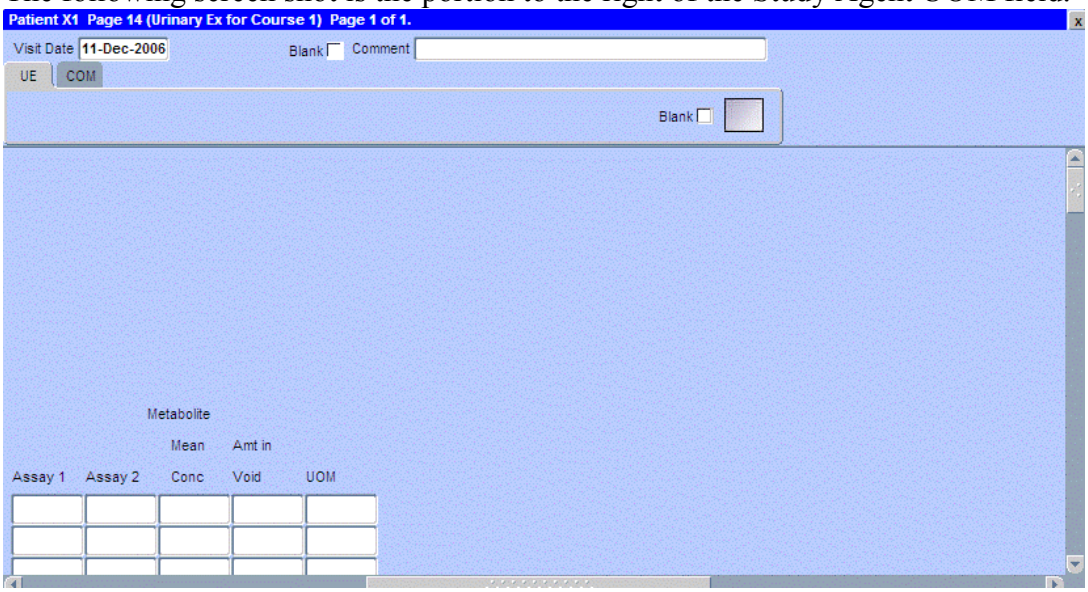
Record detailed information about the collection of urine samples for analysis of the presence and quantity of the study medication and/or its metabolites.

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.
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)

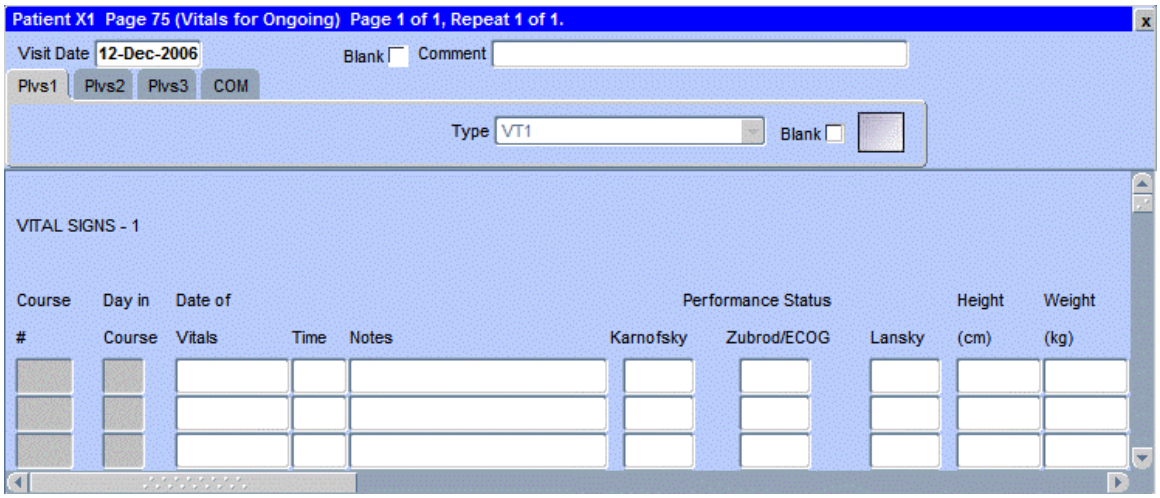
Vital Signs

Purpose

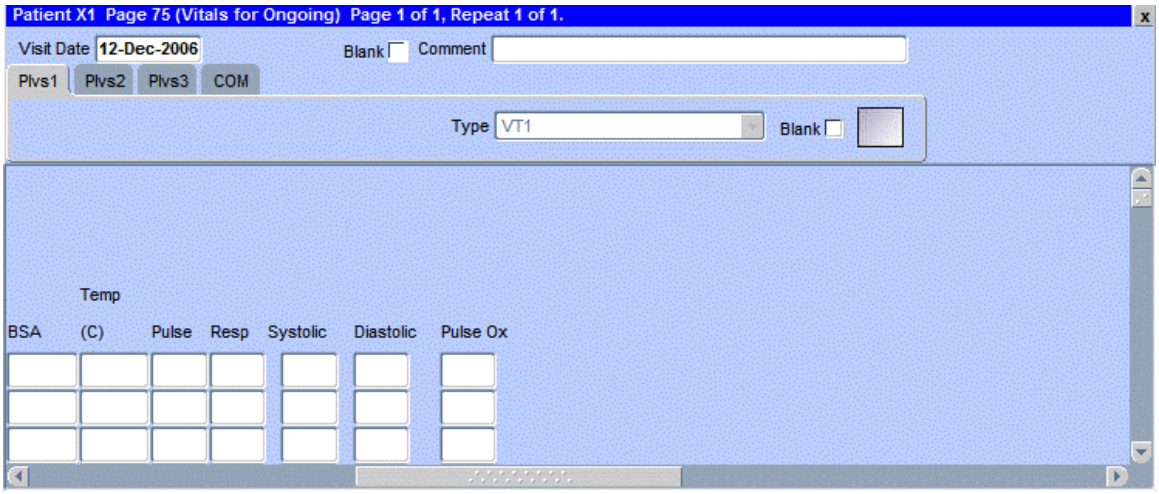
Record the patient's Vital Signs while on study. Please note that if Vital Signs are taken as a part of protocol specific Physical Exam, record those Vital Signs on the Physical Exam eCRF.

Note: This eCRF is mandatory for all CTEP sponsored CTMS monitored studies.

Vital Signs eCRF



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



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.
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
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

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: $BSA(m^2) = \sqrt{\frac{Height\ (cm)\ x\ Weight\ (kg)}{3600}}$	5 digit and 3 decimals
Temperature	Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors.	3 digits and 1 decimal
Pulse	Enter the patient's pulse rate.	3 digits
Respiration Rate	Enter the patient's respiration rate.	3 digits
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

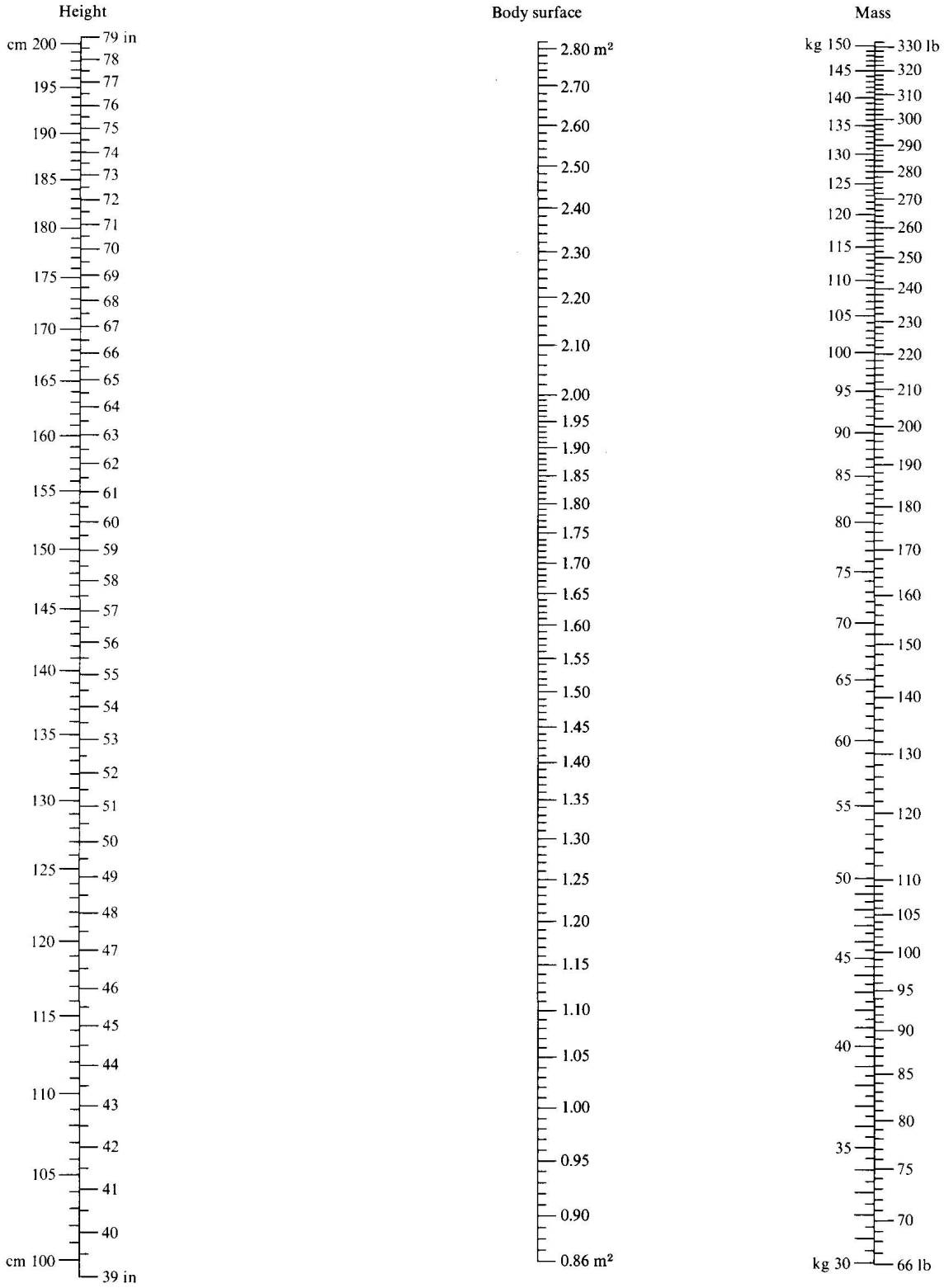
Appendix I - Conversion Tables (cont'd)

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.		

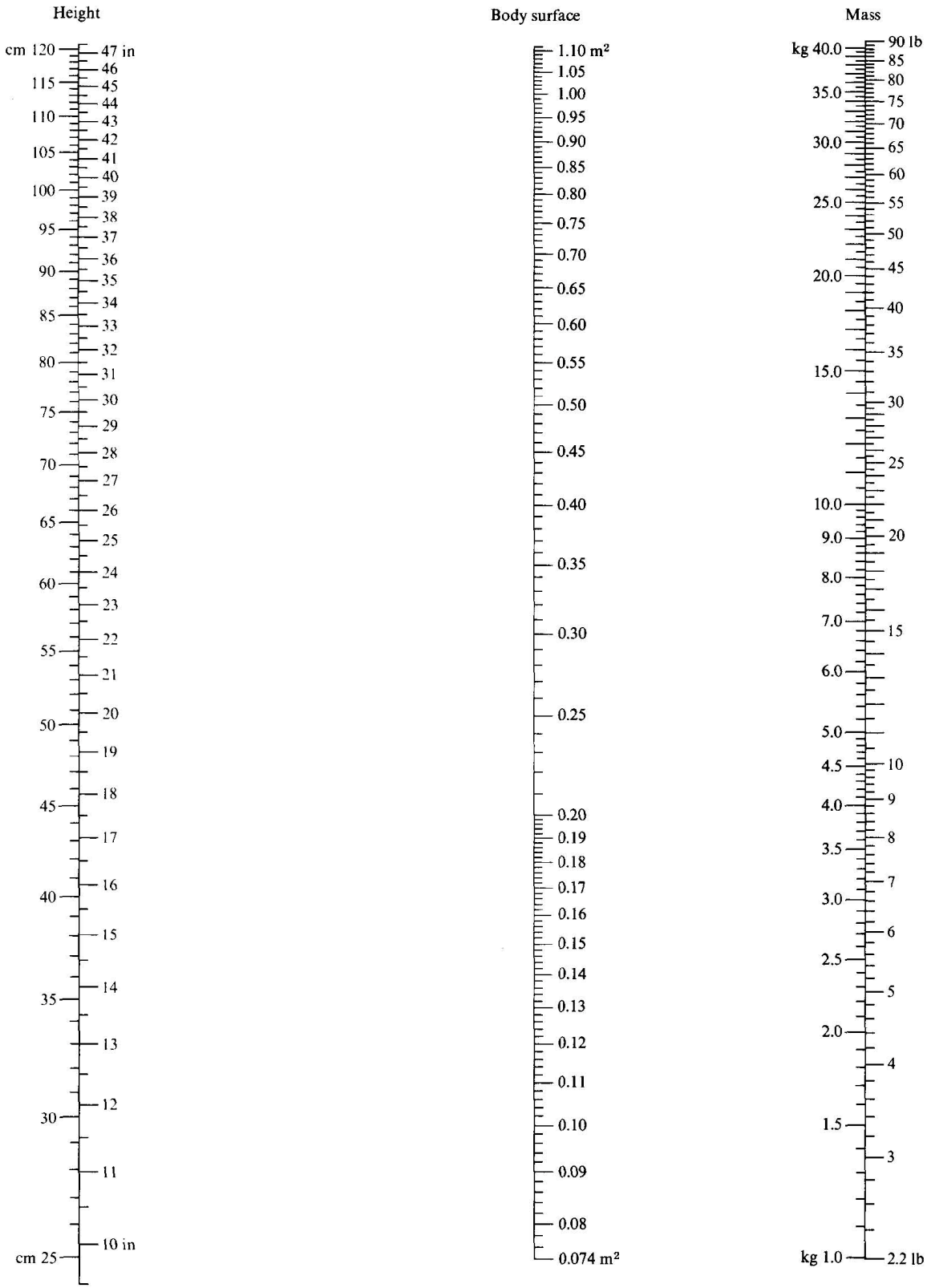
Appendix I - Conversion Tables (cont'd)

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

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/

Appendix II - Useful References (cont'd)

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/
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
CDS 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

Appendix II - Useful References (cont'd)

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_instr.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/

Appendix III

Lab Panels

Appendix III – Lab Panels (cont'd)

BLOOD CHEMISTRIES	
Lab Test	**Intent**
SODIUM_SER	Sodium, Serum
POTASSIUM_SER	Potassium, Serum
CHLORIDE_SER	Chloride, Serum
GLUCOSE_SER	Glucose, Serum
BICARB_SER	Bicarbonate, Serum
GLUCOSE_FAST_SER	Glucose, Fasting, Serum
GLUCOSE_NONFAST_SER	Glucose, Non-fasting, Serum
BUN_SER	Blood Urea Nitrogen (BUN), Serum
ALBUMIN_SER	Albumin, Serum
CALCIUM_SER	Calcium, Serum
MAGNESIUM_SER	Magnesium, Serum
PHOSPHATE_SER	Phosphate (inorganic Phosphorus), Serum
ALK_PHOS_SER	Alkaline Phosphatase, Serum
ALT_SGPT_SER	Alanine Aminostransferase (ALT or SGPT)
AST_SGOT_SER	Aspartate Aminotransferase (AST or SGOT), Serum
BILIRUB_TTL_SER	Bilirubin, Total, Serum
BILIRUB_DIR_SER	Bilirubin, Direct, Serum
LDH_SER	Lactate Dehydrogenase (LDH), Serum
CK_SER	Creatinine Kinase (CK), Serum
URATE_SER	Urate (Uric Acid), Serum
CREATININE_SER	Creatinine, Serum
TTL_PROTEIN_SER	Total Protein, Serum

Appendix III – Lab Panels (cont'd)

BLOOD GASES	
Lab Test	**Intent**
PH_BLDART	pH, Arterial Blood
PCO2_BLDART	Percent Carbon Dioxide (pCO2), Arterial Blood
PO2_BLDART	Percent Oxygen (pO2), Arterial Blood
HCO3_BLDART	Bicarbonate (HCO3), Arterial Blood
COHGB_BLDART	Carboxyhemoglobin, Arterial Blood

BONE MARROW	
Lab Test	**Intent**
PROMYELOCYTE_PC_MAR	Promyelocytes, %, Bone Marrow
MYELOCYTE_PC_MAR	Myelocytes, %, Bone Marrow
METAMYELOCYTE_PC_MAR	Metamyelocytes, %, Bone Marrow
LYMPH_PC_MAR	Lymphocytes, %, Bone Marrow
MONO_PC_MAR	Monocytes, %, Bone Marrow
PLASMA_CELL_PC_MAR	Plasma Cells, %, Bone Marrow
M_RATING_MAR	FAB Marrow Rating, Bone Marrow
RETIC_PC_MAR	Reticulocytes, %, Bone Marrow
MEGAKARYOCYTE_PC_MAR	Megakaryocytes, %, Bone Marrow

CHIMERISM LAB	
Lab Test	**Intent**
STR_C_DON_PC_BM	Nonseparated Short Tandem Repeat Chimerism, Donor, %, Bone Marrow
STR_C_D1_CD14_PC_BLD	Short Tandem Repeat Chimerism, Donor 1, Clusters of Differentiation 14 (CD14), %, Whole Blood
STR_C_D2_CD14_PC_BLD	Short Tandem Repeat Chimerism, Donor 2, Clusters of Differentiation 14 (CD14), %, Whole Blood
STR_C_R_CD14_PC_BLD	Short Tandem Repeat Chimerism, Recipient, Clusters of Differentiation 14 (CD14), %, Whole Blood

Appendix III – Lab Panels (cont'd)

CHIMERISM LAB	
Lab Test	**Intent**
STR_C_D1_CD19_PC_BLD	Short Tandem Repeat Chimerism, Donor 1, Clusters of Differentiation 19 (CD19), %, Whole Blood
STR_C_D2_CD19_PC_BLD	Short Tandem Repeat Chimerism, Donor 2, Clusters of Differentiation 19 (CD19), %, Whole Blood
STR_C_R_CD19_PC_BLD	Short Tandem Repeat Chimerism, Recipient, Clusters of Differentiation 19 (CD19), %, Whole Blood
STR_C_D1_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor 1, Dual Cord, %, Whole Blood
STR_C_D2_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor2, Dual Cord, %, Whole Blood
STR_C_R_DC_PC_BLD	Short Tandem Repeat Chimerism, Recipient, Dual Cord, %, Whole Blood
STR_C_1M_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor 1 Myeloid, Dual Cord, %, Whole Blood
STR_C_2M_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor 2 Myeloid, Dual Cord, %, Whole Blood
STR_C_RM_DC_PC_BLD	Short Tandem Repeat Chimerism, Recipient Myeloid, Dual Cord, %, Whole Blood
STR_C_1NK_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor 1, Natural Killers, Dual Cord, %, Whole Blood
STR_C_2NK_DC_PC_BLD	Short Tandem Repeat Chimerism, Donor 2, Natural Killers, Dual Cord, %, Whole Blood
STR_C_RNK_DC_PC_BLD	Short Tandem Repeat Chimerism, Recipient, Natural Killers, Dual Cord, %, Whole Blood
STR_CHI_MDONR_PC_BM	Short Tandem Repeat Chimerism, Multiple Donor, %, Bone Marrow
STR_C_MDON1_PC_BM	Short Tandem Repeat Chimerism, Multiple Donor 1, %, Bone Marrow
STR_C_MDON2_PC_BM	Short Tandem Repeat Chimerism, Multiple Donor 2, %, Bone Marrow
STR_CHI_MDONR_PC_OS	Short Tandem Repeat Chimerism, Multiple Donor, %, Other Source

Appendix III – Lab Panels (cont'd)

CHIMERISM LAB	
Lab Test	**Intent**
STR_C_MDON1_PC_OS	Short Tandem Repeat Chimerism, Multiple Donor 1, %, Other Source
STR_C_MDON2_PC_OS	Short Tandem Repeat Chimerism, Multiple Donor 2, %, Other Source
STR_CHI_PC_OS	Short Tandem Repeat Chimerism, %, Other Source
STR_C_MDON1_PC_WBC	Short Tandem Repeat Chimerism, Multiple Donor 1, %, White Blood Cells
STR_C_MDON2_PC_WBC	Short Tandem Repeat Chimerism, Multiple Donor 2, %, White Blood Cells
STR_CHI_MDONR_PC_BLD	Short Tandem Repeat Chimerism, Multiple Donor, %, Whole Blood
STR_C_MD_D1M_PC_WBC	Short Tandem Repeat Chimerism, Multiple Donor, Donor 1 %, White Blood Cells
STR_C_MD_D2M_PC_WBC	Short Tandem Repeat Chimerism, Multiple Donor, Donor 2 %, White Blood Cells
STR_C_MD_R_PC_WBC	Short Tandem Repeat Chimerism, Multiple Donor, Recipient %, White Blood Cells
STR_C_MD_D1_PC_BLD	Short Tandem Repeat Chimerism, Multiple Donor 1 %, Whole Blood
STR_C_MD_D2_PC_BLD	Short Tandem Repeat Chimerism, Multiple Donor 2 %, Whole Blood
STR_C_D1_NK_PC_BLD	Short Tandem Repeat Chimerism, Donor 1, Natural Killers, %, Whole Blood
STR_C_D2_NK_PC_BLD	Short Tandem Repeat Chimerism, Donor 2, Natural Killers, %, Whole Blood
STR_C_R_NK_PC_BLD	Short Tandem Repeat Chimerism, Recipient Natural Killers, %, Whole Blood
STR_C_PC_OS_1	Short Tandem Repeat Chimerism, %, Donor Other Source 1
STR_C_PC_OS_2	Short Tandem Repeat Chimerism, %, Donor Other Source 2
STR_C_PC_WBC	Short Tandem Repeat Chimerism, %, Locus, White Blood Cells

Appendix III – Lab Panels (cont'd)

CHIMERISM LAB	
Lab Test	**Intent**
STR_C_D_CD3_PC_WBC	Short Tandem Repeat Chimerism, Donor CD3 %, White Blood Cells
STR_C_D_M_PC_WBC	Short Tandem Repeat Chimerism, %, Donor Myeloid, White Blood Cells
STR_C_DON_PC_BLD	Nonseparated Short Tandem Repeat Chimerism, %, Donor, Whole Blood
STR_CHI_PC_BLD	Nonseparated Short Tandem Repeat Chimerism, %, Whole Blood
STR_CHI_PC_BM	Nonseparated Short Tandem Repeat Chimerism, %, Bone Marrow

COAGULATION	
Lab Test	**Intent**
PT_BLD	Prothrombin Time (PT), Blood
PTT_BLD	Partial Thromboplastin Time (PTT), Blood
INR_PT_BLD	International Normalized Ratio (INR), Prothrombin Time, Blood
FIBRINOGEN_BLD	Fibrinogen, Blood
THROMBIN_TM_BLD	Thrombin Time, Blood

CSF	
Lab Test	**Intent**
WBC_NUM_CSF	White Blood Cells (WBC), #, Cerebrospinal Fluid
RBC_NUM_CSF	Red Blood Cells (RBC), #, 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

Appendix III – Lab Panels (cont'd)

CSF	
Lab Test	**Intent**
APPEAR_CSF	Appearance, Cerebrospinal Fluid

HEMATOLOGY	
Lab Test	**Intent**
WBC_NUM_BLD	White Blood Cells (WBC), #, Blood
RBC_NUM_BLD	Red Blood Cells (RBC), #, Blood
HGB_BLD	Hemoglobin, Blood
HCT_BLD	Hematocrit, %, Blood
MCV_RBC	Mean Corpuscular Volume (MCV), Red Blood Cells
MCHC_RBC	Mean Corpuscular Hemoglobin Concentration (MCHC), Red Blood Cells
MCH_RBC	Mean Corpuscular Hemoglobin (MCH), Red Blood Cells
RDW_RBC	Red Cell Distribution Width (RDW), Red Blood Cells
PLATELET_BLD	Platelets, Blood
NRBC_NUM_BLD	Nucleated Red Blood Cells (NRBC), #, Blood
NEUT_PC_BLD	Neutrophils, %, Blood
BAND_PC_BLD	Neutrophil Bands, %, Blood
LYMPH_PC_BLD	Lymphocytes, %, Blood
MONO_PC_BLD	Monocytes, %, Blood
EOSINOPHIL_PC_BLD	Eosinophils, %, Blood
BASO_PC_BLD	Basophils, %, Blood
ANC_BLD	Absolute Neutrophil Count (ANC), Blood
BANDS_NUM_BLD	Neutrophil Bands, #, Blood
LYMPH_NUM_BLD	Lymphocytes, #, Blood
MONO_NUM_BLD	Monocytes, #, Blood
EOSINOPHIL_NUM_BLD	Eosinophils, #, Blood
BASO_NUM_BLD	Basophils, #, Blood

Appendix III – Lab Panels (cont'd)

HEMATOLOGY	
Lab Test	**Intent**
RETIC_PC_RBC	Reticulocytes, %, Red Blood Cells
PMV_BLD	Platelet Mean Volume (PMV), Blood

LYMPHOCYTE PHENOTYPE	
Lab Test	**Intent**
CD3_PC_FC_BLD	CD3 Cells, %, Flow Cytometry, Blood
CD3_NUM_BLD	CD3 Cells, #, Blood
CD4_CD3_PC_BLD	CD4 Cells to CD3 Cells, %, Blood
CD4_CD3_NUM_BLD	CD4 Cells to CD3 Cells, #, Blood
CD4_CD8_RTO_BLD	CD4 Cells to CD8 Cells Ratio, Blood
CD4_PC_FC_BLD	CD4 Cells, %, Flow Cytometry, Blood
CD4_NUM_BLD	CD4 Cells, #, Blood
CD8_PC_FC_BLD	CD8 Cells, %, Flow Cytometry, Blood
CD8_NUM_BLD	CD8 Cells, #, Blood
CD19_CELLS_PC_BLD	CD19 Cells, %, Blood
CD19_CELLS_NUM_BLD	CD19 Cells, #, Blood
NK_PC_BLD	Natural Killer (NK) Cells, %, Blood
NK_NUM_BLD	Natural Killer (NK) Cells, #, Blood

OTHER SERUM CHEMISTRIES	
Lab Test	**Intent**
CALCIUM_IONIZED_SER	Calcium, Ionized, Serum
FERRITIN_SER	Ferritin, Serum
HDLC_SER	High Density Lipoprotein, Cholesterol, Serum
INSULIN_SER	Insulin, Serum
IRON_SER	Iron, Serum
IRON_SATN_RTO_SER	Iron Saturation, Ratio, Serum

Appendix III – Lab Panels (cont'd)

OTHER SERUM CHEMISTRIES	
Lab Test	**Intent**
LDLC_SER	Low Density Lipoproteins, Cholesterol, Serum
LIPASE_SER	Lipase, Serum
AMYLASE_SER	Amylase, Serum
HAPTOGLOB_SER	Haptoglobin, Serum
OSMOLALITY_SER	Osmolality, Serum
ACP_SER	Acid Phosphatase (ACP), Serum
TRANSFERRIN_SER	Transferrin, Serum
TRIGLY_SER	Triglycerides, Serum
T3_SER	Triiodothyronine (T3), Serum
T4_SER	Thyroxine (T4), Serum
TSH_SER	Thyrotropin (Thyroid Stimulating Hormone or TSH), Serum
CHOLEST_SER	Cholesterol, Serum
CHOLESTANOL_SER	Cholestanol, Serum
BETA2_MICRGLOB_SER	Beta-2 Microglobulin, Serum
HGB_A1C_BLD	Hemoglobin (Hgb) A1C, Blood
GGT_SER	Gamma Glutamyl Transferase (GGT), Serum

OTHER URINARY RESULTS	
Lab Test	**Intent**
CALCIUM_24H_UR	Calcium, 24 hour, Urine
CHLORIDE_24H_UR	Chloride, 24 hour, Urine
OSMOLALITY_24H_UR	Osmolality, 24 hour, Urine
POTASSIUM_24H_UR	Potassium, 24 hour, Urine
SODIUM_24H_UR	Sodium, 24 hour, Urine
URATE_24H_UR	Uric Acid (Urate), 24 hour, Urine
CREATININE_CL24H_UR	Creatinine Clearance, 24 hour, Urine

Appendix III – Lab Panels (cont'd)

OTHER URINARY RESULTS	
Lab Test	**Intent**
CREATININE_UR	Creatinine, Spot or Timed Sample, Urine
PROTEIN_24H_UR	Protein, 24 hour, Urine
PROTEIN_EXC_24H_UR	Protein excretion, 24 hour, Urine
BHCG_PREG_UR	Beta Choriogonadotropin (BHCG), or Pregnancy Test, Spot Urine
VOLUME_UR	Volume, Urine

RESPIRATIORY FUNCTIONS	
Lab Test	**Intent**
VC_RESYS	Vital Capacity (VC), Respiratory System
EXP_VOL_RESYS	Expiratory Volume, Respiratory System
MAX_C_RESYS	Forced Vital Capacity (Maximum), Respiratory System
VOL_RES_RESYS	Volume Residual, Respiratory System
FUNCT_RES_C_RESYS	Functional Residual Capacity, Respiratory System
DIFFUS_CAP_RESYS	Diffusion Capacity, Respiratory System
DIFF_CAP_PRED_RESYS	Diffusing Capacity % Predicted, Respiratory System
MAX_FXP_FLOW_RESYS	Maximum Forced Expiratory Flow, Respiratory System
FEV1_RESYS	Forced Expiratory Volume, Respiratory System
FEV1_PRED_RESYS	Forced Expiratory Volume % Predicted, Respiratory System
FVC_RESYS	Forced Vital Capacity (FVC), Respiratory System
FVC_PRED_RESYS	Forced Vital Capacity (FVC) % Predicted, Respiratory System
DL_VA_RTO_RESYS	Diffusing Capacity to Alveolar Ventilation Ratio, Respiratory System
DL_VA_RTO_PRED_RESYS	Diffusing Capacity to Alveolar Ventilation Ratio %, Respiratory System
FEF25_75_RESYS	Volume expelled during midportion of expiration, Respiratory System

Appendix III – Lab Panels (cont'd)

RESPIRATIORY FUNCTIONS	
Lab Test	**Intent**
FEF25_75_PRED_RESYS	Volume expelled during midportion of expiration % Predicted, Respiratory System
CAP_TTL_RESYS	Total Lung Capacity %, Respiratory System
CAP_TTL_PRED_RESYS	Total Lung Capacity %, Predicted, Respiratory System
FEV1_FVC_RTO_RESYS	FEV1 to FVC Ratio, Respiratory System
RV_TLC_RTO_RESYS	Residual Volume to Total Lung Capacity Ratio, Respiratory System

SEROLOGY	
Lab Test	**Intent**
PSA_SER	Prostate Specific Antigen (PSA), Serum
CA125_SER	Carcinogenic Antigen 125 (CA125), Serum
CEA_SER	Carcinoembryonic Antigen (CEA), Serum
CA19_9_SER	Carcinogenic Antigen 19-9 (CA19-9), Serum
CA15_3_SER	Carcinogenic Antigen 15-3 (CA15-3), Serum
CA27_29_SER	Cancer Antigen 27-29 (CA27-29), Serum
COMP_C3_SER	Complement, C3, Serum
COMP_C4_SER	Complement, C4, Serum
HCG_SER	Human Choriogonadotropin (HCG), Serum
HIV_1_2_AB_SER	Human Immunodeficiency Virus (HIV), 1-2 Antibody, Serum
CH50_SER	CH50 Complement, Serum
HBSAG_SER	Hepatitis B Surface Antigen, Serum
HBSAG_AB_SER	Antibody to Hepatitis B surface antigen (HBSAb), Serum
HEP_C_AB_SER	Hepatitis C Antibody, Serum
BHCG_PREG_SER	Beta Choriogonadotropin BHCG, or Pregnancy Test, Serum
DAT_RBC	Direct Antiglobulin Test (Coombs), Red Blood Cells

Appendix III – Lab Panels (cont'd)

SERUM ELECTRO	
Lab Test	**Intent**
ALBUMIN_ELPH_SER	Albumin, Electrophoresis, Serum
ALPHA1_GLOB_ELPH_SER	Alpha 1 Globulin, Protein Electrophoresis, Serum
ALPHA2_GLOB_ELPH_SER	Alpha 2 Globulin, Protein Electrophoresis, Serum
BETA_GLOB_ELPH_SER	Beta Globulin, Protein Electrophoresis, Serum
GAMMA_GLOB_ELPH_SER	Gamma Globulin, Protein Electrophoresis, Serum
PROTEIN_TTL_ELPH_SER	Total Protein Electrophoresis, Serum
IGA_SER	Immunoglobulin A (IgA), Serum
IGD_SER	Immunoglobulin D (IgD), Serum
IGE_SER	Immunoglobulin E (IgE), Serum
IGG_SER	Immunoglobulin G (IgG), Serum
IGM_SER	Immunoglobulin M (IgM), Serum

URINALYSIS	
Lab Test	**Intent**
GLUCOSE_UR	Glucose, Spot Urine
PROTEIN_QUAL_UR	Protein, Qualitative, Urine
UROBILINOGEN_UR	Urobilinogen, Spot Urine
PH_UR	pH, Spot Urine
HGB_UR	Hemoglobin, Spot Urine
KETONES_UR	Ketones, Spot Urine
NITRITE_UR	Nitrite, Spot Urine
LEUK_EST_UR	Leukocyte Esterase, Spot Urine
APPEAR_UR	Appearance, Urine
SPEC_GRAV_UR	Specific Gravity, Spot Urine
COLOR_UR	Color, Urine
RBC_MICRO_NUM_UR	Red Blood Cells (RBC), Microscopy, #, Spot Urine
WBC_MICRO_NUM_UR	White Blood Cells (WBC), Microscopy, #, Spot Urine

Appendix III – Lab Panels (cont'd)

URINE IMMUNE ELECTRO	
Lab Test	**Intent**
ALBUMIN_ELPH_TUR	Albumin, Electrophoresis, Timed Urine
ALPHA1_GLOB_ELPH_TUR	Alpha 1 Globulin, Electrophoresis, Timed Urine
ALPHA2_GLOB_ELPH_TUR	Alpha 2 Globulin, Electrophoresis, Timed Urine
BETA_GLOB_ELPH_TUR	Beta Globulin, Electrophoresis, Timed Urine
GAMMA_GLOB_ELPH_TUR	Gamma Globulin, Electrophoresis, Timed Urine

Appendix IV

Lab Load Interface (LLI) Tool

Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

Overview

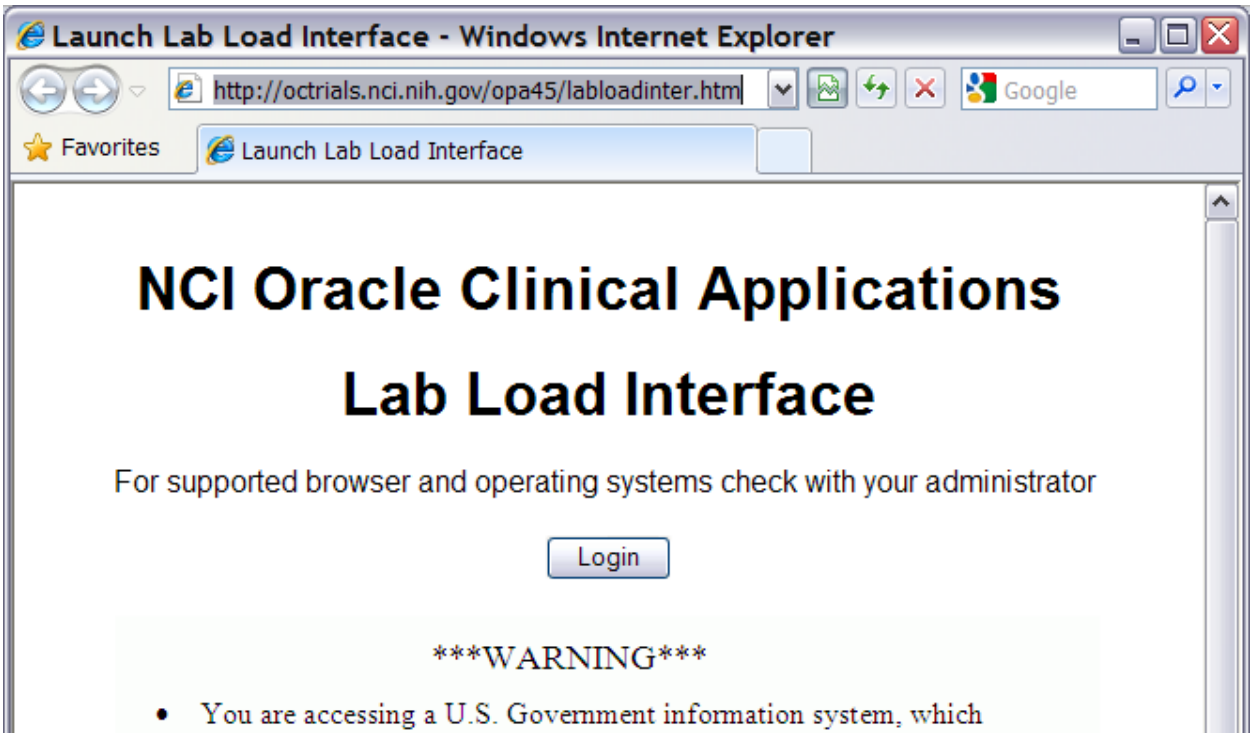
The Lab Load Interface (LLI) is a C3D companion tool used to choose which labs results to load in a C3D study. This tool is available for NCI/CCR intramural studies which have their labs drawn at the NIH Clinical Center.

Once a patient is entered in C3D, lab results are electronically transferred and made available in LLI according to the lab panels implemented in the C3D study. This transfer takes between 48 and 72 hours. The user, normally the Data Manager or Nurse, can then use LLI to select which labs to load according to the patient/study calendar and/or archive the labs that are not needed (for example, if a patient is screening for another protocol or is enrolled in another protocol). It takes another 24 hours for the selected labs to actually be loaded in the C3D study or archived.

Logging In

Open Internet Explorer and go to the following web page:
http://octrials.nci.nih.gov/opa45/labloadinter.htm

Click on the Login button, enter your C3D account, password and OCPROD for database.

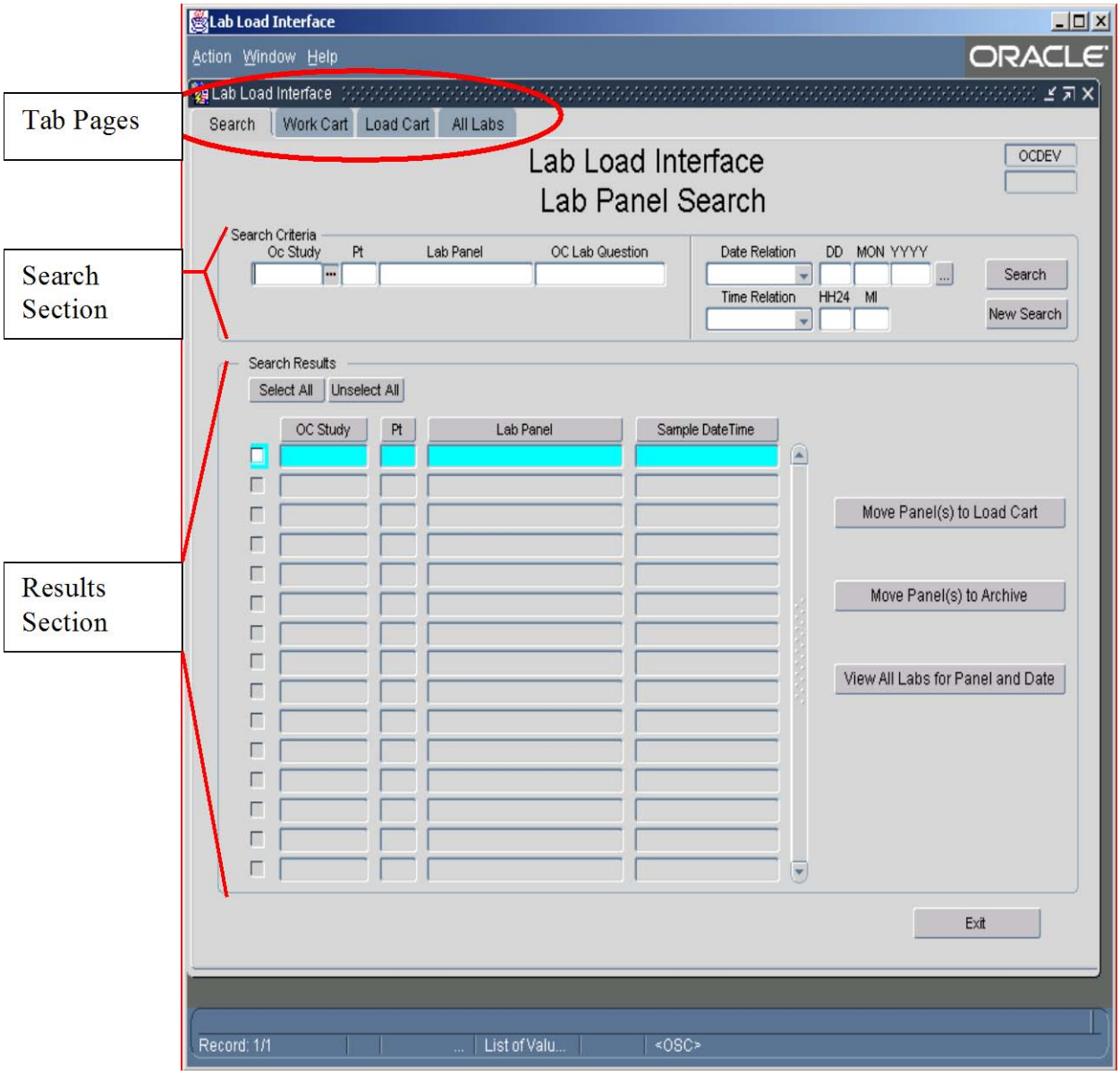


Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

Using LLI

The LLI interface is divided in 4 Tab Pages:

- Search – Used to search for the labs to load and/or archive.
- Work Cart – Used to view the details of the selected lab panel in the Search Tab
- Load Cart – Used to view the labs selected to load until they are loaded overnight.
- All Labs – Used to search all the labs (loaded, archived or awaiting to be selected/loaded.)



Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

Search Tab

The first step is to search for the labs to load or archive. Specify search criteria following the instructions below and then indicate which panels to load or archive.

Search Criteria:
Area used to specify the criteria used to filter the labs available to load. The most commonly used criteria are Study and Patient.

The following six criterions can be used and combined. As criterions are combined, the subsequent criterions available values are a subset based on the previously used criterion choices. Ex: if a study is selected, only the patients in that study will be available in the patient criterion. If then a patient is selected, only the lab panels for that study and patient are available in the Lab Panel criterions.

- **OC Study** – pick list with studies that are configured to use LLI tool that have labs to be reviewed for load or archival. Note that a study is only listed if there are labs to review. **This criterion is mandatory.**
- **Pt** – pick list with patient positions. If a study is selected, this pick list shows only patients for that study.
- **Lab Panel** – pick list with the C3D lab panel names.
- **OC Lab Question** – pick list with the C3D lab test names.
- **Date** – Allows for specifying a date and a relation ("*On or After*", "*On or Before*" or "*LIKE*"). The date criterion is then compared to the sample collection date. Day, month and year are required when using "*On or After*", "*On or Before*". When using "*LIKE*" at least Year is required.
- **Time** – Allows for specifying a time and relation. Works in the same way as the Date criterion.

Click on the Search button to initiate the search based on the specified criteria. The lab panels that satisfied the criteria are shown in the Search Results area. Click on the New Search button to clear all search criterions.

Search Results:
Area used to display the lab panels that satisfied the search criteria. Results are sorted by study, patient, lab panel and sample date/time. Click on the header of one of those columns to change the sort order. Ex: click on the sample date/time header to sort all panel by date/time in ascending order (oldest to newest). Click again to reverse the sort order (newest to oldest.)

Based on the patient/study calendar, click on the checkbox at the beginning of a row to place/remove checkmark. Optionally, use the "Select All" or "Unselect All" to place/remove checkmarks on all rows.

Click on the "Move Panel(s) to the Load Cart" or" Move Panel(s) to the Archive " to mode the selected lab panels to the Load Card or Archive.

Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

Optionally, double-click on a row to view the contents (lab results) of a lab panel in the Work Cart. Or click on the "View All Labs for the Panel and Date" to view contents of the highlighted row.

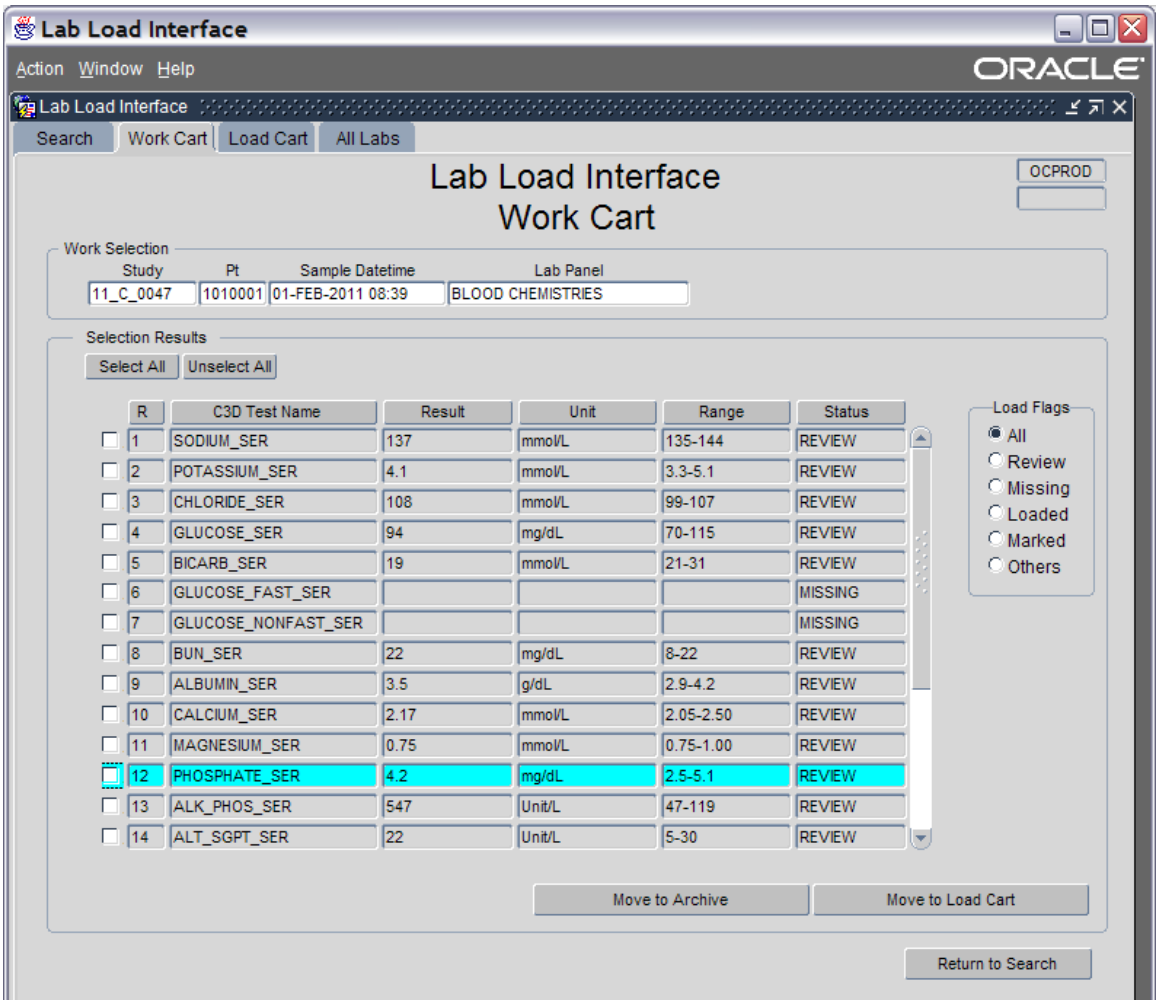
Work Cart Tab

This tab is used to view the details of a lab panel before deciding if it needs to be loaded or archived. It can also be used to load and archive individual lab test results.

The search results area works in the same was as in the Search Tab.

The Load Flags radio buttons allow the search results to be filtered by the selected option.

- All – Displays all results.
- Review – Result can be selected to load or archive.
- Missing – Result is not available – test not done or result not yet received.
- Loaded – Result already loaded in C3D.
- Marked – Result marked to load or archive.
- Others – Catch all option to show all the remaining flags.



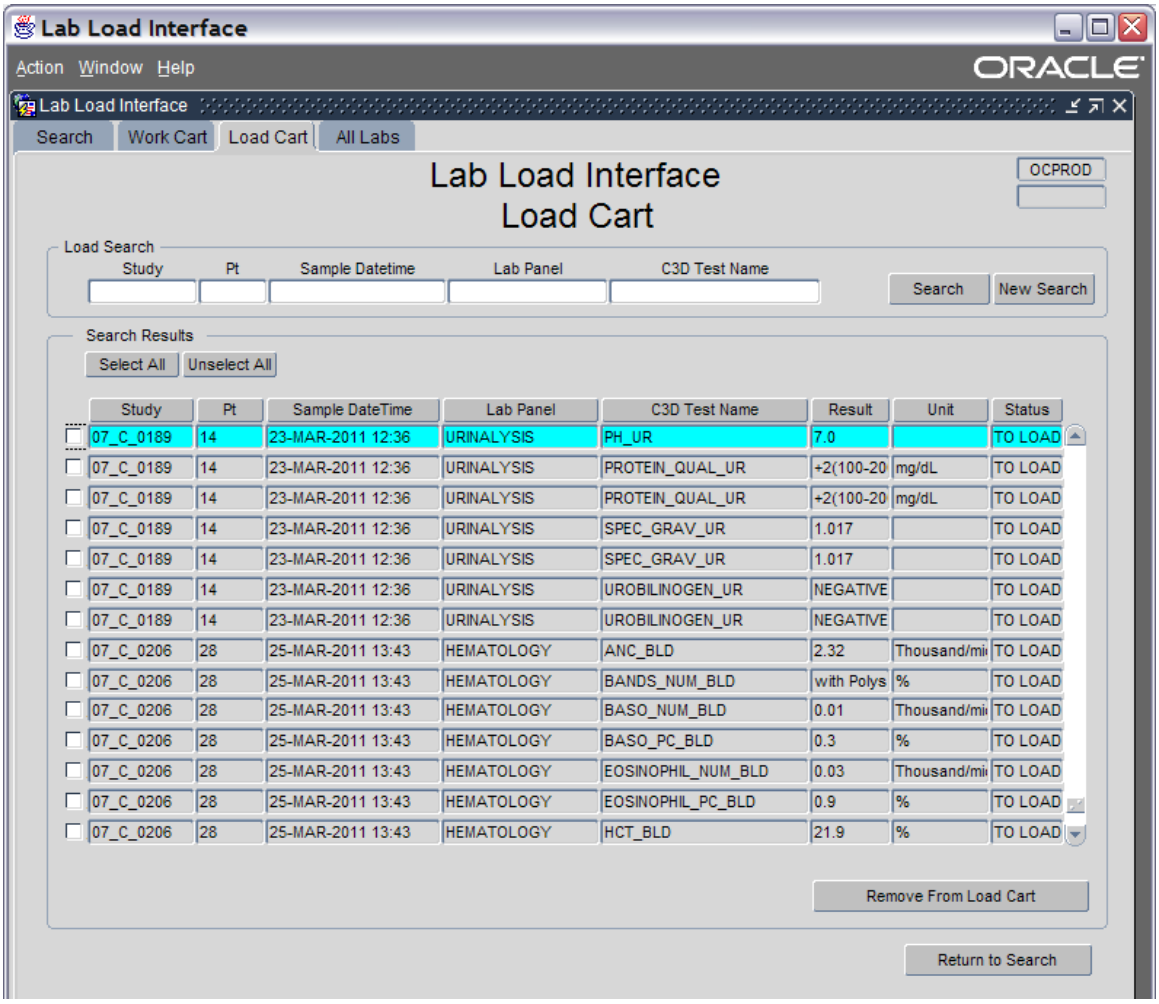
Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

Load Cart Tab

This tab displays all the lab results that have been selected to load in C3D. Overnight, these labs will be loaded in C3D and the load cart will be cleared.

When this tab is selected, it displays data for all the studies. Specify search criteria in the Load Search area to filter the Load Cart results. The criterions work in the same way as in the Search Tab. The exception is Sample DateTime which has a pick list with all the sample date/times.

Individual lab results can be selected and removed from the Load Cart. To select an entire lab panel, select all the results for a particular lab panel and sample date/time. Customize the Load Search and specify a study, patient, sample date/time to select a particular panel. Then use the "Select All" button or click on individual checkboxes to select labs and click on the "Remove From Load Cart" button. The removed labs can be immediately searched in the Search Tab.



Appendix IV – Lab Load Interface (LLI) Tool (cont'd)

All Labs Tab

This tab is used to view all labs that have been loaded or archived.

Enter search criteria that are specific as possible (study, patient, sample date/time) otherwise the search takes several minutes. Search criteria works the same way as in the Load Cart search.

Click on the checkboxes of the desired labs to un-archive and then click on the "Unarchive Selected" button.

Labs selected for un-archival will be processed overnight and be available in the Search tab the next day.