# Manual for the Completion

# of the

# NCI / CCR / C$^3$D

# Case Report Forms

Prepared by:

Harris Orkand Information Services

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

Disclaimer:

This manual was developed by Harris Orkand Information Services (HOIS) 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$^3$D) 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 $C^3D$.

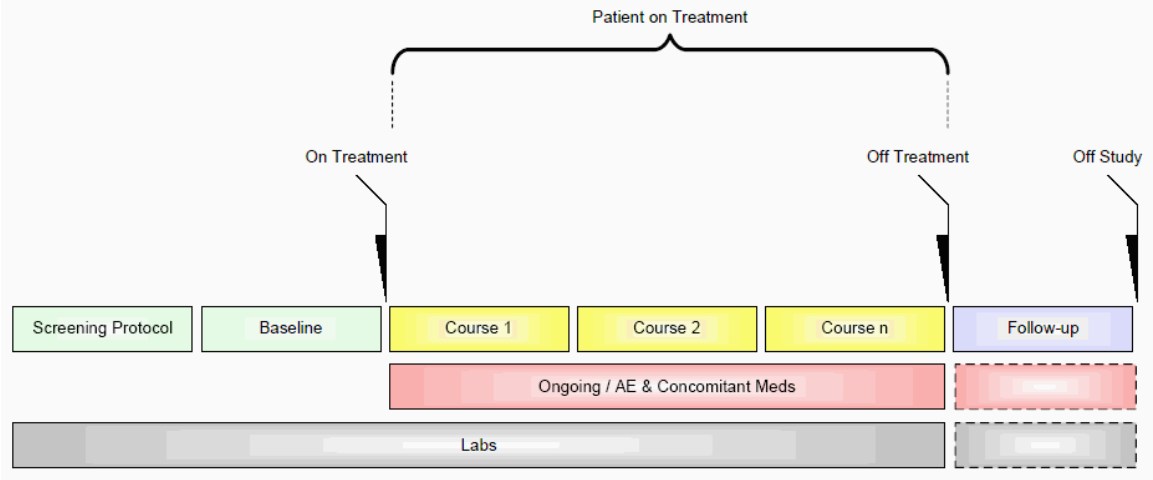
The eCRF instruction manual is preceeded by a General Instructions section which describes topics applicable to all eCRFs.This is followed by instuctions for each form which include how to complete each field, what the validation rules are for the CRF, and what fields will be dervied by the database.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

# General Instructions

## Data Entry Chronology

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

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




## Data Reporting

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

# General Instructions

## Electronic Case Report Forms

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

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

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

## Blank Case Report Forms

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

## Entering Comments

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

## Entering Dates

**Ongoing CRFs:**

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

**Course-specific CRFs**:

Refer to each 3CRF'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 to be entered, simply the numbers. To enter the year in a century format use YYYY, since years higher

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

**Partial dates** (month and year or simply year):

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

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

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

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

**Future dates:**

**Not allowed.**

## Entering Time

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

## Using Pick Lists

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

## Mandatory Fields

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

Filler Page

# Case Report Forms

# Adverse Events

## Purpose

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

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

All adverse events will be coded using either the NCI Common Toxicity Criteria (CTC) version 2.0 or the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0, as indicated in the protocol. Every attempt to code the adverse event to a term using the standard terminology will be made before selecting the "other" term in a category.

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

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

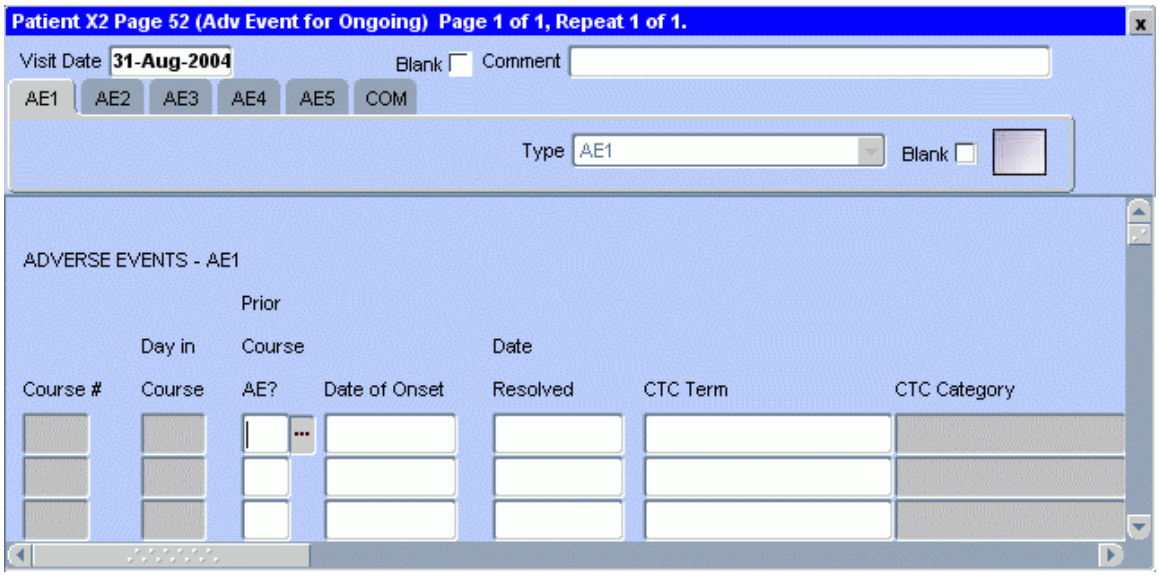
If an adverse event has not been resolved, leave the Resolved Date blank. The Resolved Date can be filled at a later time when the adverse event is considered resolved. Resolution means a change in grade to a higher or lower grade, to the normal grade (grade zero) or the return to the baseline symptom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

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

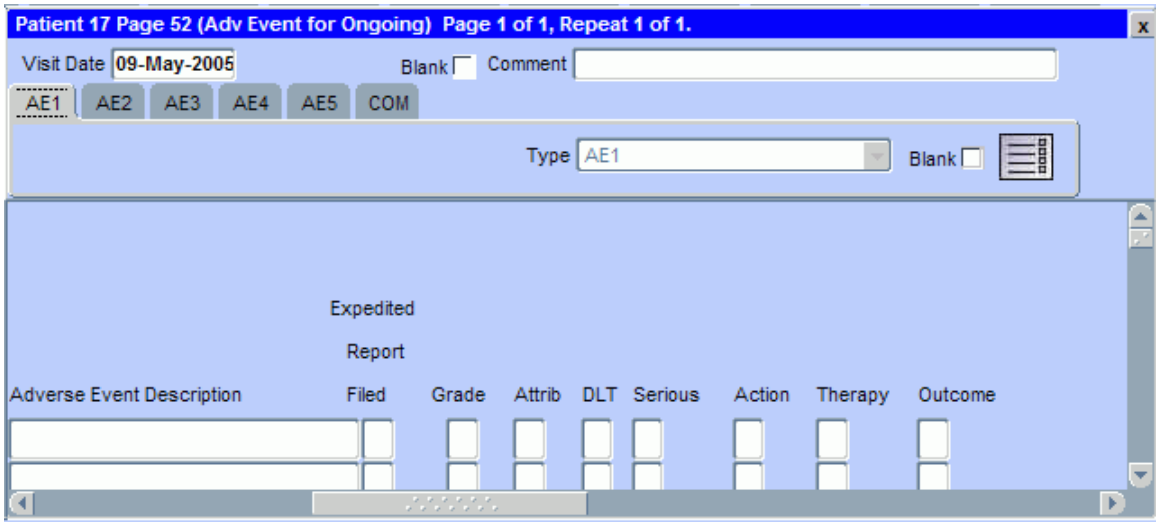
- If a pre-existing condition resolves, it does not need to be reported as an adverse event since it would have been already recorded on the Baseline Symptoms case report form. Enter the resolution date on the corresponding symptom entry on the Baseline Symptoms case report form.
- If a pre-existing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

# Adverse Events (cont'd)

## Adverse Event eCRF




The following screen shot is the portion to the right of the Adverse Event Description.



# 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. | 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 (m) | For adverse events that begin on the first day of a course, indicate if related to the prior course by entering:<br><br>Y- Related to a prior course<br>N- Not related to a prior course<br><br>For an adverse event that begins on the first day of the course **PRIOR** to any study medications being given, select "Y".<br><br>For an adverse event that begins on the first day of the course **AFTER** study medications have been given, select "N". | Use pick list. |
| Date of Onset (m) | Enter the date of first observation of the adverse event and grade. | DD-MMM-YYYY |
| 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.**<br><br>Resolution means a change in grade to a higher or lower grade, to the normal grade (grade zero) or the return to the baseline symptom grade. | DD-MMM-YYYY |

# Adverse Events (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| CTC Term (m) ... | Using either the Common Toxicity Criteria (CTC) version 2.0 or the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 as indicated in the protocol, select the appropriate general category with the appropriate adverse event term.<br><br>Note: For CTCAE version 3.0, several terms are classified as supraordinate terms that have a select value associated with the term, both are included for selection of the Adverse Event term. Visit CTEP website for further explanation of supraordinate categories and usage of the select term (http://ctep.cancer.gov).<br><br>In the absence of a specific adverse event term, choose the "Other" term from the appropriate general category and be sure a meaningful adverse event description is entered in the "adverse event description" field. | Use pick list. |
| CTC Category (d) | Broad classification of adverse events based on anatomy and/or pathophysiology. Within each category there is the adverse event term/CTC Term Description.<br><br>*Note: This field is derived from the selected CTC Term.* | 40 Characters |
| Adverse Event Description | Enter a **succinct clinical description** of the adverse event.<br><br>*Note: This field is mandatory, unless the CTCAE term is the same as the description (e.g. nausea, diarrhea).*<br><br>DO NOT enter raw data (i.e.: lab result). Use the term increase or decrease.<br><br>DO NOT enter the attribution in this field. Use the Attribution field for this purpose. | 100 characters (Only 33 characters are reported for CTMS monitored studies.) |

# Adverse Events (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | For CTC 2.0: Enter the diagnosis, e.g. flu, and not each specific symptom (e.g. chills fever, muscle aches). For CTC 3.0: Use the syndrome category when appropriate (e.g.: Flu-like syndome).<br><br>For example:<br>• Enter 'Low back pain' when selecting the term 'Pain: Back'.<br>• Enter 'Intermittent headache' when selecting the term 'Pain Head/Headache'<br>• Enter 'Left arm pain' when selecting the term 'Pain-Other' | |
| Expedited Report Filed (m) | Indicate if an expedited adverse event report was sent to sponsor/IRB by entering:<br><br>Y- Yes<br>N- No<br>U- Unknown<br><br>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).<br><br>For pharmaceutical sponsored studies, this means that a Serious Adverse Event (SAE) was sent to the sponsor.<br><br>For investigator-held IND studies, this means that a SAE report was sent to the IRB.<br><br>For all other studies not mentioned above, this means the SAE report was sent to the IRB. | Use pick list. |
| Grade (m) | Grade adverse events using either the Common Toxicity Criteria (CTC) version 2.0 or the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 as indicated in the protocol.<br><br>*Note: Some grades are disallowed for some categories in the CTC/CTCAE. In the* | Use pick list. |

# Adverse Events (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | *CTC/CTCAE tables this will be noted by the use of an em-dash "—".. For example, Hair loss/Alopecia can only be graded as a 1 or 2, so grade 3, 4, and 5 do not exist and will be noted in the table with a "—" verses a description.*<br><br>If the protocol does not use either CTC or CTCAE, grade according to the following general criteria:<br><br>0. Normal – no adverse event or within normal limits<br>1. Mild – barely noticeable, does not influence functioning<br>2. Moderate – makes subject uncomfortable, influences functioning<br>3. Severe – severe discomfort, treatment given<br>4. Life threatening – immediate risk of death<br>5. Fatal – causes death of the patient – **Outcome must be 4-Died.** | |
| Attribution (m) ▪▪▪ | Every entry must be evaluated for relationship to the study therapy. Select one of the following codes to record this evaluation:<br><br>1. Unrelated – clearly not related<br>2. Unlikely – doubtfully related<br>3. Possible – may be related<br>4. Probable – likely related<br>5. Definite – clearly related | Use pick list. |
| DLT (m) ▪▪▪ | Indicate if the adverse event is dose limiting, as defined in the protocol, by entering:<br><br>Y- Yes<br>N- No<br><br>*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.*<br><br>*Note: Mandatory for Phase I Clinical Trials.* | Use pick list. |

# Adverse Events (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Serious (m) ... | Indicate if the adverse event was a "serious" event by selecting from the following codes, as per the Code of Federal Regulations 21 Part 312. If multiple categories are applicable, select the worst.<br><br>1. Not serious.<br>2. Life-threatening.<br>3. Death as a result of the adverse event.<br>4. Disability: significant, persistent or permanent.<br>5. Hospitalized or prolonged hospitalization (not including emergency room visits).<br>6. Caused congenital anomaly in child of patient.<br>7. Jeopardizes patient / requires intervention to prevent permanent impairment or damage to patient. | Use pick list. |
| Action (m) ... | Indicate any changes made to the study regimen in response to the adverse event using the following codes. "Action" refers to the decision to reduce or continue the **investigational medication**.<br><br>1. None<br>2. Dose Reduced<br>3. Regimen Interrupted<br>4. Therapy Discontinued<br>5. Interrupted & Reduced<br><br>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.<br><br>*Note: Interrupted also means therapy was delayed.* | Use pick list. |

# Adverse Events (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Therapy (m) ... | Indicate if additional therapy is required to treat the adverse event.<br><br>1. None<br>2. Symptomatic (i.e.: required medications to treat event)<br>3. Supportive (i.e.: required medications and/or IV fluids, blood products)<br>4. Vigorous Supportive (i.e.: required surgery, intubation)<br><br>A corresponding entry of the therapy given to treat the adverse event must be recorded on the Concomitant Measures/Medication form. | Use pick list. |
| Outcome ... | Select the final status of the patient when the adverse event is considered "resolved".<br><br>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.<br>4- Died - Record outcome of death only for adverse events that resulted in the patient's death.<br><br>*Note: For ongoing adverse events, leave this and the Resolution Date fields empty.*<br><br>*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. |
| 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 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.<br><br>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.<br><br>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. |

| 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. |

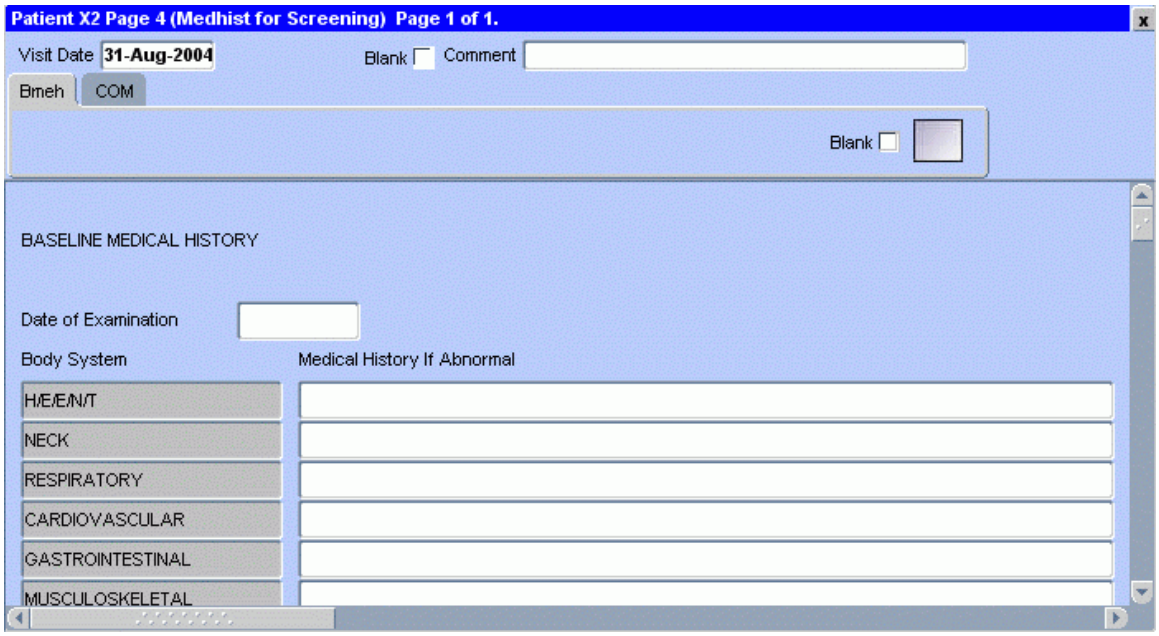
(ADVERSE-EVENTS)

# 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.

## 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 |
| 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).<br><br>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. | | |

| 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. |

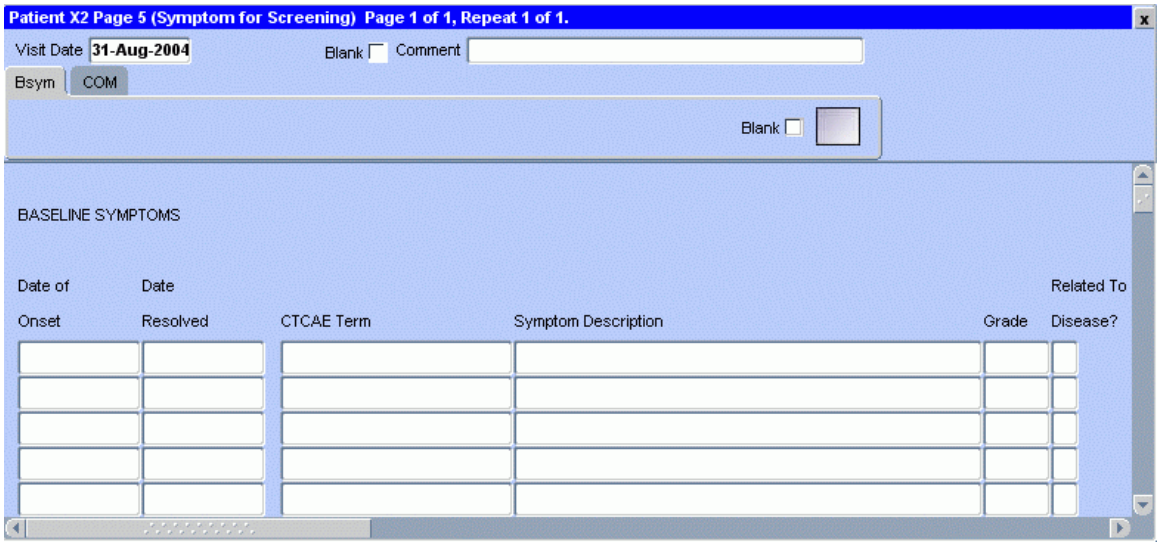
(BASELINE-MEDICAL-HISTORY)

# Baseline Symptoms

## Purpose

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

## Baseline Symptoms eCRF



# Baseline Symptoms (cont'd)

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

# Baseline Symptoms (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | aches). For CTC 3.0: Use the syndrome category when appropriate (e.g.: Flu-like syndome).<br><br>For example:<br>• Enter 'Low back pain' when selecting the term 'Pain: Back'.<br>• Enter 'Intermittent headache' when selecting the term 'Pain Head/Headache'<br>• Enter 'Left arm pain' when selecting the term 'Pain-Other' | |
| Grade (m) ... | Enter the severity of the symptom by using the protocol specified version of CTC version 2.0 or CTCAE version 3.0. If the symptom is not explicitly mentioned it should be coded in the appropriate "other" category and graded according to the general criteria:<br><br>1. Mild – barely noticeable, does not influence functioning<br>2. Moderate – makes subject uncomfortable, influences functioning<br>3. Severe – severe discomfort, treatment given<br>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:<br><br>Y- Yes<br>N- No<br>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. |

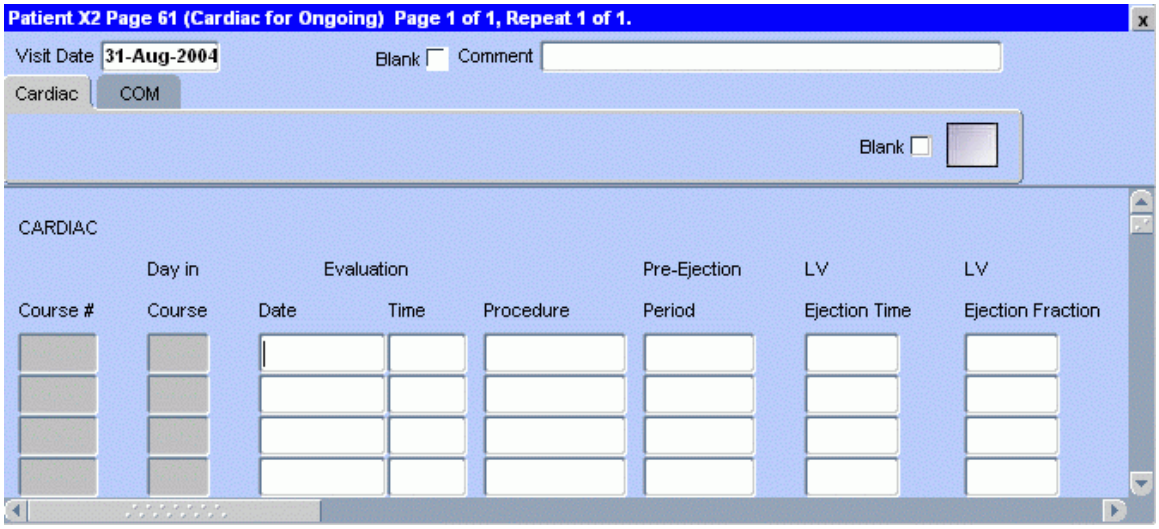
(BASELINE-SYMPTOMS)

# 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:<br>• MUGA<br>• MRI<br>• Echocardiogram<br>• Cardiac Catheterization.<br>• Nuclear stress test. | Use pick list. |
| Pre-Ejection Period | Enter the Pre-Ejection Period. | 4 digits and 3 decimals |
| LV Ejection Time | Enter the Left Ventricular Ejection Time. | HH(24):MM |
| LV Ejection Fraction (%) (m) | Enter the Left Ventricular Fraction percentage. | 4 digits and 3 decimals |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

# Cardiac (cont'd)

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

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

(CARDIAC)

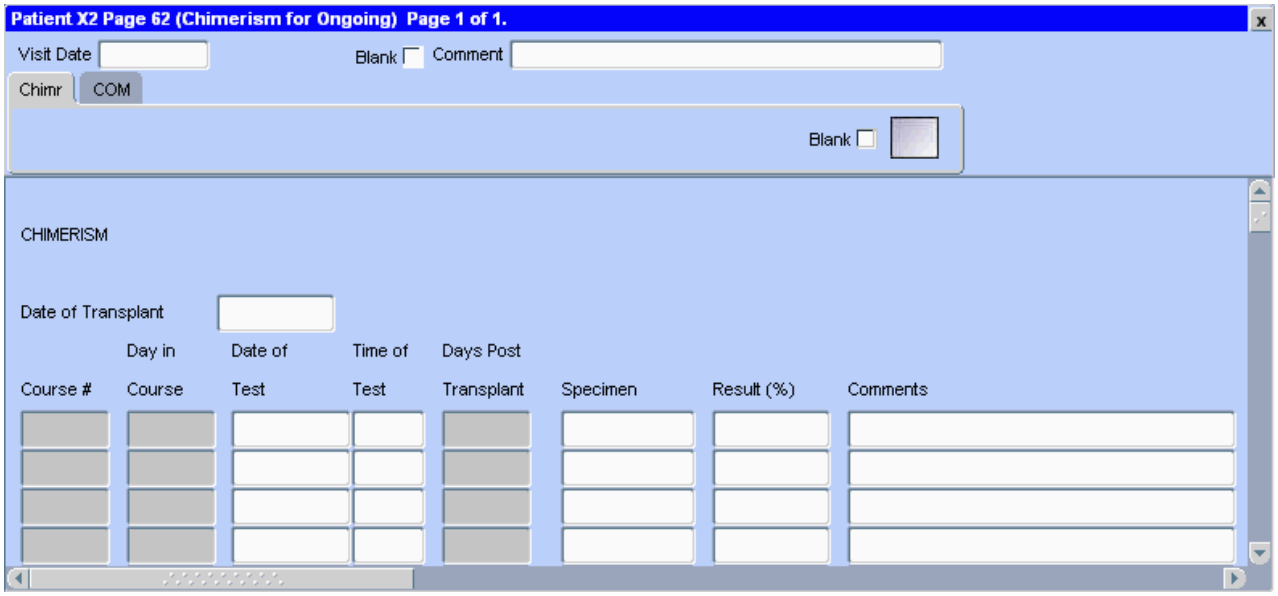
Filler Page

# Chimerism

## Purpose

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

## Chimerism eCRF



# Chimerism (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Date the first test was performed. | DD-MMM-YYYY |
| Date of Transplant (m) | Date the transplant was performed. | DD-MMM-YYYY |
| 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.<br>A- Apheresis Cells<br>B- Whole Blood<br>C- CSF<br>D- CD33 Myeloid Cells<br>L- CD33 Lymphoid Cells<br>M- PBMC<br>O- Bone Marrow<br>P- Plasma<br>S- Serum<br>T- Tumor Tissue<br>U- Urine<br>V- Saliva<br>Y- CD14/15 Myeloid | Use pick list. |
| Result (%) (m) | Test results in percentage. | 3 digits and 1 decimal |
| 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)

Filler Page

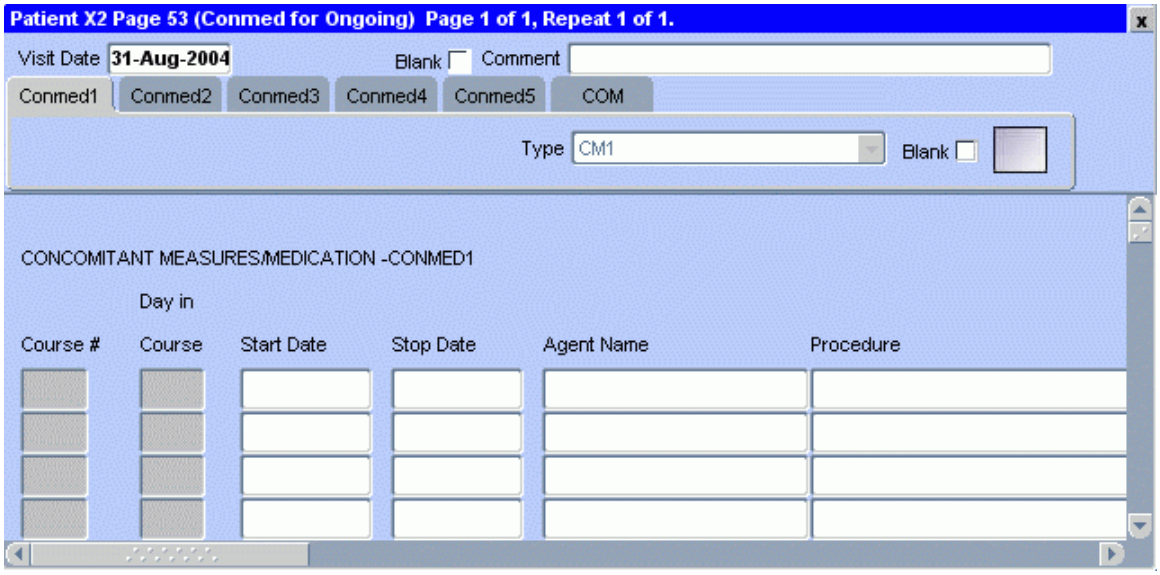
# Concomitant Measures / Medications

## Purpose

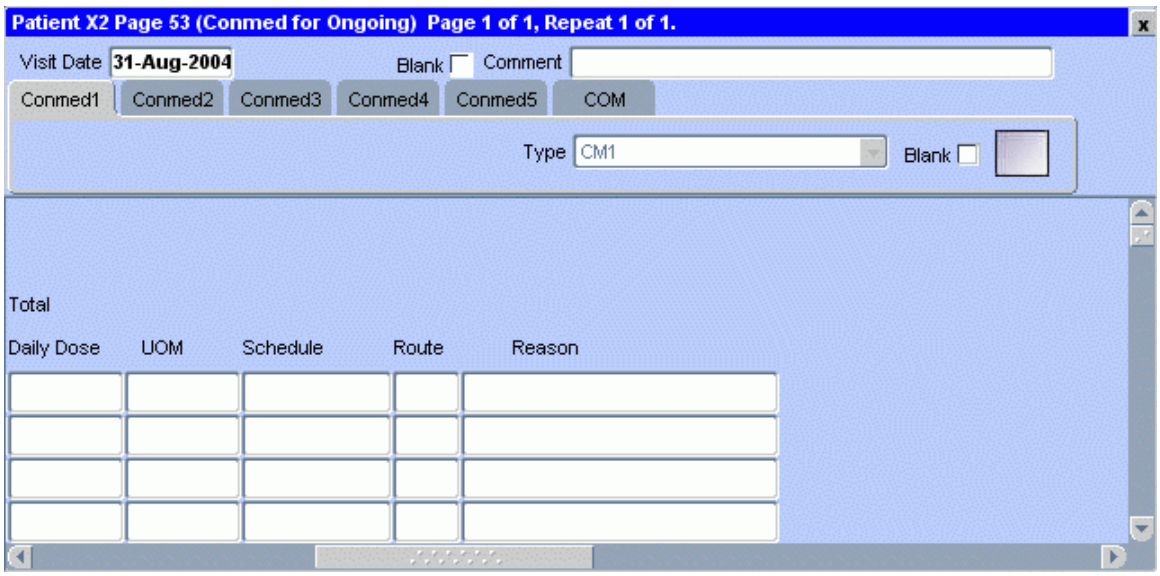
Record all concomitant medications, including therapies given to treat adverse events.

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.<br><br>*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.<br><br>*Note: Partial date is only acceptable for baseline measure or medication.* | DD-MMM-YYYY or MMM-YYYY |
| Agent Name ... | In the case of agents, state the generic name of the medication administered, or, in the case of combinations such as trimethoprim / sulfamethoxazole, state the brand name (i.e., Bactrim).<br><br>*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.*<br><br>*Note: Do not select an agent name if a procedure has been entered.* | Use pick list. |
| Procedure ... | If a procedure/measure, state e.g., oxygen administration, pleural tapping, etc.<br><br>*Note: Do not select a procedure if an agent name has been entered.* | Use pick list. |

# Concomitant Measures / Medications (cont'd)

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

# Concomitant Measures / Medications (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Reason (m) ... | Select the reason the medication is being administered or why measure done. For example, if Bactrim is being given as a prophylactic, select "pneumocystis prophylaxis".<br><br>*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. | | |

| 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 is after the first Course Initiation Date. | Partial Start and Stop Dates are only acceptable for baseline measures and/or procedures. |

# Concomitant Measures / Medications (cont'd)

| Derivations | | |
|---|---|---|
| **Code** | **Field Name** | **Description** |
| CM1001 | Course # | Course number is derived based on the course initiation start dates and the concomitant measure / medication start date. |
| CM1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the concomitant measure / medication start date. |

(CONCOMITANT-MEASURES-MEDICATIONS)

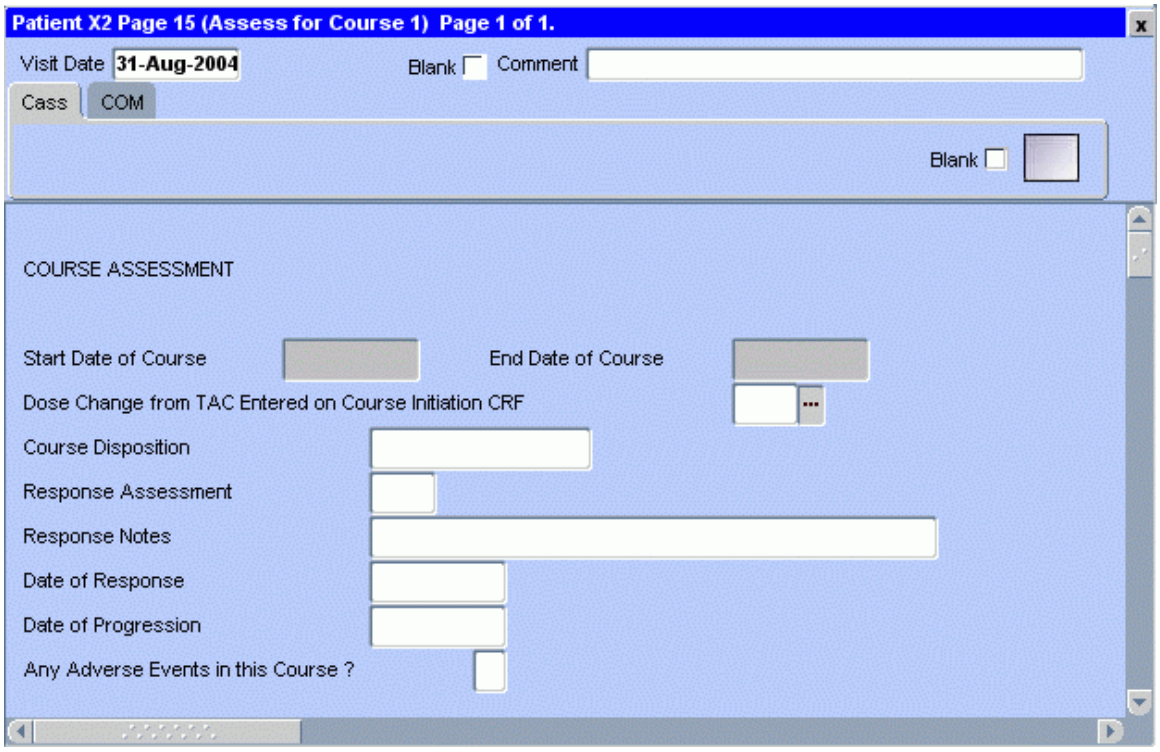
Filler Page

# Course Assessment

## Purpose

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

## Course Assessment eCRF



# Course Assessment (cont'd)

| Field Descriptions / Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Enter the date the course started. | DD-MMM-YYYY |
| Start Date of Course (d) | Shows the Start Date of Course entered in the Course Initiation case report form. | DD-MMM-YYYY |
| End Date of Course (d) | Shows the derived end date of the course which is the day before the start date of the following course or the off treatment date. | DD-MMM-YYYY |
| Dose change from TAC entered on Course Initiation CRF (m) ... | Indicate if the patient's treatment was different from that specified by the Treatment Assignment Code (TAC) for this course as entered on the Course Initiation CRF. If the treatment was different, indicate whether this was planned or unplanned, and record the reason, e.g. dose reduction due to toxicity, on the Comments tab of this CRF.<br><br>1- **Yes, Planned** - change in treatment had been decided before the **start** of the course, e.g., due to toxicity on a previous course.<br><br>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.<br><br>3- **No** - patient received the treatment specified in the Course Initiation TAC.<br><br>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:<br><br>Comp- Completed<br>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.<br><br>NE- Not Evaluable - State the reason in the "Response Note" field.<br><br>NA- Not Assessed - State the reason in the "Response Note" field.<br><br>NP- Protocol does not require a response assessment during the specific course.<br><br>TE- Too Early to confirm a response.<br><br>Unless the protocol includes specific response evaluation criteria, the following guidelines should be observed:<br><br>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.<br><br>PR or MR- Partial Response or Marginal Response - Response is assessed relative to the baseline at start of | Use pick list. |

# Course Assessment (cont'd)

| Field Descriptions / Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | treatment, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR.<br><br>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".<br><br>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.<br><br>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.<br><br>**RECIST:** Many protocols specify that the following RECIST criteria are to be used in assessing response. Please use the following selections when assessing response using RECIST criteria only.<br><br>Evaluation of target lesions:<br><br>CR- Complete Response - Disappearance of all target lesions.<br><br>PR- Partial Response At least a 30% decrease in the sum of the LD (longest dimension) of | |

# Course Assessment (cont'd)

| Field Descriptions / Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | target lesions, taking as reference the baseline sum LD.<br><br>PD- Progressive Disease - At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum LD recorded since the treatment started or the appearance of one or more new lesions.<br><br>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.<br><br><u>Evaluation of non-target lesions</u>:<br><br>CR- Complete Response - Disappearance of all non-target lesions and normalization of tumor marker level.<br><br>SD- Incomplete Response/Stable Disease - Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits.<br><br>PD- Progressive Disease - Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. | |
| Response Notes | Enter the reason why the Response Assessment is Not Evaluable (NE) or Not Assessed (NA). Some examples could include: protocol not followed, poor quality of scan, patient already treated. | 32 characters |

# Course Assessment (cont'd)

| Field Descriptions / Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Date of Response | Enter the date of the earliest evaluation which, upon confirmation, justifies an assessment of CR, PR, MR, or SD/DU. This date will be the same date as the scan, or other method of disease assessment.<br><br>For NE, record the date the patient's disease was assessed and deemed to be Not Evaluable.<br><br>*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.<br><br>Select "No" if no adverse events occurred during this course.<br><br>*Note: The event(s) must be recorded on the Adverse Events case report form.* | Use pick list. |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

# Course Assessment (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| CAS02, CAS03 | Date of Response or Onset Date of Progress must not be future dates. | Change the date to a value no later than the current date. |
| CAS05 | Response Notes entered and Response Assessment is different than "Not Evaluable" and "Not Assessed". | Remove the Response Notes if Response Assessment is different than "Not Evaluable" and "Not Assessed". Otherwise change the Response Assessment to "Not Evaluable" and "Not Assessed". |
| CAS06 | Response Assessment is "Not Evaluable" or "Not Assessed" and no Response Notes were entered. | Enter the Response Notes if Response Assessment is "Not Evaluable" or "Not Assessed". Otherwise change the Response Assessment to a selection other than "Not Evaluable" and "Not Assessed". |
| CAS07 | Date of Response is required when Response Assessment is CR, PR, MR, SD, DU or NE. | Enter the Date of Response or Review the Response Assessment. |
| CAS08 | Date of Progression is required when Response Assessment is PD. | Enter the Date of Progression or Review the Response Assessment. |
| CAS09 | Course Assessment marked as having adverse events, but there are no adverse events with an onset date that falls within this course start and end dates. | Change the field "Any Adverse Events in this Course?" to "NO" if no related adverse events exist. Otherwise enter the appropriate adverse events or adjust the appropriate adverse events dates. |
| CAS10 | Course Assessment marked as not having adverse events, but there is at least one adverse event with an onset date that falls within this course start and end dates. | Change the field "Any Adverse Events in this Course?" to "YES" if the related adverse events are appropriate. Otherwise remove the adverse events or correct the adverse events dates. |

# Course Assessment (cont'd)

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

(COURSE-ASSESSMENT)

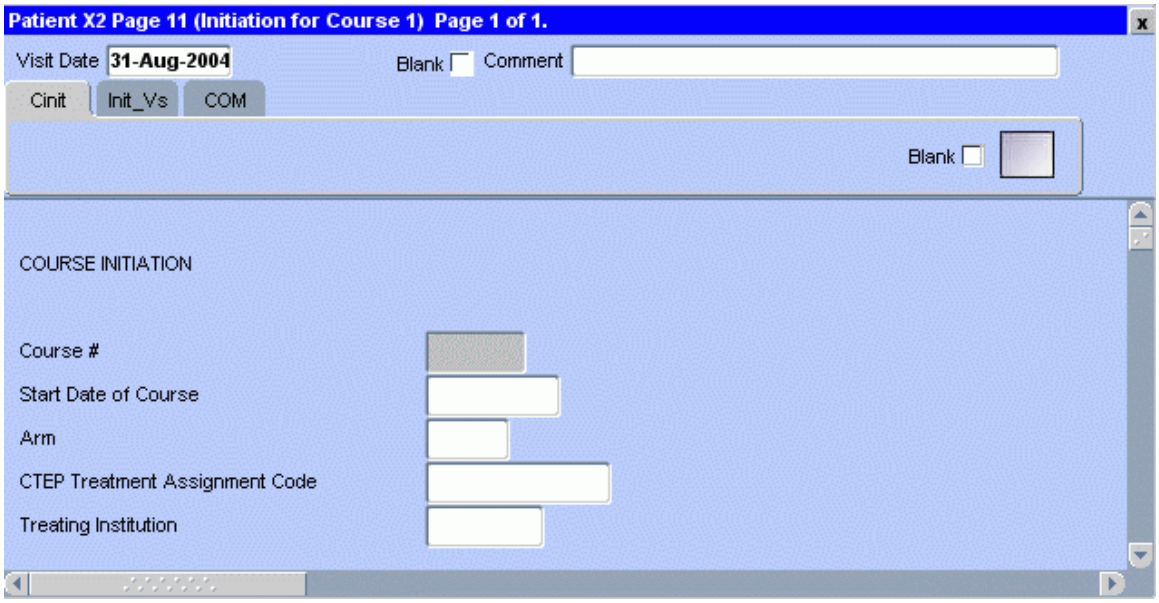
# Course Initiation

## Purpose

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

## Course Initiation eCRF

Course Initiation tab



# 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.<br><br>*Note: this is only mandatory for CTMS monitored, CTEP- sponsored studies.* | Use pick list. |
| CTEP Treatment Assignment Code (m) (c) ... | Select the appropriate Treatment Assignment Code (TAC) for the regimen and dose level of this course.<br><br>"Treatment Assignment Codes" are provided by CTEP to the investigator at the time of protocol approval, and are updated as required following approval of protocol amendments.<br><br>Each TAC will have a description that will outline the treatment schedule for the intended course.<br><br>**A new TAC is selected if the dose was**:<br>• reduced for a dose limiting toxicity (DLT), as defined in the protocol;<br>• escalated, as defined in the protocol for intrapatient dose escalation;<br>• changed or crossed over to another dosing schedule or set of medications due to progression or new treatment, as defined in the protocol.<br><br>**A new TAC is not selected if the dose was**:<br>• modified for a non-dose limiting toxicity;<br>• titrated to patient tolerance. | Use pick list. |

# Course Initiation (cont'd)

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

| **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. |
| CINI02, 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. |

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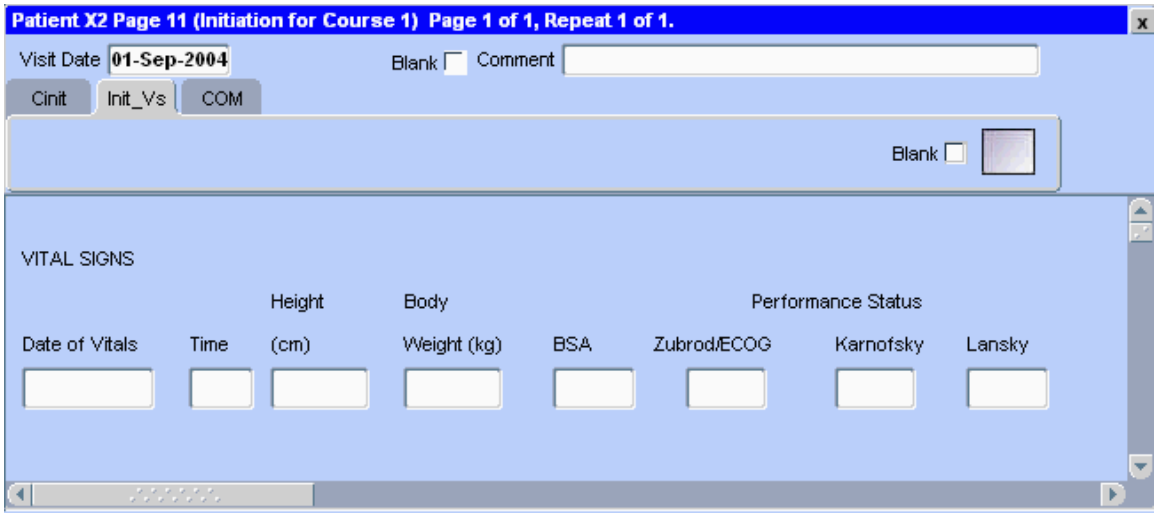
## Course Initiation eCRF

Initial Vitals tab



# Course Initiation (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Date of Vitals (m) | Enter the date the vital signs were taken. | DD-MMM-YYYY |
| Time (m) | Enter the time the vital signs were taken. | HH(24):MM |
| Height | Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors. | 3 digits and 2 decimals |
| Weight | Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors. | 3 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.<br><br>The following simple approximation may be used for persons of "normal" height and weight:<br><br>$BSA(m^2) = \sqrt{\frac{Height\ (cm)\ x\ Weight\ (kg)}{3600}}$ | 1 digit and 2 decimals |
| Performance Status (Karnofsky) ... | Select a value from the Karnofsky performance status scale.<br><br>0- Dead<br>10- Moribund<br>20- Very Sick<br>30- Hospitalized<br>40- Disabled<br>50- Frequent Assistance<br>60- Occasional Assistance<br>70- Self Care<br>80- Effort<br>90- Able<br>100- Normal | Use pick list. |

# Course Initiation (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Performance Status (Zubrod) ▪▪▪ | Select a value from the Zubrod/ECOG performance status scale.<br><br>0. Asymptomatic<br>1. Symptomatic, fully ambulatory<br>2. Symptomatic, in bed less than 50% of day<br>3. Symptomatic, in bed more than 50% of the day, but not bedridden<br>4. Bedridden | Use pick list. |
| Performance Status (Lansky) ▪▪▪ | Select a value from the Lansky performance status scale.<br><br>0- Unresponsive<br>10- No play; does not get out of bed<br>20- Often sleeping; play entirely limited to very passive activities<br>30- In bed; needs assistance even for quiet play<br>40- Mostly in bed; participates in quiet activities<br>50- Gets dressed but lies around much of the day; no active play; able to participate in all quiet play<br>60- Up and around; but minimal active play; keeps busy with quieter activities<br>70- Both greater restriction of and less time spent in play activity<br>80- Active; but tires more quickly<br>90- Minor restrictions in physically strenuous activity<br>100- Fully active, normal | 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** |
| VIT06, VIT07 | Height or Weight must be greater than zero. | Enter a positive value for Height or Weight. |
| VIT03 | Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula. | Correct the BSA.<br>The MIS BSA formula is:<br>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.<br>The Mosteller BSA formula is:<br>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. |
| VIT15 | Date of Vitals is prior to the Start Date of Course or after the End Date of Course. | Date of Vitals must not be prior to the Start Date Course or after End Date of Course. |
| VIT16 | Height and Weight were not entered. | Height or Weight should be entered. |
| VIT17 | BSA is not provided for Vital Signs inside Courses. | BSA is mandatory for Vital Signs inside Courses. |

(COURSE-INITIATION)

# Eligibility Checklist

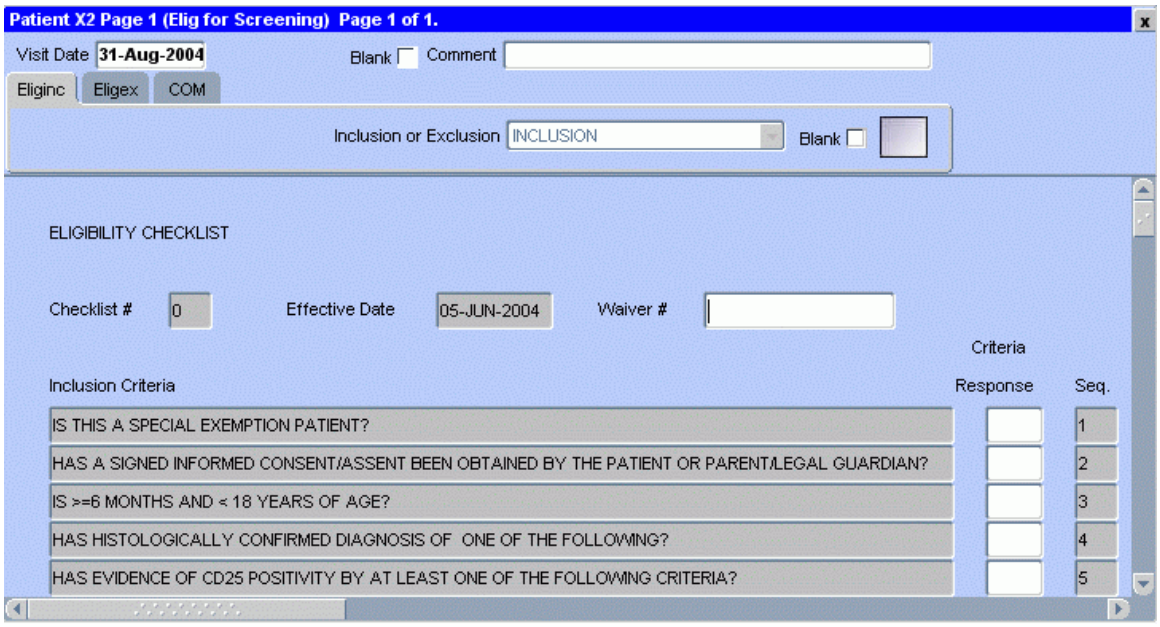
## Purpose

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

Each activated protocol has a customized eligibility checklist.

## Eligibility Checklist eCRF

Inclusion Criteria tab (sample criteria)



# Eligibility Checklist (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date [(m)] | Enter the date the form was completed (i.e. the date information was gathered). | DD-MMM-YYYY |
| Checklist Number | Checklists are numbered sequentially based on NCI approval of amendments that change the eligibility criteria. The eligibility checklist from the original protocol must number 0. Each time the eligibility criteria for a protocol are amended, the checklist number is incremented. (The checklist number may not be the same as the amendment number, since some amendments do not affect the criteria.) The appropriate checklist number is provided by CTMS along with a new customized CRF each time a revised protocol-specific Eligibility Checklist is formulated.<br><br>*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.<br><br>*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.<br><br>*Note: Not applicable for NCI/DCTD/CTEP sponsored studies.* | 12 characters |

# Eligibility Checklist (cont'd)

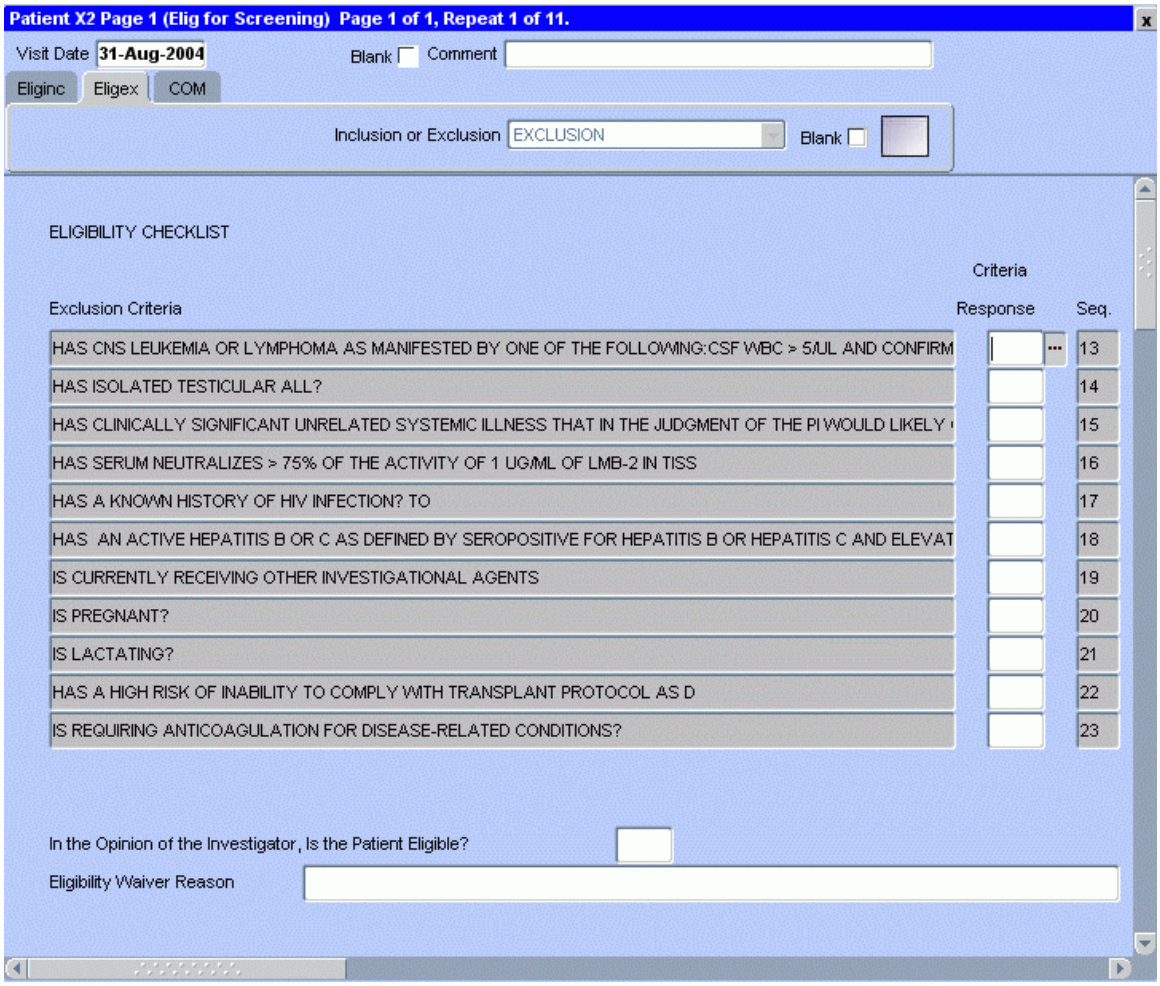
| | | |
|---|---|---|
| Criterion Response (m) ▪▪▪ | Select the patient's status relative to the eligibility inclusion criterion.<br><br>Y- Yes<br>N- No<br>X- Not Applicable<br><br>*Note: Do not leave this field empty. Select one of the above responses.* | Use pick list. |
| Sequence | The inclusion criterion sequence number.<br><br>*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. |

Filler Page

## 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.<br><br>Y- Yes<br>N- No<br>X- Not Applicable<br><br>*Note: Do not leave this field empty. Select one of the above responses.* | Use pick list. |
| Sequence | The exclusion criterion sequence number.<br><br>*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.<br><br>Y- Yes<br>N- No<br>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.<br><br>*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. |
| EC02 | One or more Criterion Response was not provide. | All Criterion Responses must be provided. |

(ELIGIBILITY-CHECKLIST)

Filler Page

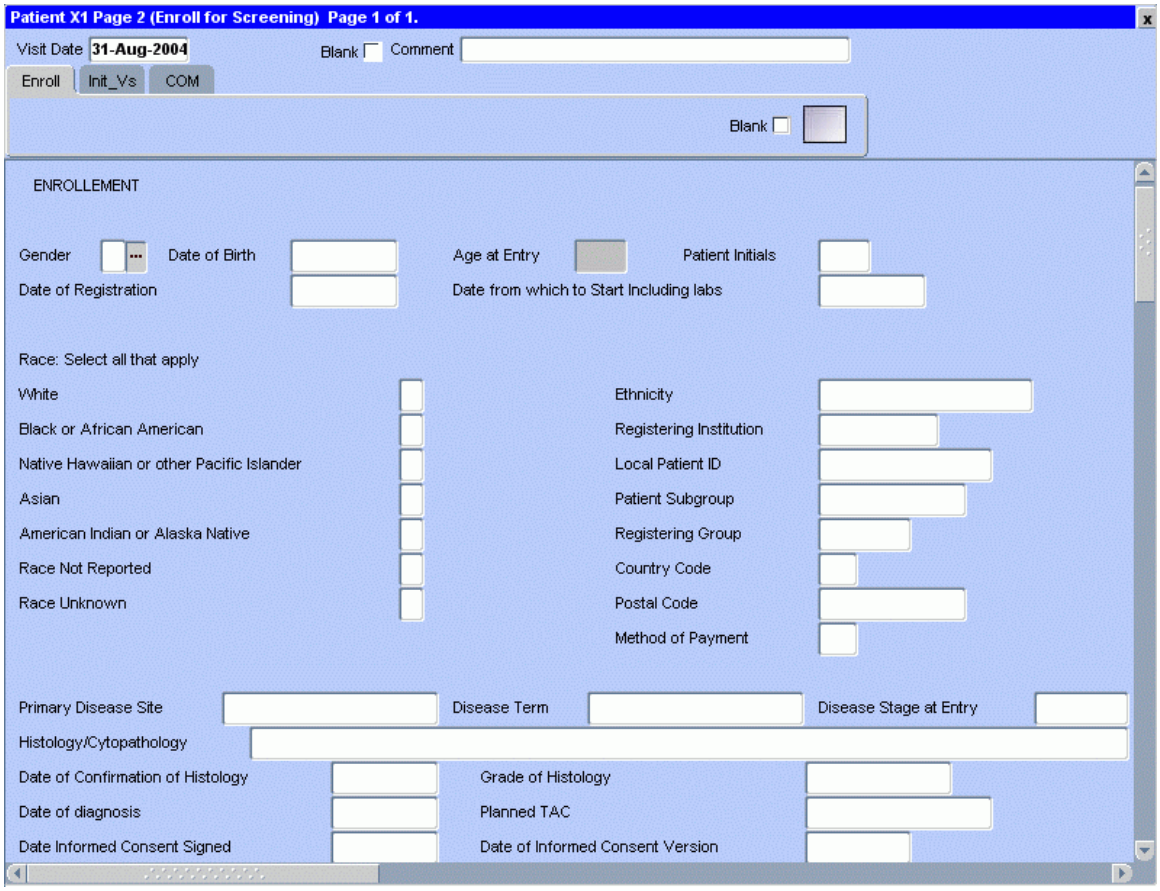
# Enrollment

## Purpose

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

## Enrollment eCRF

Enrollment tab.



# 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:<br><br>M- Male<br>F- Female<br>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.<br><br>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.) | 2 digits and 1 decimal |
| Patient Initials (m) | Enter the patient's initials. Usually 3 characters – first, middle and last name initials. | 3 characters |
| Date of Registration (m) | Enter the date when patient was registered to the study.<br><br>*Note: For CCR protocols, this date is the same as the Date Informed Consent Signed.* | DD-MMM-YYYY |
| Date from which to Start Including Labs | 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 (note that there is no "Other" category):<br><br>• White: a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.<br>• Black or African American: a person having origins in any of the black racial groups of Africa.<br>• 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).<br>• 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.<br>• Native Hawaiian or other Pacific Islander: a person having origins in any of the original peoples of Hawaii, or other Pacific Islands.<br>• Not Reported: patient refused or data not available.<br>• Unknown: race unknown.<br><br>*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:<br>• Hispanic or Latino: a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.<br>• Non-Hispanic or Latino: a person not meeting the definition for Hispanic or Latino.<br>• Unknown: a person of unknown ethnicity. | Use pick list. |
| Registering Institution (m) ▪▪▪ | 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). | Use pick list. |
| Local Patient ID | Enter the patient's local identifier used by the treating institution. | 12 characters |
| 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 Update System (CDUS). 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 ▪▪▪ | Enter the unique CTEP Group code (as listed on the CTEP Web site) from which the patient was originally registered on study.<br><br>*Note: This is required for Inter-Group trials only – otherwise leave blank.* | Use pick list. |
| Country Code ▪▪▪ | 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. |

# Enrollment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Postal Code | 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 |
| Method of Payment ▪▪▪ | Select the patient's primary method of payment using the following codes:<br><br>1- Private Insurance<br>2- Medicare<br>3- Medicare and Private Insurance<br>4- Medicaid<br>5- Medicaid and Medicare<br>6- Military or Veterans Sponsored NOS<br>6A- Military (including CHAMPUS or TRICARE)<br>6B- Veterans Sponsored<br>7- Self pay (no insurance)<br>8- No means of payment (no insurance)<br>98- Other<br>99- Unknown<br><br>*Note: Currently the only acceptable entry is "98-Other".* | Use pick list. |
| Primary Disease Site (m) ▪▪▪ | Select the primary disease site of the malignancy, using the nomenclature used by CTEP.<br><br>If the primary site is unknown, state "UNKNOWN". If the diagnosis is leukemia, enter LEUKEMIA, not bone marrow. If the diagnosis is lymphoma, enter LYMPHOMA, not lymph nodes. Do not give detailed descriptions. For example, do not state "anterior tibial surface of the left leg", state only "leg". In the case of brain lesions, give the closest anatomical description of the originating site (e.g., frontal lobe). | Use pick list. |

# Enrollment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| 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. Leave it blank otherwise.<br>• 0<br>• I<br>• I A<br>• I B<br>• I C<br>• II<br>• II A<br>• II B<br>• III<br>• III A<br>• III B<br>• III C<br>• IV<br>• IV A<br>• IV B | Use pick list. |
| Histology / Cytopathology | State briefly the type of histology or cytopathology found at the time of original diagnosis. Do not state broad categories (e.g., "lymphoma", but rather state "Non-Hodgkin's lymphoma"). | 50 characters<br>( 40 reported ) |
| Date of Confirmation of Histology | Enter the date when the patient's disease status was confirmed, at the treating institution, prior to study entry (if required by the protocol). | DD-MMM-YYYY |
| Grade of Histology | Enter the grade of histology at study entry, if appropriate. Leave it blank otherwise. | 10 characters<br>( 4 reported ) |
| Date of Diagnosis | Enter the first date of original diagnosis (e.g., when a positive biopsy or surgical result was obtained). Do not give the start date of symptoms as the date of diagnosis. | DD-MMM-YYYY or MMM-YY |

# Enrollment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Planned TAC (m) (c) ▪▪▪ | Select the appropriate code for the patient's treatment assignment as specified by CTEP. "Treatment Assignment" codes are provided by CTEP to the investigator at the time of protocol approval, and are updated as required following approval of protocol amendments. Advice on TACs is available from the CTEP's Protocol and Information Office (pio@ctep.nci.nih.gov). | Use pick list. |
| Date Informed Consent Signed (m) | Enter the date the patient signed the informed consent form. | DD-MMM-YYYY |
| Date of Informed Consent Version (m) | Enter the date of the informed consent version of the IRB-approved informed consent form that was signed by the patient at the time of study entry.<br><br>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 CDUS reporting only. | | |

# Enrollment (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| ENR01 | Date Informed Consent Signed is before Date of Birth. | Change the Date Informed Consent Signed to be after the Date of Birth. |
| ENR02, ENR03, ENR04, ENR05, ENR06, ENR17 | Date of Birth, Date of Registration, Date of Confirmation of Histology, Date of Diagnosis, Date Informed Consent Signed, Date of Informed Consent Version are in the future. | Enter a date that is prior or equals to today's date. |
| ENR07 | All Races are unchecked. | Select at least one Race. |
| ENR08, ENR09, ENR10, ENR11, ENR12 | Birth Date is after the Date of Registration, Date from which to include labs, Date of Confirmation of Histology, Date of Diagnosis, Date Informed Consent Signed, Informed Consent Version Date. | Correct the Date of Birth or the other date fields. |
| ENR13 | Date of Registration is different than Date Informed Consent Signed. | Date of Registration must be the same the Date Informed Consent Signed. |
| 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. |

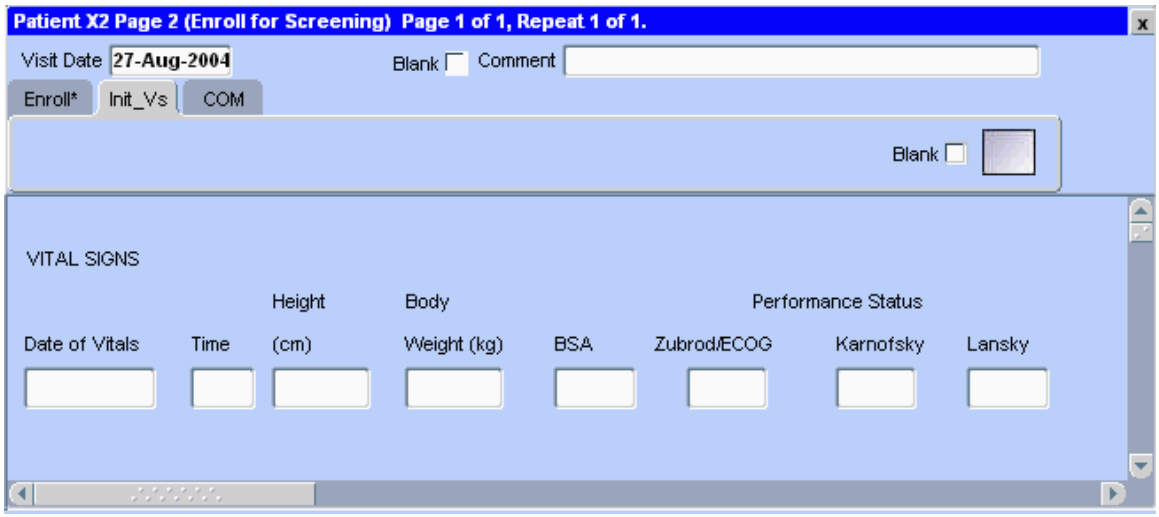
# Enrollment (cont'd)

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

Filler Page

## Enrollment eCRF

Initial Vitals tab.



# Enrollment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Date of Vitals (m) | Enter the date the vital signs were taken. | DD-MMM-YYYY |
| Time (m) | Enter the time the vital signs were taken. | HH(24):MM |
| Height | Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors. | 3 digits and 2 decimals |
| Weight | Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors. | 3 digits and 2 decimals |
| BSA | 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.<br><br>The following simple approximation may be used for persons of "normal" height and weight:<br><br>$BSA(m^2) = \sqrt{\frac{Height\ (cm)\ x Weight\ (kg)}{3600}}$ | 1 digit and 2 decimals |
| Performance Status (Karnofsky) ... | Select a value from the Karnofsky performance status scale.<br><br>0- Dead<br>10- Moribund<br>20- Very Sick<br>30- Hospitalized<br>40- Disabled<br>50- Frequent Assistance<br>60- Occasional Assistance<br>70- Self Care<br>80- Effort<br>90- Able<br>100- Normal | Use pick list. |

# Enrollment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Performance Status (Zubrod) ▪▪▪ | Select a value from the Zubrod/ECOG performance status scale.<br><br>0. Asymptomatic<br>1. Symptomatic, fully ambulatory<br>2. Symptomatic, in bed less than 50% of day<br>3. Symptomatic, in bed more than 50% of the day, but not bedridden<br>4. Bedridden | Use pick list. |
| Performance Status (Lansky) ▪▪▪ | Select a value from the Lansky performance status scale.<br><br>0- Unresponsive<br>10- No play; does not get out of bed<br>20- Often sleeping; play entirely limited to very passive activities<br>30- In bed; needs assistance even for quiet play<br>40- Mostly in bed; participates in quiet activities<br>50- Gets dressed but lies around much of the day; no active play; able to participate in all quiet play<br>60- Up and around; but minimal active play; keeps busy with quieter activities<br>70- Both greater restriction of and less time spent in play activity<br>80- Active; but tires more quickly<br>90- Minor restrictions in physically strenuous activity<br>100- Fully active, normal | Use pick list. |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

# Enrollment (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| VIT06, VIT07 | Height or Weight must be greater than zero. | Enter a positive value for Height or Weight. |
| VIT03 | Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula. | Correct the BSA.<br>The MIS BSA formula is:<br>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.<br>The Mosteller BSA formula is:<br>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. |
| VIT16 | Height and Weight were not entered. | Height or Weight should be entered. |
| VIT17 | BSA is not provided for Vital Signs inside Courses. | BSA is mandatory for Vital Signs inside Courses. |

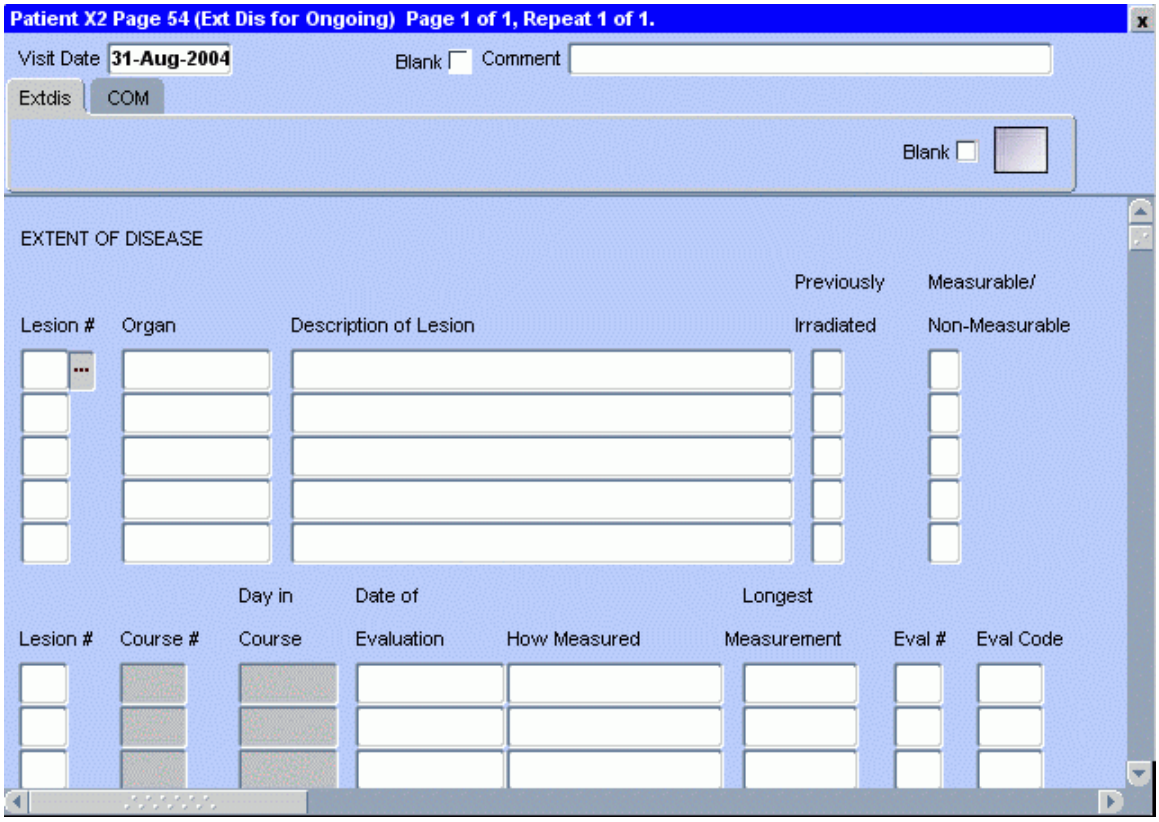
(ENROLLMENT)

# 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.<br><br>*Note: This lesion number must appear at least once on the bottom repeating group.* | Use pick list. |
| Organ (m) ... | Select the organ system where the lesion is located, i.e. Lung, Brain, etc. | Use pick list. |
| Description of Lesion (m) | Enter a brief description of the anatomical site of each lesion, e.g. right lobe. | 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. |
| Followed for Response (m) ... | Enter "Y" for target lesions that will be assessed for response (e.g. using the RECIST response criteria). Enter "N" for non target lesions. | Use pick list. |
| Lesion # (m) | Select a lesion number from the pick list.<br><br>*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 |

# Extent of Disease (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| 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. |
| Longest Measurement (m) | Enter the longest lesion measurement in centimeters (for consistency with the RECIST criteria.) | 3 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. | 2 digits |
| Evaluation Code ▪▪▪ | Select the status of non-measurable lesions at the time of each evaluation.<br><br>B- Baseline (use for the initial lesion evaluation that were when the treatment started.)<br>D- Decreasing<br>I- Increasing<br>N- New (use for lesions that appear after treatment has started.)<br>R- Resolved<br>S- Stable | 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 provided. | Lesion is marked as "Non-Measurable" cannot have an Evaluation Code. |
| EXT10 | Lesion is marked as "Measurable" and Evaluation Code is missing. | Lesion is marked as "Measurable" must have an Evaluation Code. |
| EXT11 | The initial evaluation measurement entry for a particular lesion (based on the earliest Evaluation Date of the lesion) does not have an Evaluation Number of "0". | Correct the Evaluation Date or the Evaluation Number. |
| 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. |

# 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)

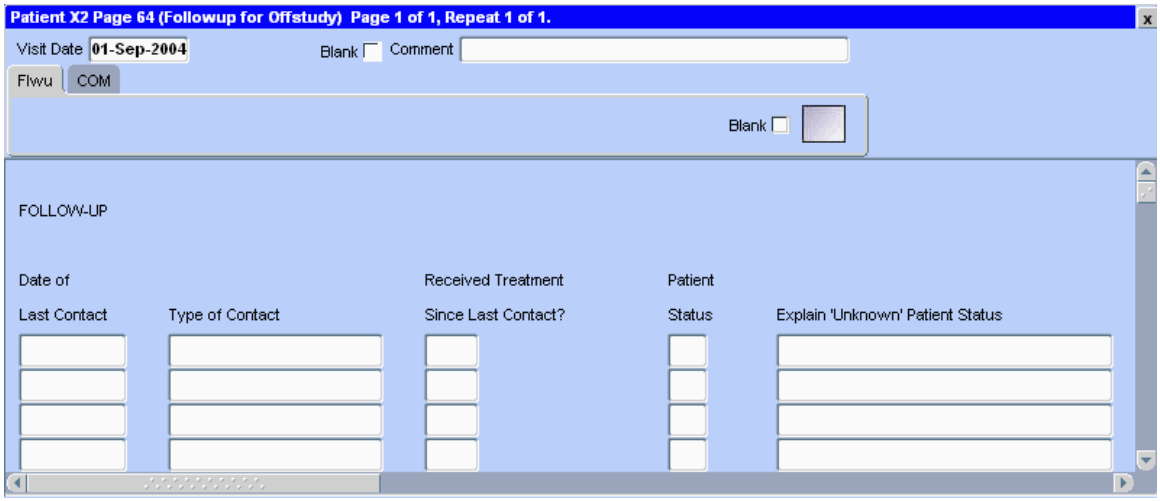
Filler Page

# Follow-up

## Purpose

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

## Follow-up eCRF



# Follow-up (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date | The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Last Contact field. | DD-MMM-YYYY |
| Date of Last Contact (m) | Enter the date the patient was last contacted.<br><br>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:<br><br>1. Telephone contact with patient<br>2. Telephone contact with patient's family<br>3. Telephone contact with patient's local physician<br>4. Social Security Death Index (SSDI)<br>5. Clinic Appointment<br>6. Mail contact with the patient<br>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<br><br>Y- Yes<br>N- No<br><br>*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)".<br><br>1. Alive with disease<br>2. Alive with no evidence of disease<br>3. Alive disease status unknown<br>4. Unknown (Explain)<br>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. |

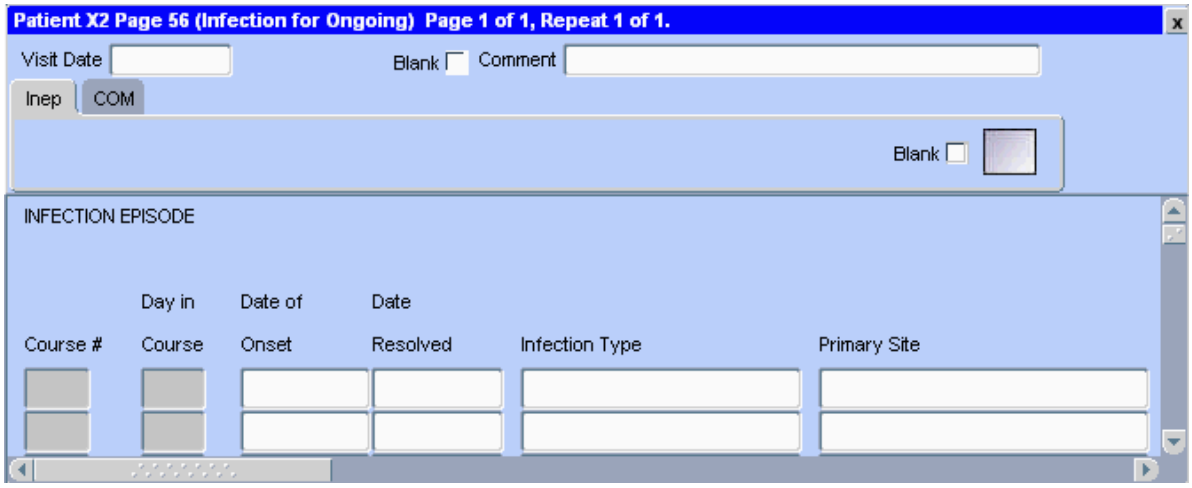
(FOLLOW-UP)

# Infection Episode

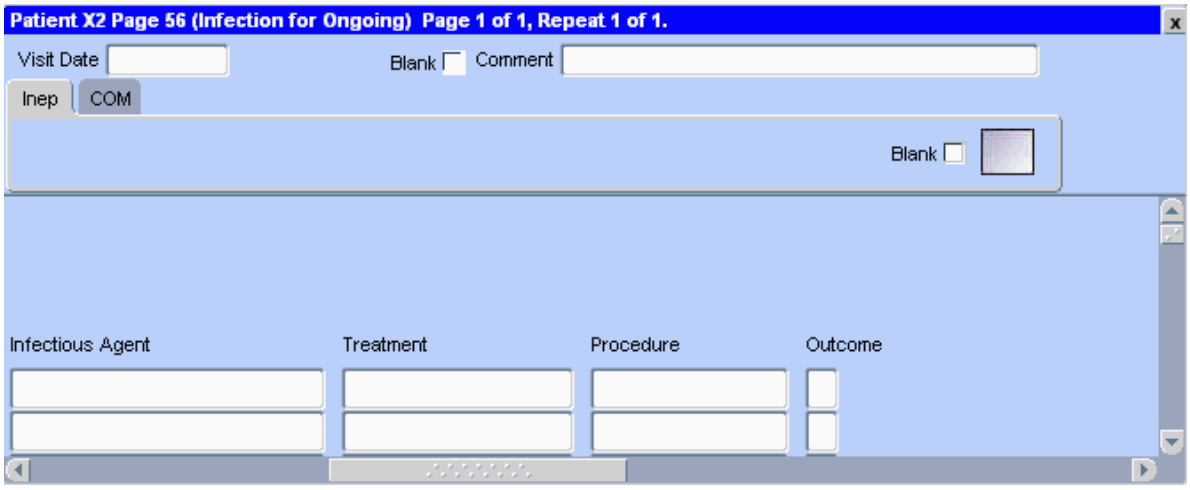
## Purpose

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.<br><br>1. Recovered<br>4. Died | Use pick list. |
| Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

# Infection Episode (cont'd)

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

# Infection Episode (cont'd)

| Derivations | | |
|---|---|---|
| **Code** | **Field Name** | **Description** |
| IFE1001 | Course # | Course number is derived based on the course initiation start dates and the infection episode Date of Onset. |
| IFE1002 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the infection episode Date of Onset. |

(INFECTION-EPISODES)

# Labs

## Purpose

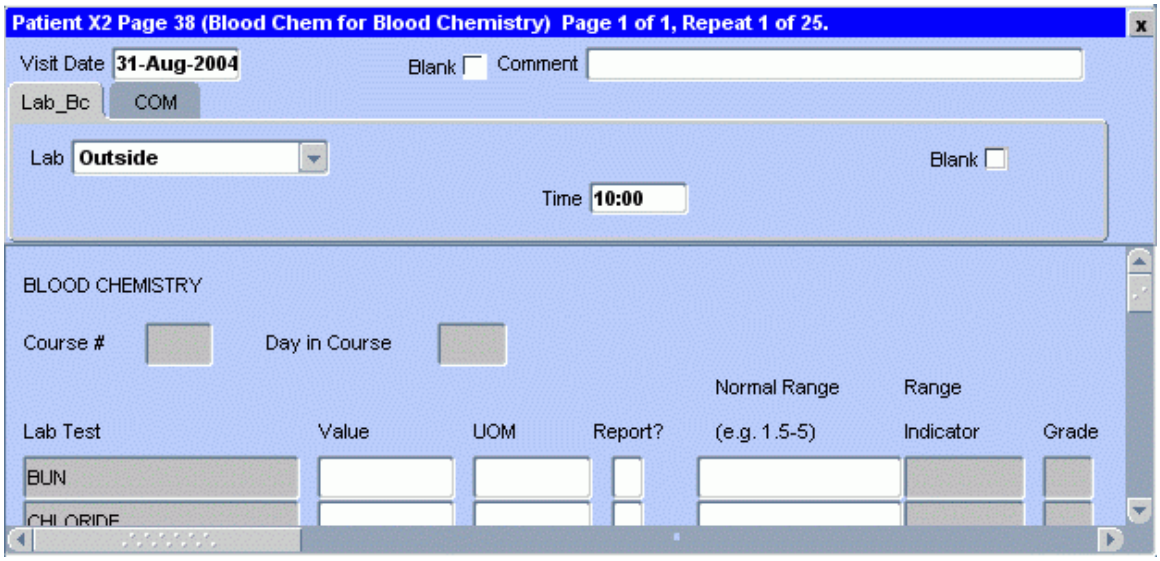
Record the patient's lab results.

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

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

| | |
|---|---|
| • Blood Chemistry<br>• Blood Gases<br>• Bone Marrow<br>• Flow Cytometry<br>• Hematology<br>• Immune Parameters<br>• Other Serum Chemistries<br>• Other Urinary Results<br>• Pulmonary Function | • Red Cell Indices<br>• Serology<br>• Serum Electro<br>• Special Literal Labs<br>• Special Numeric Labs<br>• Urinalysis<br>• Urine Immune Electro<br>• Other Labs |

## 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.<br><br>Dlm- Lab results automatically loaded from another system.<br>Dlm$Diabetic- Not in use. **Do not use.**<br>Outside- Outside lab results entered manually.<br>Respfunc- Not in use. **Do not use.** | Use pick list. |
| Course # (d) | Indicates the course number this lab is related to. | 5 digits |
| Day in Course (d) | Indicates the day since the beginning of course this lab is related to. | 5 digits |
| Lab Test (d) | Pre-defined name of the lab test. Each lab has a different set of tests which are listed at the end of this document.<br><br>*Note: The Other Labs eCRF has a pick list with the available Lab Test.* | 20 characters |

# Labs (cont'd)

<table>
<tr><th colspan="3">Field Descriptions and Instructions</th></tr>
<tr><th>Field Name</th><th>Description / Instructions</th><th>Format</th></tr>
<tr><td>Value</td><td>Enter the lab test result value. Except for Bone Marrow and Urinalysis, all other lab values are numeric.<br><br>The following coding scheme should be used for lab tests where results may be qualitative.<br><br>
<table>
<tr><th>WBC, RBC</th><th>Ketones, Bile</th></tr>
<tr><td>0. None<br>1. Few<br>2. Several<br>3. Many<br>4. Too numerous to count</td><td>0. None<br>1. +<br>2. ++<br>3. +++<br>4. ++++</td></tr>
<tr><td colspan="2">Note: these terms may be institution or lab dependent. Please be consistent throughout the protocol.</td></tr>
</table>
<br>HIV, HbsAg, Pregnancy, Stool Guiac<br>1- Positive<br>0- Negative<br><br>M-Rating<br>1-7: integer part of the standard M-Rating</td><td>20 characters.</td></tr>
<tr><td>UOM ▪▪▪</td><td>Select the appropriate lab test value units of measurement.</td><td>Use pick list.</td></tr>
<tr><td>Report ▪▪▪</td><td>Select whether the lab test result is to be sent to reporting agency.<br><br>Y- Yes<br>N- No<br><br>Note: This field is only visible and applicable to the Other Labs form. The lab tests of the Other Labs forms, listed in this documentation, have this field's value pre-define depending on the lab test and the reporting requirements.</td><td>Use pick list.</td></tr>
</table>

# Labs (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Normal Range | For labs loaded from the MIS/CRIS system, the range is automatically populated.<br><br>For labs obtained outside the NCI Clinical Center, enter the appropriate normal range. | 30 characters |
| Range Indicator (d) | Indicates how the lab result value compares to the lab test normal range.<br><br>NORMAL- Falls within the normal range.<br>HIGH- Above the normal range.<br>LOW- Below the normal range.<br>NONNUM- Not a valid number (e.g. "No Data").<br>NORANG- No normal values are provided. | 6 characters |
| Grade (d) | Derived from the lab test result value and the lab test ranges from the NCI Common Toxicity Criteria (CTC) version 2.0 or the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0.<br><br>*Note: The age and gender is also factor in some cases.* | 13 characters |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| LB01 | Lab test has a grade higher than zero or the baseline lab test grade, but no relevant Adverse Event exists. | Correct the lab grade or make sure a relevant Adverse Event exists. |
| LB02 | Lab Test with same date and time exist in Other Labs panels as well as regular lab panels (i.e. Blood Chemistry, Hematology, etc). | Review both labs and delete/correct one of them. |

# Labs (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| 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, LBBC1003, LBBM1003, LBHM1003, LBIP1003, LBOU1003, LBRC1003, LBRF1003, LBSC1003, LBSE1003, LBSR1003, LBUI1003, LBUS1003 | Course # | Course number is derived from the course initiation start date and the lab date (visit date). |
| LBAL1004, LBBC1004, LBBM1004, LBHM1004, LBIP1004, LBOU1004, LBRC1004, LBRF1004, LBSC1004, LBSE1004, LBSR1004, LBUI1004, LBUS1004 | Day in Course | Number of days since the beginning of the course is derived from the course initiation start date and the lab date (visit date). |
| Not Applicable | Lab Test | The lab tests are pre-defined. See the following table for a list of the pre-define lab tests for each lab. |
| Not Applicable | Panel # | The panel number is pre-defined and is provided on the CTMS Protocol Start-Up Letter. |
| LBAL1001, LBBC1001, LBBM1001, LBHM1001, LBIP1001, LBOU1001, LBRC1001, LBRF1001, LBSC1001, LBSE1001, LBSR1001, LBUI1001, LBUS1001 | Range Indicator | Derived based on the lab value result and normal high/low range. |
| LBAL1002, LBBC1002, LBBM1002, LBHM1002, LBIP1002, LBOU1002, LBRC1002, LBRF1002, LBSC1002, LBSE1002, LBSR1002, LBUE1002, LBUS1002 | Grade | Derived from the lab test result value and the lab test normal range. |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| BLOOD CHEMISTRY | BUN | Blood Urea Nitrogen, Serum |
| | CREATININE | Creatinine, Serum |
| | SODIUM | Sodium, Serum |
| | POTASSIUM | Potassium, Serum |
| | CHLORIDE | Chloride, Serum |
| | MAGNESIUM | Magnesium, Serum |
| | BICARB_SERUM | Bicarbonate, Serum |
| | URIC_ACID | Uric Acid, Serum |
| | BILIRUBIN_TOTAL | Bilirubin, Total, Serum |
| | ALK_PHOS | Alkaline Phosphatase, Serum |
| | SGOT_AST | SGOT/AST, Serum |
| | SGPT_ALT | SGPT/ALT, Serum |
| | SGGT | GGT, Serum |
| | LDH | Lactate Dehydrogenase, Serum |
| | TOT_PROT | Protein, Serum |
| | ALBUMIN_SERUM | Albumin, Serum |
| | GLOBULIN | Globulin, Serum |
| | CALCIUM | Calcium, Serum |
| | INORG_PHOS | Phosphorus, Inorganic, Serum |
| | GLUC_FASTING | Glucose, Fasting, Serum |
| | GLUC_NONFASTING | Glucose, Nonfasting, Serum |
| | CHOLESTEROL_TOTAL | Cholesterol, Total, Serum |
| | AMYLASE_SERUM | Amylase, Serum |
| | 5_NUCLEOTIDASE | 5'Nucleotidase, Serum |
| | CPK | Creatine Kinase, Serum |
| BLOOD GASES | PH_BLOOD | Ph, Blood |
| | PCO2 | PCO2, Blood |
| | PO2 | Po2, Blood |
| | BICARB | Bicarbonate, Respiratory |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | BASE_EXCESS | Base Excess, Blood |
| | BASE_DEFICIT | Base Deficit, Blood |
| | OXYGEN_SATURATION | Oxygen Saturation, Blood |
| PULMONARY FUNCTION | CO | Carboxyhemoglobin (CO), Serum |
| | METHEMOGLOBIN | Methemoglobulin, Blood |
| | VITAL_CAPACITY | Pulmonary Function |
| | EXPIRATORY_VOL | Expiratory Volume, Respiratory |
| | MAX_CAPACITY | Pulmonary Function |
| | RESIDUAL_VOLUME | Pulmonary Function |
| | TIDAL_VOLUME | Pulmonary Function |
| | FUNC_RESIDUAL_CAP | Functional Residual Capacity, Respiratory |
| | PULM_COMPLIANCE | Pulmonary Function |
| | DIFFUSING_CAPACITY | Dlco, Respiratory |
| | MAX_FXP_FLOW | Pulmonary Function |
| | MAX_MID_FXP_FLOW | Pulmonary Function |
| BONE MARROW | MYELOBLASTS | Myeloblasts,%, Bone Marrow |
| | PROMYELOCYTES | Promyelocytes, %, Bone Marrow |
| | MYELOCYTES_NEUTROS | Neutrophilic Myelocytes, %, Bone Marrow |
| | MYELOCYTES_EOSINOS | Eosinophilic Myelocytes, %, Bone Marrow |
| | MYELOCYTES_BASOS | Basophilic Myelocytes, %, Bone Marrow |
| | METAMYELOCYTES | Metamyelocytes, Bone Marrow |
| | POLYMORPHS_NEUTROS | Polymorphic Neutrophils, Bone Marrow |
| | POLYMORPHS_EOSINOS | Polymorphic Eosinophils, Bone Marrow |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | POLYMORPHS_BASOS | Polymorphic Basophils, Bone Marrow |
| | LYMPHOCYTES | Lymphocytes, %, Bone Marrow |
| | PLASMA_CELLS | Plasma Cells, Bone Marrow |
| | MONOCYTES | Monocytes, %, Bone Marrow |
| | RETICULUM_CELLS | Reticulum Cells, %, Bone Marrow |
| | MEGAKARYOCYTES | Megakaryocytes, Bone Marrow |
| | PRONORMOBLASTS | Pronormoblasts, %, Bone Marrow |
| | NORMOBLASTS | Normoblasts, %, Bone Marrow |
| | CELLULARITY | Cellularity, bone marrow |
| | M_RATING | M Rating |
| FLOW CYTOMETRY | FMC7_BLD | FMC7, blood |
| | MNC_BLD | MNC, blood |
| | CD56_BLD | CD56, blood |
| | CD8_BLD | CD8, blood |
| | CD4_BLD | CD4, blood |
| | LAMBDA_LC_BLD | LAMBDA, blood |
| | KAPPA_LC_BLD | KAPPA, blood |
| | CD11C_BLD | CD11C, blood |
| | CD5_BLD | CD5, blood |
| | CD10_BLD | CD10, blood |
| | CD19_BLD | CD19, blood |
| | CD20_BLD | CD20, blood |
| | CD22_BLD | CD22, blood |
| | CD23_BLD | CD23, blood |
| | CD25_BLD | CD25, blood |
| | CD103_BLD | CD103, blood |
| HEMATOLOGY | HEMOGLOBIN | Hemoglobin, Blood |
| | HEMATOCRIT | Hematocrit, Blood |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | WBC_SERUM | WBC, Blood |
| | BANDS | Bands, #, Blood |
| | NEUT | Neutrophils, %, Blood |
| | LYMPHOCYTES_SERUM | Lymphocytes, %, Blood |
| | BASO | Basophils, #, Blood |
| | MONOCYTES_SERUM | Monocytes, %, Serum |
| | EOSIN | Esoinophils, %, Blood |
| | BLAST_CELLS | Blast Cells, #, Blood |
| | A_LYMPH | Lymphs, Atypical, #, Blood |
| | OTHR_DIFF | Other – Diff. |
| | PLT | Platelets, Blood |
| | ANC | Neutrophil Count, #, Blood |
| | RBC_SERUM | RBC, Blood |
| | RETIC | Reticulocytes, Blood |
| | ESR | Erythrocyte Sedimentation Rate, Blood |
| | PT | PT, Automated, Blood |
| | PTT | PTT, Automated, Blood |
| IMMUNE PARAMETERS | LYMPHOCYTE_BLASTS | Lymphoblasts, %, Blood |
| | B_CELL_LEVEL | B Cell, Serum |
| | T_CELL_TOT | Total T-Cells, Blood |
| | T_CELL_HELPER | Helper T-Cells, Blood |
| | T_CELL_SUPPRESSOR | Suppressor T-Cells, Blood |
| | T_CELL_DTH | DTH T-Cells, Blood |
| | T_CELL_CTL | CTL T-Cells, Blood |
| | NK_ACTIVITY | Normal Killed Cells, Blood |
| | ADCC | ADCC, Immune Pathology |
| | MACROS_CYTOTXITY | Macrophage Cytotoxicity |
| | MACROS_CYTOSTASIS | Macrophage Cytostasis |
| | PEROXIDE_GENERATION | Peroxide Generation, Blood |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | SERUM_INTERFERON | Interferon, Serum |
| OTHER SERUM CHEMISTRIES | ALDOLASE | Aldolase, Serum |
| | AMMONIA | Ammonia, Serum |
| | CALCIUM_IONIZD_SERUM | Calcium, Ionized, Serum |
| | COPPER_SERUM | Copper, Serum |
| | FERRITIN | Ferritin, Serum |
| | HDL | High Density Lipoprotein Cholesterol, Serum |
| | INSULIN | Insulin, Serum |
| | IRON_SERUM | Iron, Serum |
| | IRON_BINDING_CAP | Iron Binding Capacity, Total, Serum |
| | IRON_SATURATION | Iron Saturation, Serum |
| | LDL | Low Density Lipoprotein Cholesterol, Direct, Serum |
| | LIPASE_SERUM | Lipase, Serum |
| | OSMOLALITY_SERUM | Osmolality, Urine |
| | ACID_PHOSPHATASE | Acid Phosphatase, Serum |
| | TRANSFERRIN | Transferrin, Serum |
| | TRIGLYCERIDES | Triglycerides, Serum |
| | T3 | T3, Serum |
| | T4 | T4 (Thyroxine), Serum |
| | TSH | Thyroid Stimulating Hormone, Serum |
| OTHER URINARY RESULTS | CALCIUM_URINE | Calcium, Urine |
| | CHLORIDE_URINE | Chloride, Urine |
| | OSMOLALITY_URINE | Osmolarity, Urine |
| | OXALATE_URINE | Oxalate, Urine |
| | POTASSIUM_URINE | Potassium, Urine |
| | PROTEIN_ALBUMIN | Protein Albumin, Urine |
| | PROTEIN_ALPHA_1 | Protein Alpha 1, Urine |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | PROTEIN_ALPHA_2 | Protein Alpha 2, Urine |
| | PROTEIN_BETA | Protein Beta, Urine |
| | PROTEIN_GAMMA | Protein Gamma, Urine |
| | SODIUM_URINE | Sodium, Urine |
| | UREA_NITROGEN_URINE | Urea Nitrogen, Urine |
| | URIC_ACID_URINE | Uric Acid, Urine |
| RED CELL INDICES | MCH | MCH, Blood |
| | MCHC | MCHC, Blood |
| | MCV | MCV, Blood |
| | BLEEDING_TIME | Bleeding Time Pt, Blood |
| | CLOT_RETRACTION_SCR | Clot Retraction, Blood |
| | SEMI_QUANT | Semi Quantitative |
| | QUANTITIVE | Quantitative |
| | CLOTTING_TIME | Clotting Time, Blood |
| | FDP | Fbrin(ogen) Split Product, Blood |
| | FIBRINOGEN | Fibrinogen, Auto, Plasma |
| | THROMBIN_TIME | Thrombin Time, Blood |
| | NUCLEATED_RBC | Nucleated RBCs, Blood |
| | COMPLEMENT | Complement Level CH50, Serum |
| | COOMBS_TEST | Coombs, Blood |
| | ANF | Atrial Natriuretic Factor, Blood |
| | TOT_SERUM_PROTEIN | Protein, Serum |
| | ALBUMIN | Albumin, Serum |
| | ALPHA_1 | Alpha-1 Antitrypsin, Serum |
| | ALPHA_2 | Alpha-2 Antitrypsin, Red Cells |
| | BETA | Beta, Red Cell |
| | GAMMA | Gamma, Red Cell |
| SEROLOGY | PSA | PSA, Serum |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | CA125 | CA-125, Serum |
| | CEA | Carcino-Embryonic Antigen (CEA), Serum |
| | CA19_9 | CA 19-9, Serum |
| | CA15_3 | CA 15-3, Serum |
| | CA27_29 | CA 27-29, Serum |
| | AFP | Alpha-fetoprotein, Serum |
| | HCG | Human Chorionic Gonadotropin, Serum |
| | HIV | HIV 1-2 Antibody, Serum |
| | HBS_AG | Hepatitis B Surface Antigen Antibody, Serum |
| | PREGNANCY | BHCG, Serum |
| | STOOL_GUAIAC | Guaiac, Stool |
| | NEUT_ANTI_BL22_SER | Neutralizing Antibody BL22, Serum |
| SERUM ELECTRO | IG_A_SERUM | Immunoglobulin A, Serum |
| | IG_D_SERUM | Immunoglobulin D, Serum |
| | IG_E_SERUM | Immunoglobulin E, Serum |
| | IG_G_SERUM | Immunoglobulin G, Serum |
| | IG_M_SERUM | Immunoglobulin M, Serum |
| | MONOCLONAL_SERUM | Monoclonal, Serum |
| | POLYCLONAL_SERUM | Polyclonal, Serum |
| | KAPPA_SERUM | Kappa, Serum |
| | LAMBDA_SERUM | Lambda, Serum |
| | BENCE_JONES_SERUM | Bence-Jones Protein, Serum |
| URINALYSIS | CREATININE_CLEARANCE | Creatinine Clearance, Urine |
| | PH_URINE | pH, Urine |
| | SPECIFIC_GRAVITY | Specific Gravity, Urine |
| | WBC_URINE | WBC, Micro, Urine |
| | RBC_URINE | RBC, Micro, Urine |

# Labs (cont'd)

| Lab Tests | | |
|---|---|---|
| **Lab** | **Test** | **Description** |
| | CASTS | Casts, Urine |
| | GLUCOSE | Glucose, Urine |
| | PROTEIN | Protein, Serum |
| | KETONES | Ketones, Urine |
| | BILE | Bile, Urine |
| | CREATININE_URINE | Creatinine, Urine |
| | VOLUME_URINE | Volume, Urine |
| | COLLECTION_PERIOD | Collection period, urinalysis |
| URINE IMMUNE ELECTRO | IG_A_URINE | Immunoglobulin A, Urine |
| | IG_D_URINE | Immunoglobulin D, Urine |
| | IG_E_URINE | Immunoglobulin E, Urine |
| | IG_G_URINE | Immunoglobulin G, Urine |
| | IG_M_URINE | Immunoglobulin M, Urine |
| | MONOCLONAL_URINE | Monoclonal, Urine |
| | POLYCLONAL_URINE | Polyclonal, Urine |
| | KAPPA_URINE | Kappa, Urine |
| | LAMBDA_URINE | Lambda, Urine |
| | BENCE_JONES_URINE | Bence-Jones Protein, Urine |
| OTHER LABS | Not applicable. Select a lab test from the pick list. | Not applicable. |
| SPECIAL LITERAL LABS | Tests are protocol specific and listed on the CTMS Protocol Start-up Letter. | Not applicable. |
| SPECIAL NUMERIC LABS | Tests are protocol specific and listed on the CTMS Protocol Start-up Letter. | Not applicable. |

(LABS)

Filler Page

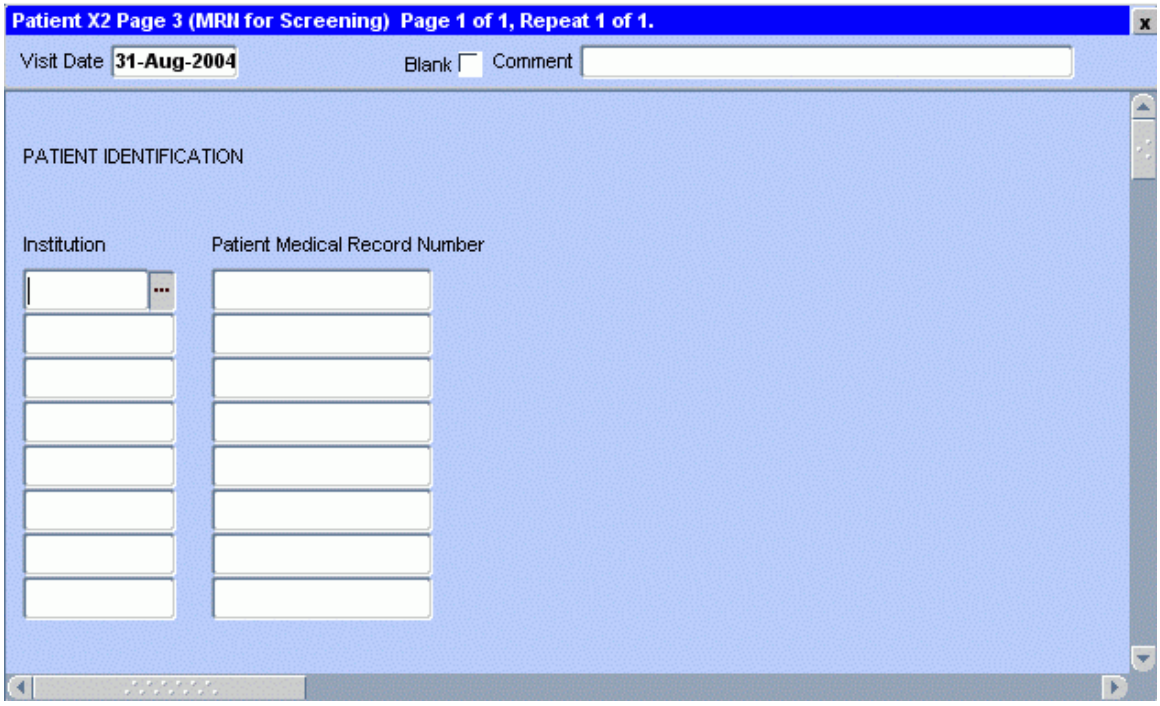
# Medical Record Numbers

## Purpose

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

Lab data electronically loaded rely on the medical record numbers entered in this case report form.

## 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::<br><br>99-99-99-9<br><br>For NCINAV and other institutions, enter the medical record number following the institution's format.<br><br>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 | Institution starts with NCI (except for NCINAV) and Patient Medical Record Number does not have 10 characters. | For Institutions starting with NCI (except NCINAV) the Patient Medical Record Number must be entered in the following format:<br>99-99-99-9 |
| MRN02 | Institution starts with NCI (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

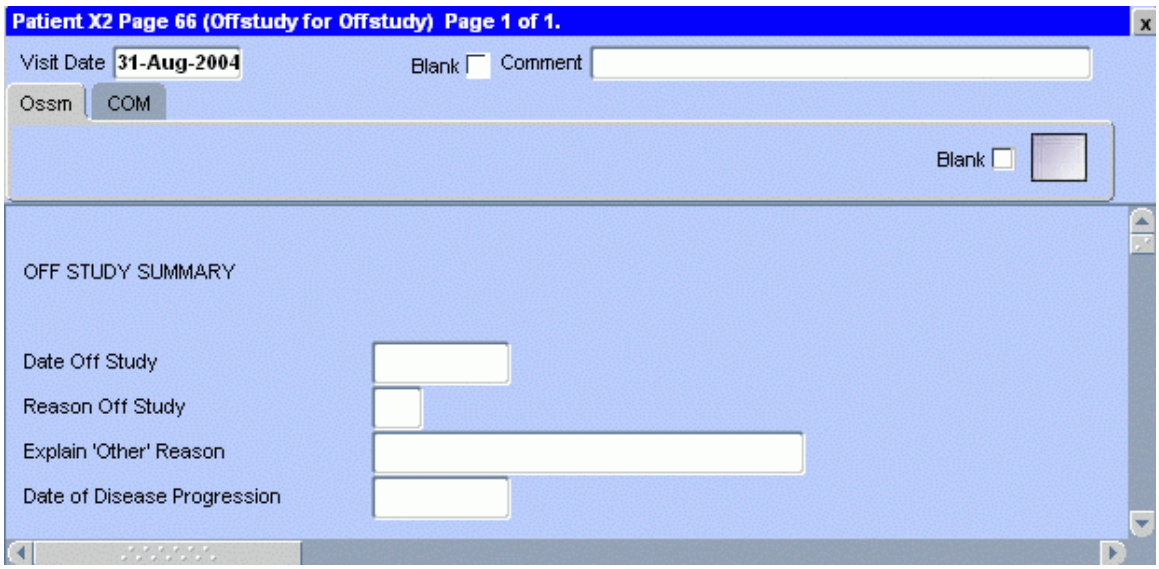
Record information concerning the patient's off study date and reason. Complete this form after the patient has been taken off study.

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.<br><br>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**.<br><br>The date off study will correspond to a progress note in the medical record stating that the patient has been taken off study. | 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**.<br><br>For protocols with a follow-up period, the following off study reasons are also available.<br><br>**Y-** Completed treatment period but refused the Protocol-Specified Follow-up. Date Off Treatment and Date Off Study must be the same.<br>**H-** **Follow-up Period Completed**: The patient completed all protocol specified follow-up evaluations.<br>**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 certificate letter, checking SSDI.<br>**W-** **Refused Further Follow-up**: The patient has refused to have any further follow-up | Use pick list. |

# Off Study (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | evaluations.<br>**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).<br>**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'.<br>**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.<br><br>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.<br><br>*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. |

(OFF-STUDY)

Filler Page

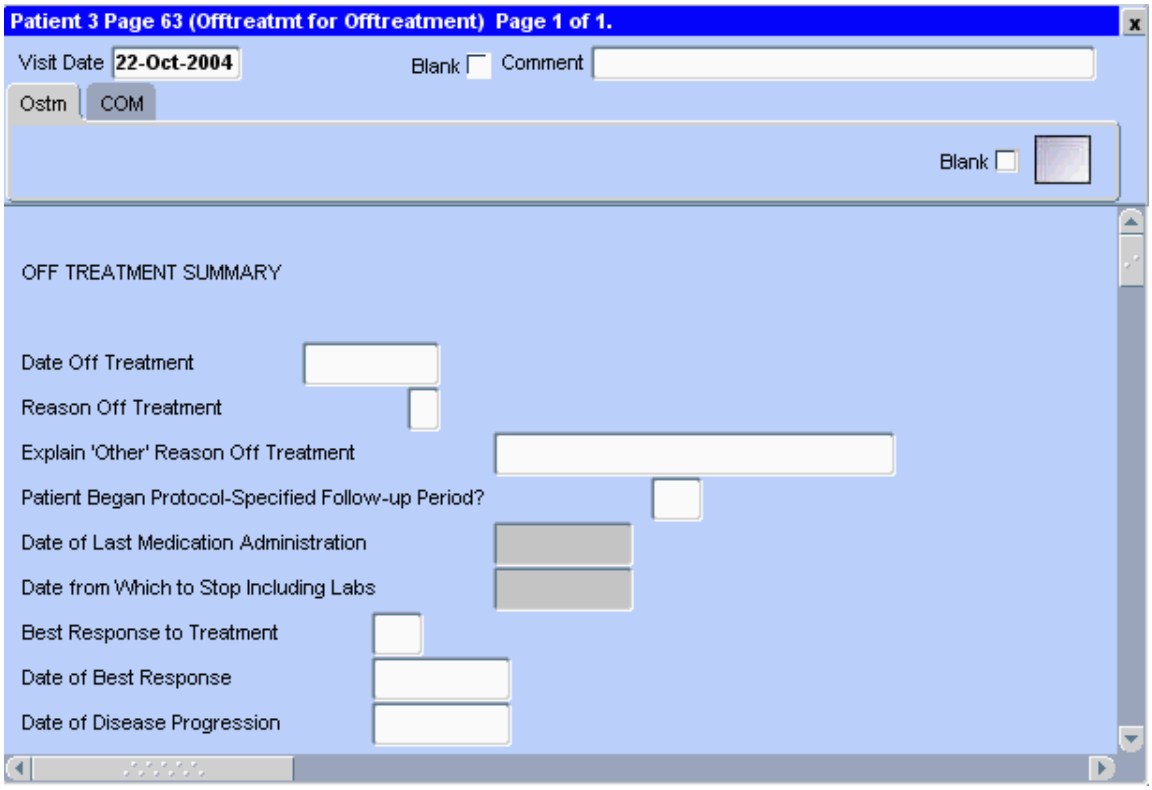
# Off Treatment

## Purpose

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

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

## Off Treatment eCRF



# Off Treatment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Enter the date the form is being completed. | DD-MMM-YYYY |
| Date Off Treatment (m) | Enter the date when all courses have been completed (including the normal observation period) or discontinued and no further treatment courses are planned. This date will correspond to the clinic visit that would have served as the pre-course visit had the patient continued on therapy. This is the date the patient has been officially taken off treatment. | DD-MMM-YYYY |
| Reason Off Treatment (m) | Select an off treatment reason from one of the following reason groups:<br><br>1) If the patient's participation has been completed as per protocol, and the protocol does not specify a follow-up observation period, select:<br><br>**C- Study Completed**<br><br>*Note: Option 'C' is only available for studies without a follow-up period.*<br><br>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:<br><br>**X- Patient Declined to Participate** (before treatment started.)<br>**B- Disease Progression before Treatment.**<br>**Z- No Treatment, per protocol.**<br>**U- Not Treated - Other Reasons, explain** - Enter an explanation in the Reason Other field.<br><br>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.**<br>**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.<br>**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.<br>**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.<br>**G- Cytogenetic Resistance.**<br>**A- Switched to Alternative Treatment:** The patient was taken off treatment due to a decision to pursue alternative therapy (such as palliative radiation)**.**<br>**R- Refused Further Treatment:** If at any time the patient refused further treatment.<br>**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.<br>**V- Protocol Violation:** If a major protocol violation has occurred, the reason must be stated in the Comments part of this case report form.<br>**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.<br><br>4) When the patient completes protocol-specified treatment period, select the following:<br><br>**Q- Treatment Period Completed**<br><br>*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. | 24 characters |
| Patient Began Protocol Specified Follow-up (m) | Indicate whether or not the patient began the protocol-specified follow-up period.<br><br>Y- Yes<br>N- No<br><br>*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 |

# Off Treatment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Date from Which to Stop Including Labs (d) | Indicates when lab data stops being loaded. It is the same date as the Date Off Treatment. **Any lab data after this date must be entered manually.**<br><br>*Note: If the Date Off Treatment is not provided or this form is not completed in a timely manner, lab data will continue until the Date Off Treatment is provided.* | DD-MMM-YYYY |
| Best Response to Treatment (m) | Select the best overall response to treatment while on protocol.<br><br>CR- Complete response<br>MR- Less than partial response<br>NA- Not assessed<br>NE- Not evaluable<br>NP- Not applicable per protocol<br>PD- Progressive disease<br>PR- Partial response<br>SD- Stable disease<br>TE- Too early to access, per protocol<br><br>According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression.<br><br>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.<br><br>**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".<br><br>If response was not assessed at all during the protocol treatment, enter the best response as NA; similarly for NE and NP. | Use pick list. |

# Off Treatment (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| | RECIST: Unless the protocol includes specific response evaluation criteria, the following RECIST and WHO guidelines should be observed:<br><br>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.<br><br>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.**<br><br>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.<br><br>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** |
| OSS10<br>OSS12<br>OSS13 | 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. |
| OSS15 | 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. |
| OSS05 | Best Response to Treatment is not 'Disease Progression' and Date of Best Response is missing. | If anything other than 'Disease Progression' is checked for Best Response to Treatment, then Date of Best Response must be entered. |

# Off Treatment (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| OSS07 | 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. |
| OSS08 | 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). |
| OSS09 | 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). |
| OSS16 | 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. |
| OSS17 | 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. |
| OSS26 | 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. |

| Derivations | | |
|---|---|---|
| **Code** | **Field Name** | **Description** |
| OSS1001 | Date from Which to Stop Including Labs | Indicates when lab data stops being loaded. It is the same date as the Date Off Treatment. |
| OSS1002 | Date of Last Medication Administration | Indicates date the last medication was administered. |

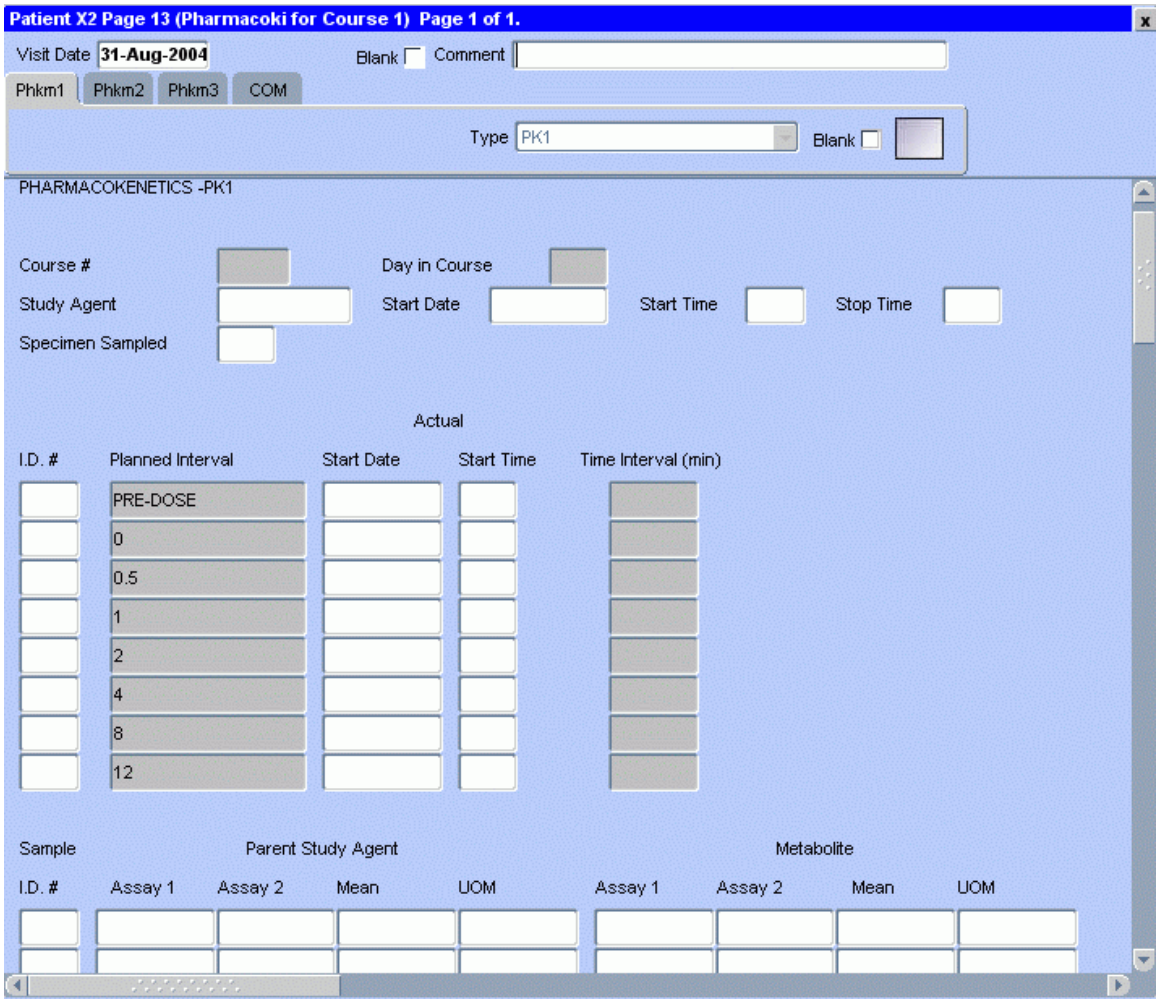
(OFF-TREATMENT)

# 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.<br><br>*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 Time (m) | Enter the time the study agent administration was stopped. | HH(24):MM |
| Specimen Sampled (m) ... | Select the body fluid that is being collected for the biological samples.<br><br>A- Apheresis Cells<br>B- Whole Blood<br>C- Cerebrospinal<br>M- Peripheral Blood Mononuclear Cells<br>P- Plasma<br>S- Serum<br>V- Saliva<br><br>*Note: Urine sample collection will be documented on the Urinary Excretion Case Report Form.* | Use pick list. |

# Pharmacokinetics (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Sample ID Number (m) | 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. | 3 digits |
| Planned Interval | Planned interval pre-determined per protocol. | 8 characters |
| Sample Date (m) | Enter the specimen collection date. | DD-MMM-YYYY |
| Sample Time (m) | Enter the specimen collection time. | HH(24):MM |
| Time Interval (d) | Actual interval in minutes from the study agent start time. | 8 digits |
| Sample ID Number (m) | 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. | 3 digits |
| Parent Study Agent Assay 1 | Enter the results of the parent assay for the study agent indicated in the study agent field.<br><br>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.<br><br>*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. |

# Pharmacokinetics (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| 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.<br><br>*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. | | |

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| PHM01 | Start Date is less than or equal to the Enrollment Date of Registration. | Start Date must be after the Enrollment Date of Registration. |
| PHM02 | Start Date is in the future. | Enter a date earlier than or equal to the current date. |
| PHM03 | Sample ID number is repeated. | Sample ID number must be unique. |
| PHM04 | Sample ID number in the assays/metabolites repeating group not found in the planned intervals repeating group. | Sample ID number must appear on both planned interval and assays/metabolites repeating groups. |
| 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. |

# Pharmacokinetics (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| PHM06 | Parent Study Agent UOM entered, but Assay 1, Assay 2 and Mean Concentration are missing. | Enter a Parent Study Agent Assay 1, Assay 2 and/or Mean Concentration. |
| PHM07 | Parent Study Agent Assay 1, Assay 2 and/or Mean Concentration entered, but UOM is missing. | Enter the Parent Study Agent UOM. |
| PHM08 | Metabolite UOM entered, but Assay 1, Assay 2 and Mean Concentration are missing. | Enter a Metabolite Assay 1, Assay 2 and Mean Concentration. |
| PHM09 | Metabolite Assay 1, Assay 2 and/or Mean Concentration entered, but UOM is missing. | Enter the Metabolite UOM. |
| PHM10 | No Parent Study Agent and Metabolite results and UOM were provided. | At least one Parent Study Agent or Metabolite results, with respective UOM, are required. |

| 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. |

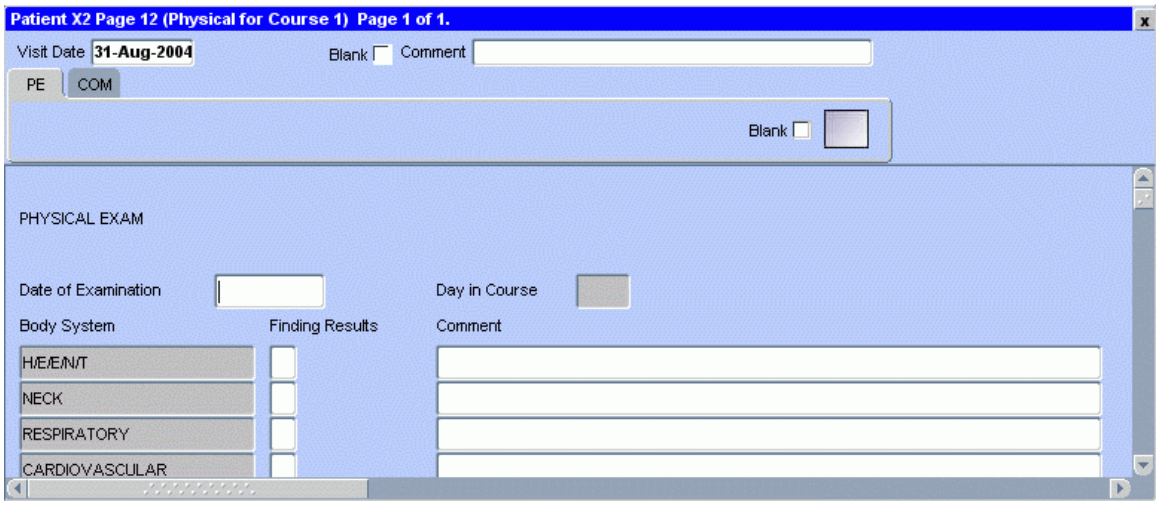
Filler Page

# Physical Exams - Courses

## Purpose

Record follow-up physical exam results.

## 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 |
| Date of Examination (m) | 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 |
| Finding Results (m) ▪▪▪ | Indicate whether the finding results for the particular body system were either:<br><br>N- Normal<br>A- Abnormal<br>X- Not Examined<br><br>Comments are required for abnormal finding results.<br><br>*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).*<br><br>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 has changed from baseline, give a brief description of the change.<br><br>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. |
| PE02 | Comment is specified and Finding Results is not marked abnormal. | Change the Finding Results to abnormal or remove the comments. |
| 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. |
| PE05 | At least one Finding Results was not provided. | All Finding Results must be provided. |

| 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)

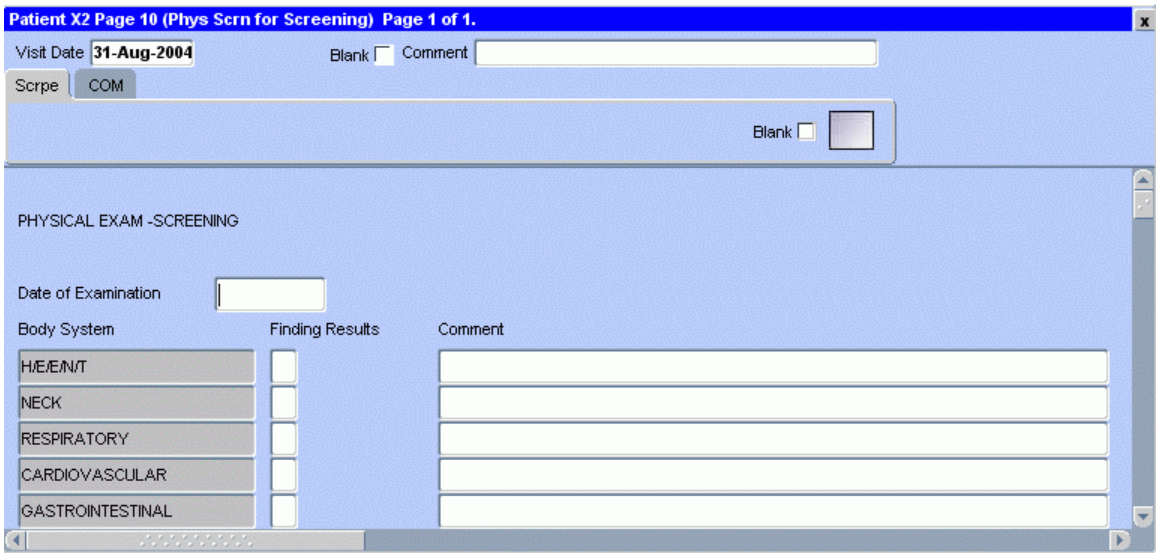
Filler Page

# 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 |
| Date of Examination (m) | Enter the date the physical examination took place. | DD-MM-YYYY |
| Finding Results (m) ▪▪▪ | Indicate whether the finding results for the particular body system were either:<br><br>N- Normal<br>A- Abnormal<br>X- Not Examined<br><br>Comments are required for abnormal finding results.<br><br>*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.<br><br>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. |
| PE02 | Comment is specified and Finding Results is not marked abnormal. | Change the Finding Results to abnormal or remove the comments. |
| PE04 | Date of Examination is in the future. | Enter an earlier date. |
| PE05 | At least one Finding Results was not provided. | All Finding Results must be provided. |

(PHYSICAL-EXAMS-SCREENING)

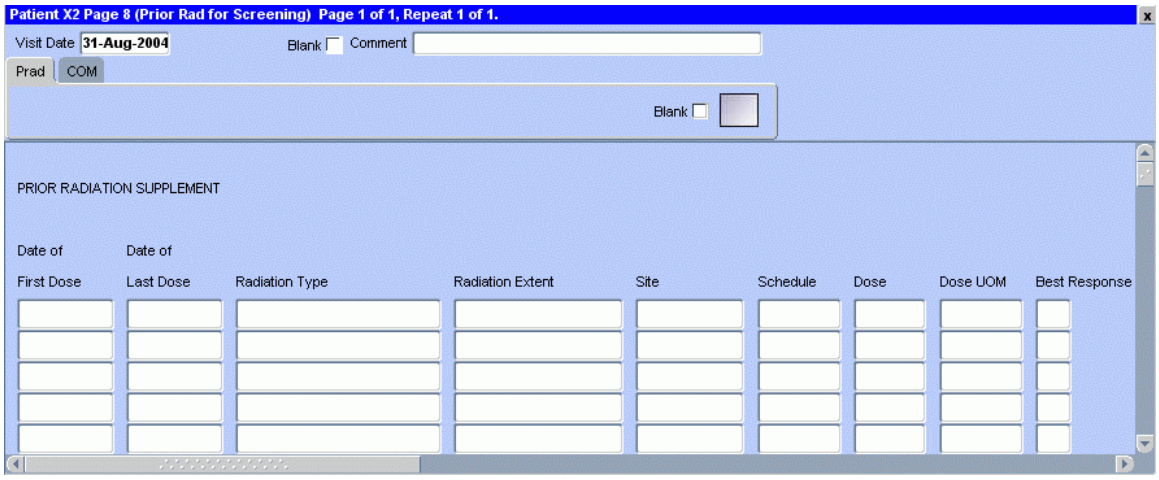
Filler Page

# Prior Radiation Supplement

## Purpose

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

## Prior Radiation Supplement eCRF



# Prior Radiation Supplement (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Enter the date the form was completed.<br><br>*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 (m) ... | Enter the date of the last dose of the radiation therapy. Partial dates are acceptable when the day is not known.<br><br>If the date of last dose is not available, select:<br><br>Ongoing- if the therapy is currently being received. | DD-MMM-YYYY, MMM-YYYY or Use pick list. |
| Radiation Type (m) ... | Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant". | Use pick list. |
| Radiation Extent (m) ... | Select the extent of the radiation therapy as follows:<br><br>LR- Limited Radiation: therapy using ionizing radiation to a limited (<50%) portion of the body.<br>ER- Extensive Radiation: therapy using ionizing radiation to a significant portion of the body (>50%), e.g. cardiospinal, pelvic, or total-body.<br>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. | Use pick list. |
| Radiation Dose | State the total radiation dose the patient received during the treatment period. | 8 characters |

# Prior Radiation Supplement (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Radiation Dose UOM ▪▪▪ | Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem). | Use pick list. |
| Best Response (m) ▪▪▪ | Select the best response for the irradiated lesion:<br>CR- Complete Response<br>PR- Partial Response<br>MR- Minimal/Marginal Response<br>SD- Stable Disease<br>PD- Progressive Disease<br>AJ- Adjuvant Therapy<br>PA- Palliative Therapy<br>NE- Not Evaluable<br>NA- Not Assessed<br>UK- Unknown | Use pick list. |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

| 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. |

(PRIOR-RADIATION-SUPPLEMENT)

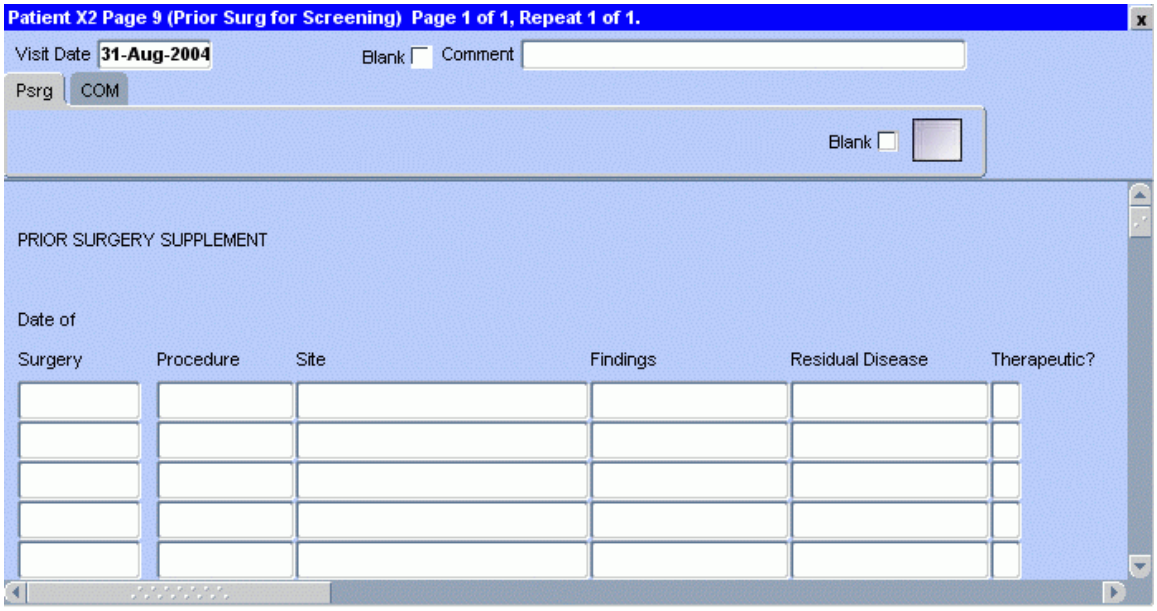
Filler Page

# Prior Surgery Supplement

## Purpose

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

## Prior Surgery Supplement eCRF



# Prior Surgery Supplement (cont'd)

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

# Prior Surgery Supplement (cont'd)

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

(PRIOR-SURGERY-SUPPLEMENT)

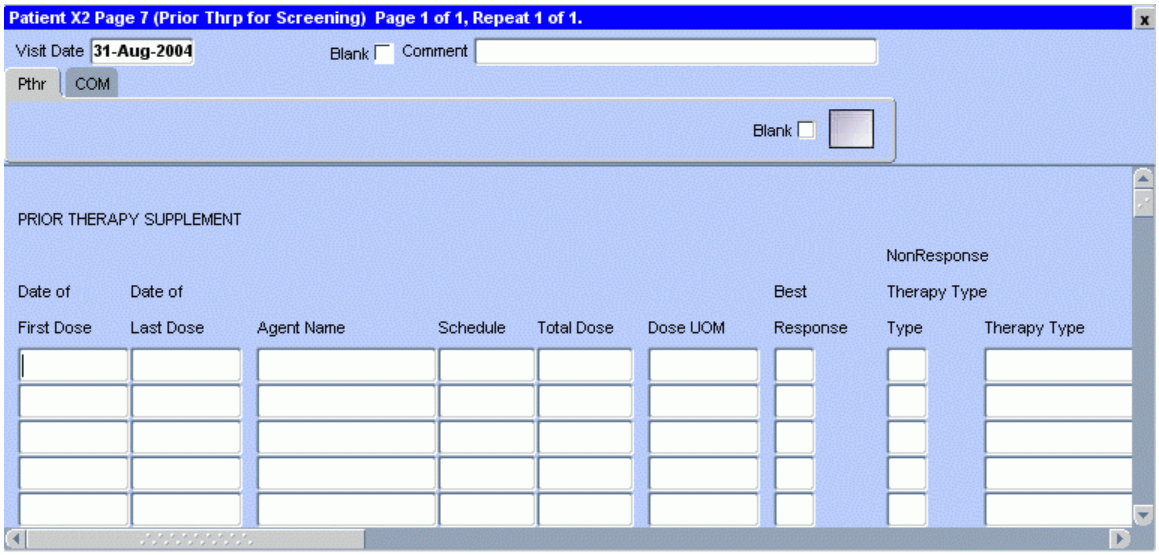
Filler Page

# Prior Therapy Supplement

## Purpose

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

## Prior Therapy Supplement eCRF



# Prior Therapy Supplement (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Enter the date the form was completed (i.e. the date information was gathered). | DD-MMM-YYYY |
| Date of First Dose (m) ... | Enter the date of the first dose of the prior therapy. Partial dates are acceptable when the day is not known. | DD-MMM-YYYY or MMM-YYYY |
| Date of Last Dose (m) ... | Enter the date of the last dose of the prior therapy. Partial dates are acceptable when the day is not known.<br><br>If the date of last dose is not available, select:<br><br>Ongoing- if the treatment is currently being received. | DD-MMM-YYYY, MMM-YYYY or Use pick list. |
| Agent Name (m) ... | Select the generic name of the agent that was used. In the case of a standard regimen of multiple agents, the conventional abbreviation for the regimen (i.e., MOPP, CHOP, CAF, etc.) may be used. | Use pick list. |
| Schedule ... | Select the schedule on which the agent (or combination) was given. | Use pick list. |
| Total Dose | Enter the total dose of the agent. If a combination regimen, record the total dose of the relevant agent (e.g. doxorubicin in CHOP). | 8 characters |
| Total Dose UOM ... | Enter the total dose units of measurement. | 5 digits |

# Prior Therapy Supplement (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Best Response (m) ▪▪▪ | Select the best response encountered:<br><br>AJ- Adjuvant Therapy<br>CR- Complete Response<br>MR- Minimal/Marginal Response<br>NA- Not Assessed<br>NE- Not Evaluable<br>PA- Palliative Therapy<br>PD- Progressive Disease<br>PR- Partial Response<br>SD- Stable Disease<br>UK- Unknown | Use pick list. |
| Therapy Type (m) ▪▪▪ | Select the appropriate type of prior therapy:<br><br>AR- Anti-Retroviral Therapy<br>AS- Antisense Therapy<br>BM- Bone Marrow<br>C- Chemotherapy (NOS)<br>CM- Chemotherapy multiple agents<br>CS- Chemotherapy single agent<br>G- Gene Transfer<br>H- Hormonal Therapy<br>I- Immunotherapy<br>NC- Non-Cytotoxic Chemo<br>OC- Oncolytic Virotherapy<br>PT- Prior Therapy (NOS)<br>V- Vaccine 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. |

(PRIOR-THERAPY-SUPPLEMENT)

# Prior Treatment Summary

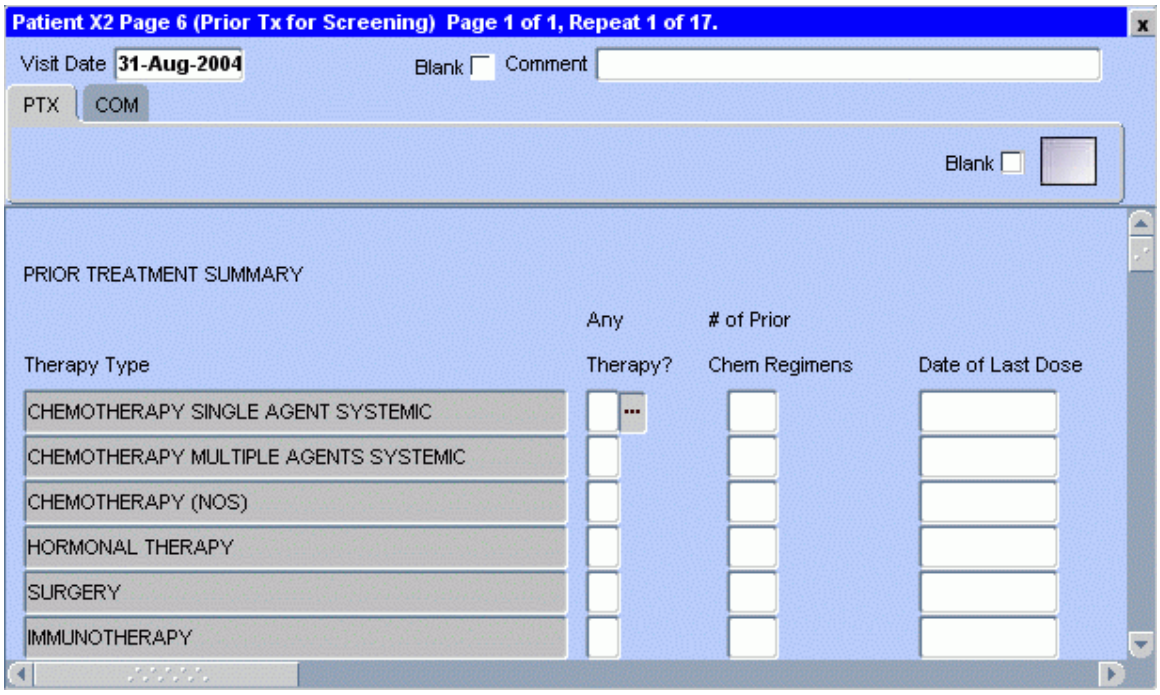
## Purpose

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

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.<br><br>*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.*<br><br>*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.<br><br>Y- Yes - then Date of Last Dose must be provided.<br>N- No | Use pick list. |
| Number of Prior Regimens (u) (m) | Enter the number of prior regimes received for the type of therapy.<br><br>*Note: This field is only mandatory for studies that report data to CDUS.* | 2 digits |
| Date of Last Dose ▪▪▪ | Enter the date of the last dose of the most recent prior treatment regimen for each therapy type. Partial dates are acceptable when the day and/or month are not known. Select "Ongoing" if the treatment is currently being received.<br><br>For combination therapies, record the date of the last dose of medication for the combination. | DD-MMM-YYYY, MMM-YYYY, YYYY or<br>Use pick list. |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only, (u) for CDUS reporting only. | | |

# Prior Treatment Summary (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| PTX01 | "Any Therapy?" is 'Yes' for a therapy type but the respective Date of Last Dose is missing. | Verify Date of Last Dose and/or "Any Therapy?". |
| PTX02 | Date of Last Dose is specified for a therapy type but the respective "Any Therapy?" is not checked 'Yes'. | Verify Date of Last Dose and/or "Any Therapy?". |
| PTX03 | Date of Last Dose, which could be partial, is in the future. | Enter a Date of Last Dose that is equal to or earlier than the current date. |
| PTX04 | Number of Prior Regimens is negative or not a number. (Note: only for studies reporting data to CDUS) | Enter a number between 0 and 99 when applicable. |
| PTX05 | Some of the 'Any Therapy?' answers were not provided. | Answer 'Y' or 'N' for all the 'Any Therapy?' questions. |

(PRIOR-TREATMENT-SUMMARY)

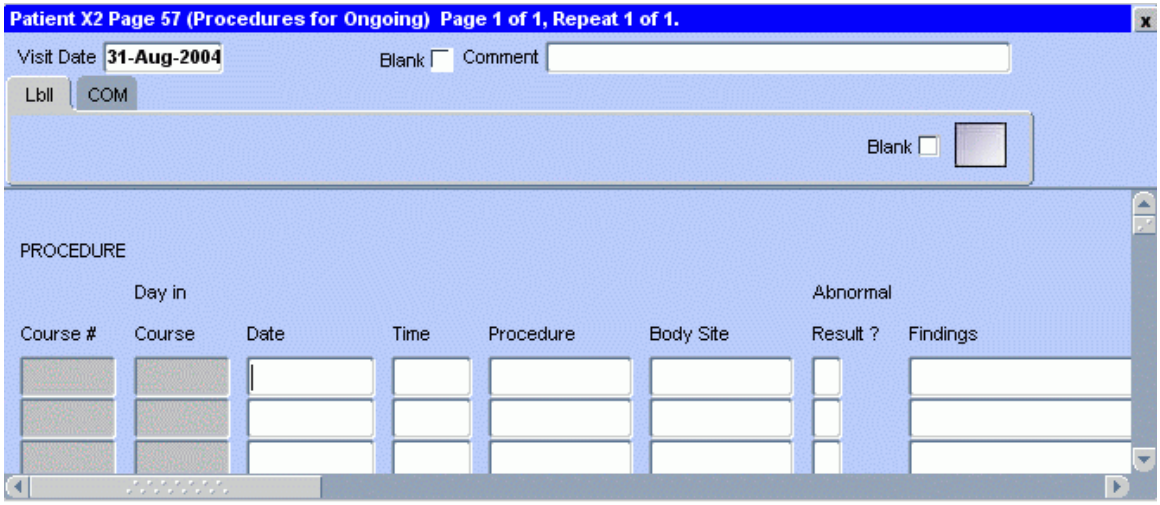
Filler Page

# Procedures

## Purpose

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

## Procedures eCRF



# Procedures (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date | The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date field. | DD-MMM-YYYY |
| Course # (d) | Indicates the course number the procedure is related to based on their date and time. | 5 digits |
| Day in Course (d) | Indicates the day since the beginning of course the procedure is related to based on their date and time. | 5 digits |
| Date (m) | Enter the date that the procedure was done, not the date it was interpreted by the radiologist or investigator. | DD-MMM-YYYY |
| Time | Enter the time the procedure was done. | HH(24):MM |
| Procedure (m) | Select the procedure from the pick list.<br><br>*Note: For CTMS monitored protocols, these are the only Procedures sent:*<br><br>EKG Electrocardiogram<br>CXR Chest X-ray<br>BRNCHGRM Bronchogram<br>UPGISER Upper GI Series<br>LOGISER Lower GI Series<br>SKELSURV Skeletal Survey<br>HOLTMON Holter Monitor<br>BONESCAN Bone Scan<br>EEG Electroencephalogram<br>BMCELLUTY Bone Marrow Cellularity<br>UCASTS Urine Casts<br>MUGASCAN Muga Scan<br>ULTRASND Ultrasound<br>CATSCAN CAT Scan<br>MRI MRI<br>X-RAY X-ray<br>PETSCAN PET Scan<br>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.<br><br>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:<br><br>A- Abnormal<br>N- Normal | Use pick list. |
| Findings | If abnormal, enter as summary of the abnormal findings. | 128 characters |
| Legend: ... pick list available, [(d)] derived field, [(m)] RDC mandatory, [(c)] for CTEP reporting only. | | |

| 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. |

# Procedures (cont'd)

| **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)

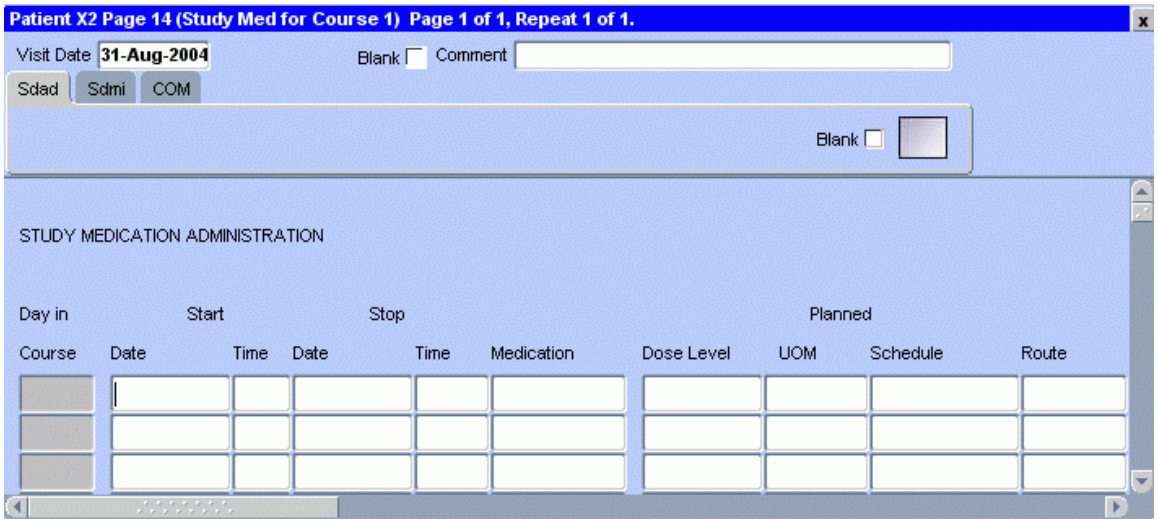
# Study Medication Administration

## Purpose

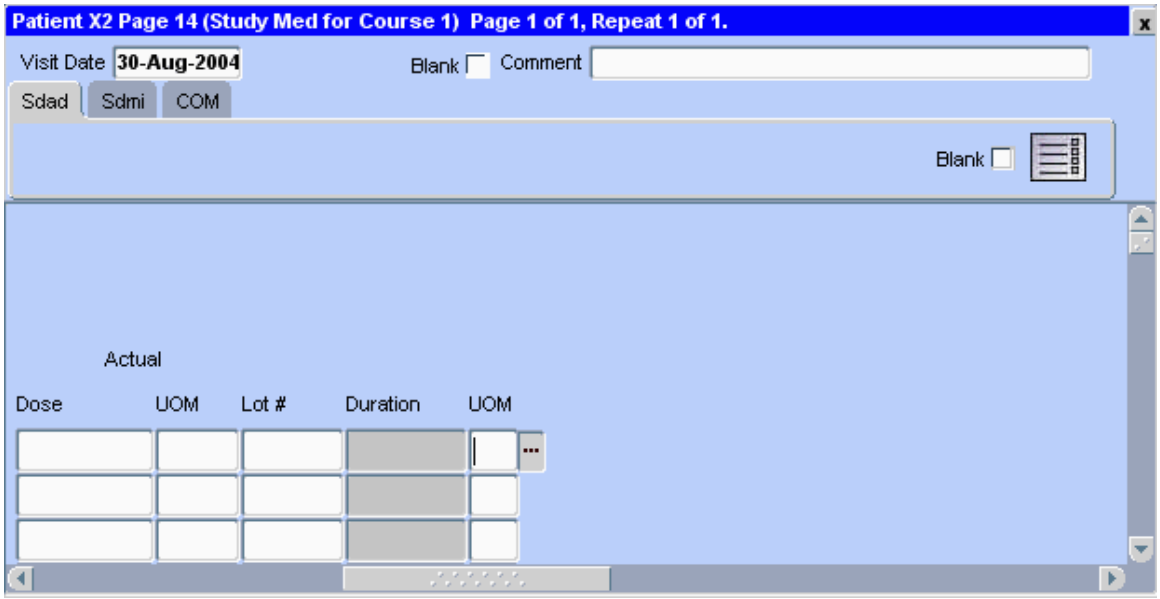
Record medication administration. Use a separate line for each medication.

## Study Medication Administration eCRF

Study Medication Administration Tab




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



# Study Medication Administration (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Visit Date (m) | Enter the date the course started. | DD-MMM-YYYY |
| Day in Course (d) | Indicates the day since the beginning of course initiation. Derived from the course initiation start date. | 5 digits |
| Start Date (m) | Enter the date the medication was administered. | DD-MMM-YYYY |
| Start Time | For IV infusions only: Enter the start time of the infusion. | HH(24):MM |
| Stop Date | Enter the date the medication was discontinued. | DD-MMM-YYYY |
| Stop Time | For IV infusions only: Enter the stop time of the infusion. | HH(24):MM |
| Medication (m) ... | Select a medication from the list.<br><br>*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. |
| Planned Dose Level (m) | Enter the amount of medication (a number) that was planned to be given for the dose level.<br><br>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.<br><br>For dose levels that are expressed with scientific exponential units using powers of 10 such as vaccines and viral particles, enter as 10EX. For example, dose level description is $2 \times 10^6$ PFUs, the dose level would be 2x10E6 and the PFUs would be noted in the Planned UOM (Units of Measurement) field. | 8 characters |

# Study Medication Administration (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Planned UOM (m) ... | Select the Planned Dose Level unit of measurement. | Use pick list. |
| Planned Schedule (m) ... | Select the schedule of medication administration as indicated in the protocol. | Use pick list. |
| Planned Route (m) ... | Select the route given:<br><br>**IM**- intramuscular<br>**ID**- intradermal<br>**IV**- intravenous bolus ( less than 30 minutes )<br>**IVI**- intravenous infusion ( greater than 30 minutes, but less than 24 hours )<br>**CIV**- continuous intravenous infusion ( greater than 24 hours )<br>**IA**- intra-arterial<br>**IT**- intrathecal<br>**IP**- intraperitoneal<br>**IH**- intrahepatic<br>**IHI**- intrahepatic infusion<br>**SC**- subcutaneous<br>**T**- topical<br>**PO**- oral<br>**RT**- radiation<br><br>or other route as specified in the protocol. | Use pick list. |
| Actual 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.<br><br>Note: In the case of medications (such as vaccines and viral particles) where the dose is expressed with scientific exponential units using powers of 10, record (for example) $10^6$ as 1X10E6. | 8 characters |
| 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 |

# Study Medication Administration (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Duration (d) | Duration derived from the start date/time and stop date/time. | 6 digits & 2 decimals |
| Duration UOM (m) ... | Select the a units of measurement so that the duration can be derived.<br><br>**DY**- Days<br>**HR**- Hours<br>**MN**- Minutes<br>**MO**- Months<br>**Wk**- Weeks | Use pick list. |
| Legend: ... pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

| 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. |
| SD02 | Actual Dose Level is not within +/- 10% of the product of Actual Dose Level and BSA in course initiation. | Enter the correct Actual Dose Level or review the course initiation BSA. |
| 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. |

# Study Medication Administration (cont'd)

| Derivations | | |
|---|---|---|
| **Code** | **Field Name** | **Description** |
| SD1001 | Day in Course | Derived from the respective course initiation start date. |
| SD1002 | Duration | Derived from the start and stop dates/times. A duration of less than 1 hour is shown in minutes. The duration between 1 hour and 24 hours is shown in hours. The duration between 1 day and 7 days is shown in days. The duration above 7 days is shown in weeks. |

Filler Page

# Study Medication Administration (cont'd)

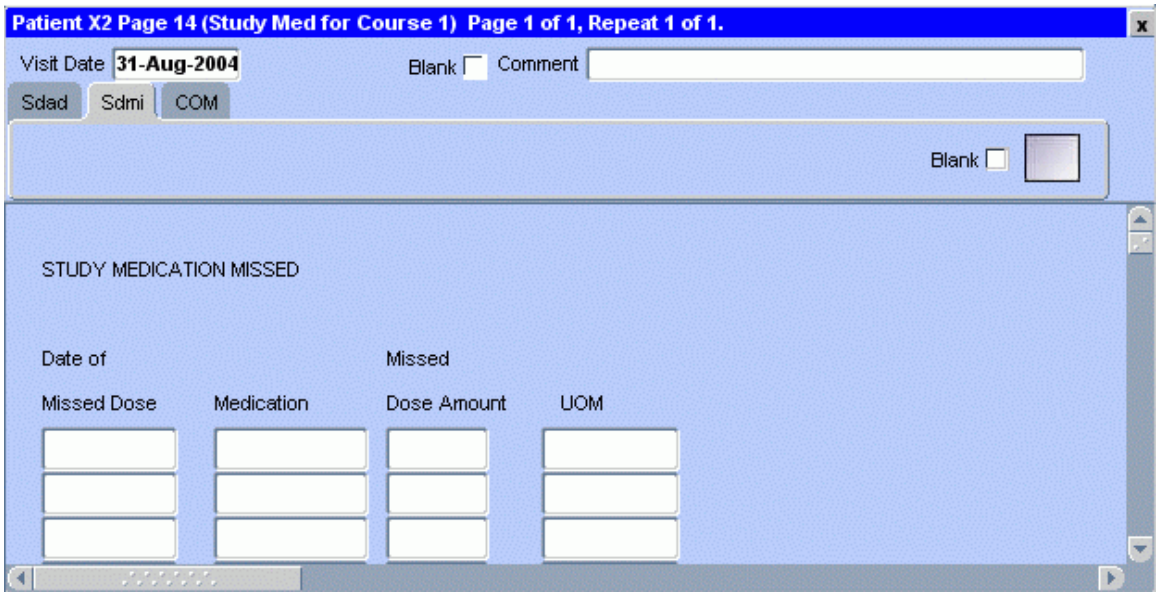
## Purpose

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

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** |
| Missed Dose Date (m) | Enter the date the medication was not administered. | DD-MMM-YYYY |
| Medication (m) ▪▪▪ | Select the name of the missed medication. | Use pick list. |
| Missed Dose Amount (m) | Enter the actual amount of medication missed for the date entered above.<br><br>*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 |
| Missed Dose UOM (m) ▪▪▪ | Select the Missed Dose Amount unit of measurement. | Use pick list. |
| Legend: ▪▪▪ pick list available, (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only. | | |

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| SD11 | Missed medication does not have a respective planned medication administration record. | Verify the selected Medication. |
| SD12 | Missed Dose Date cannot be prior to the respective medication administration start date/time or after the stop date/time. | Change the Missed Dose Date. |

(STUDY-MEDICATION-ADMINISTRATION)

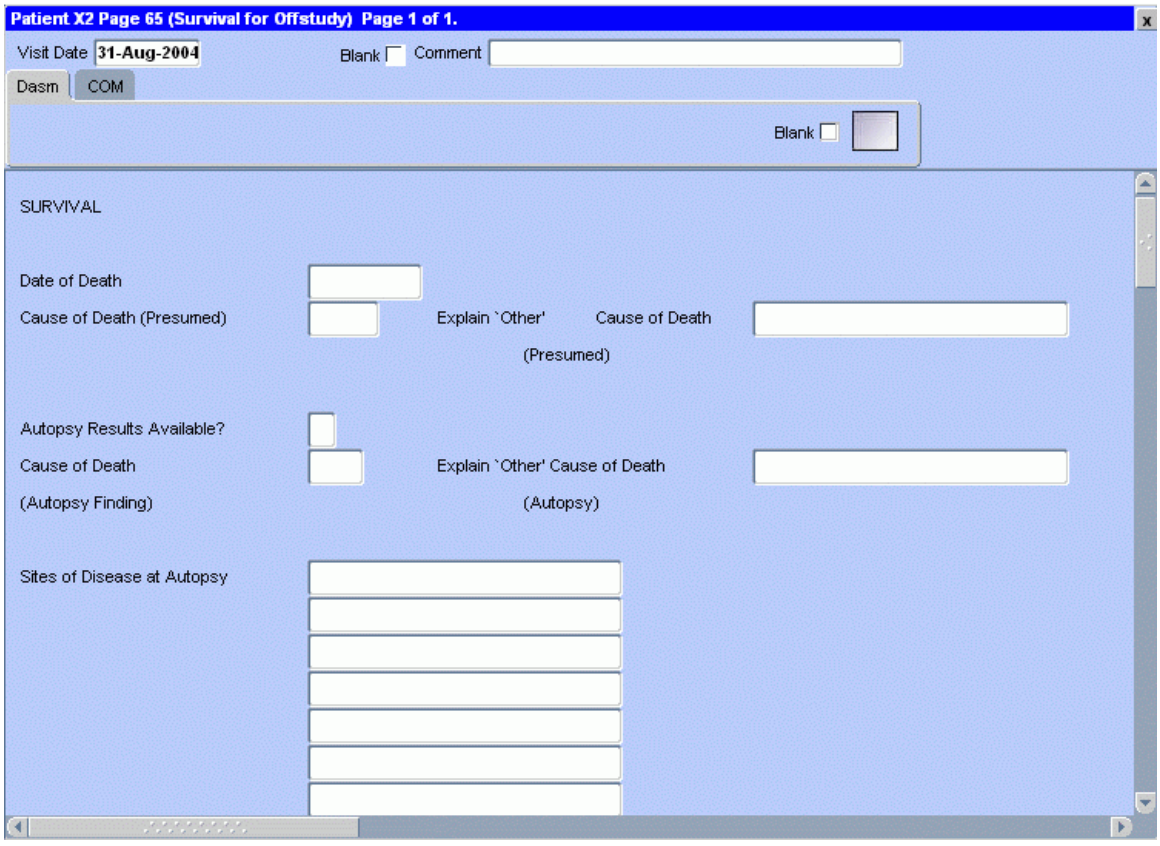
# Survival

## 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.<br><br>Categorize the cause as due to:<br><br>M- Malignant Disease<br>T- Toxicity from Protocol Treatment<br>I- Infection<br>O- Other (Explain)<br><br>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.<br><br>Y- **Yes** - Autopsy done and results available.<br>N- **No** - Autopsy not done or autopsy done, but results not yet available.<br>U- **Unknown** - Do not know if an autopsy was done.<br><br>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:<br><br>M- Malignant Disease<br>T- Toxicity from Protocol Treatment<br>I- Infection<br>O- Other<br><br>Only one category should be checked.<br><br>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. | | |

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| FLW06 | Date of Death is in the future. | Enter a date earlier than, or equals to, the current date. |
| FLW07 | Autopsy Results Available is "Yes", but no other autopsy information has been entered. | Verify Autopsy Results Available and the other autopsy fields. |

# Survival (cont’d)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| 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. |
| 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". |

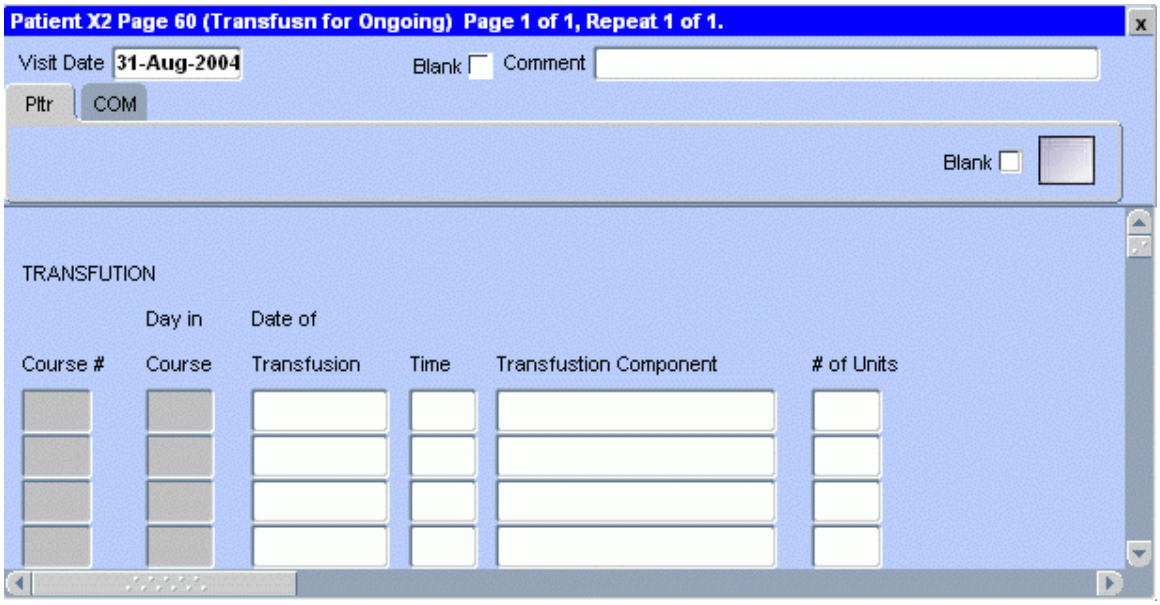
(SURVIVAL)

# 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. | | |

| 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. |

# Transfusions (cont'd)

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

(TRANSFUSIONS)

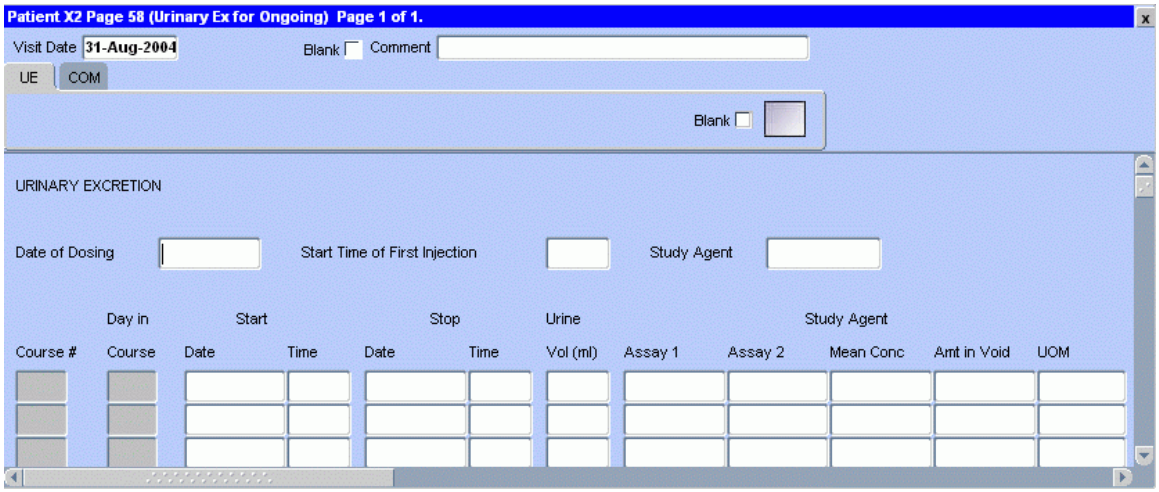
Filler Page

# Urinary Excretions

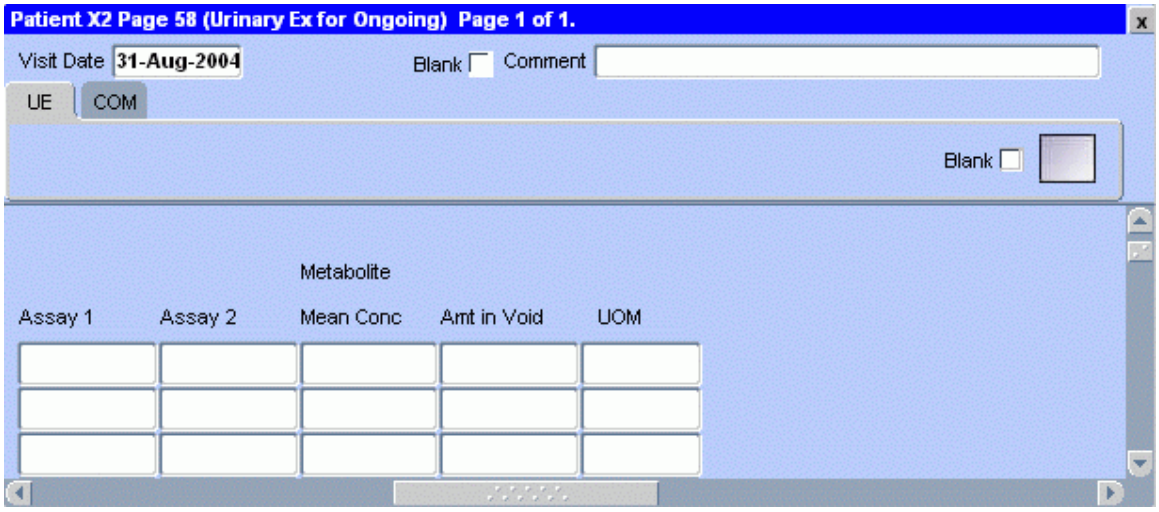
## Purpose

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

## Urinary Excretion eCRF




The following screen shot is the portion to the right of the Parent Study Agent Units of Measurement 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 |
| 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.<br><br>*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. |
| Course # (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 (m) | Enter the collection start date. | DD-MMM-YYYY |
| Start Time (m) | Enter the collection start time even if the assay results are not available. | HH(24):MM |
| End Date | Enter the collection end date. | DD-MMM-YYYY |
| End Time | Enter the collection end time even if the assay results are not available. | HH(24):MM |
| Urine Volume (m) | Enter the urine volume collected in milliliters. | 4 digits. |

# Urinary Excretions (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Parent Study Agent Assay 1 | Enter the first parent study agent assay results in the biological samples.<br><br>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.<br><br>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 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.<br><br>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.<br><br>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.<br><br>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 |

# Urinary Excretions (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| Metabolite in Void | Enter the metabolite in void results in the biological samples.<br><br>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. | | |

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| UE01, UE02, UE07 | Urinary excretion dates are in the future. | Enter dates that are equal to or prior to the current date. |
| UE06 | Collection End Date/Time is prior to the collection Start Date/Time. | Collection End Date/Time must be after the collection Start Date/Time. |
| UE08 | Start Date / Time and Stop Date / Time pair appears more than once – duplicate entry. | Remove the duplicate record or correct the Start Date / Time and Stop Date / Time of one of them. |
| UE10 | No Study Agent and Metabolite results and UOM were provided. | At least one Study Agent or Metabolite results, with respective UOM, are required. |
| UE11 | Study Agent UOM entered, but Assay 1, Assay 2, Mean Concentration and Amount in Void are missing. | Enter a Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void. |
| UE12 | Study Agent Assay 1, Assay 2, Mean Concentration and/or Amount in Void entered, but UOM is missing. | Enter the Study Agent UOM. |

# Urinary Excretions (cont'd)

| Validations | | |
|---|---|---|
| **Code** | **Description** | **Resolution** |
| 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. |

| 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)

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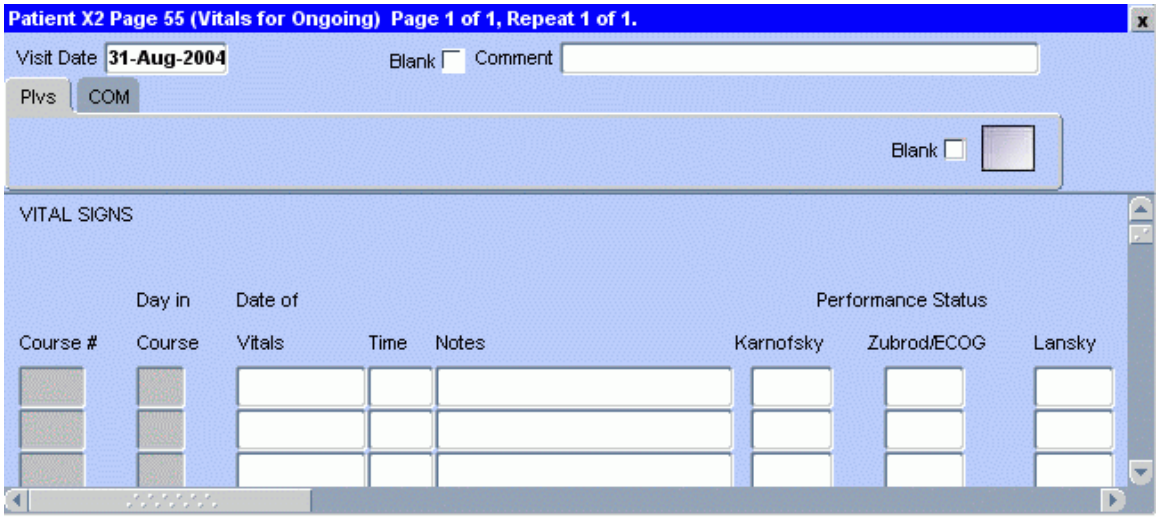
# Vital Signs

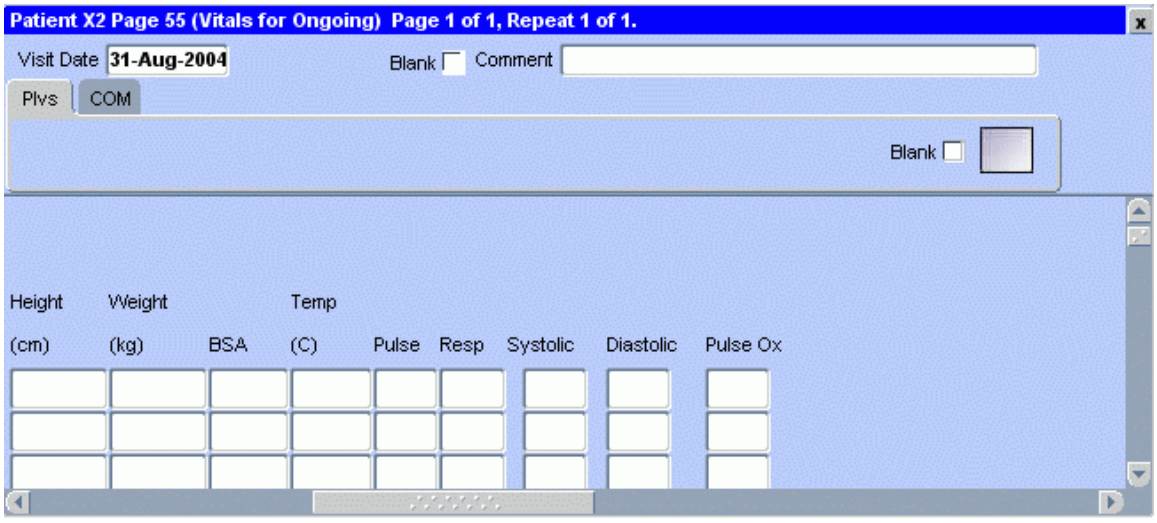
## Purpose

Record the patient's vital signs during treatment.

## Vital Signs eCRF




The following screen shot is the portion to the right of the Lansky Performance Status.



# 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 (m) | Enter the time the vital signs were taken. | HH(24):MM |
| Notes | If necessary, enter some brief notes.<br><br>*Note: This information is not sent to the reporting agency.* | 200 characters |
| Performance Status (Karnofsky) | Select a value from the Karnofsky performance status scale.<br><br>0- Dead<br>10- Moribund<br>20- Very Sick<br>30- Hospitalized<br>40- Disabled<br>50- Frequent Assistance<br>60- Occasional Assistance<br>70- Self Care<br>80- Effort<br>90- Able<br>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.<br><br>0. Asymptomatic<br>1. Symptomatic, fully ambulatory<br>2. Symptomatic, in bed less than 50% of day<br>3. Symptomatic, in bed more than 50% of the day, but not bedridden<br>4. Bedridden | Use pick list. |
| Performance Status (Lansky) ▪▪▪ | Select a value from the Lansky performance status scale.<br><br>0- Unresponsive<br>10- No play; does not get out of bed<br>20- Often sleeping; play entirely limited to very passive activities<br>30- In bed; needs assistance even for quiet play<br>40- Mostly in bed; participates in quiet activities<br>50- Gets dressed but lies around much of the day; no active play; able to participate in all quiet play<br>60- Up and around; but minimal active play; keeps busy with quieter activities<br>70- Both greater restriction of and less time spent in play activity<br>80- Active; but tires more quickly<br>90- Minor restrictions in physically strenuous activity<br>100- Fully active, normal | Use pick list. |
| Height | Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors. | 3 digits and 2 decimals |
| Body Weight | Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors. | 3 digits and 2 decimals |

# Vital Signs (cont'd)

| Field Descriptions and Instructions | | |
|---|---|---|
| **Field Name** | **Description / Instructions** | **Format** |
| BSA | 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.<br><br>The following simple approximation may be used for persons of "normal" height and weight:<br><br>$BSA(m^2) = \sqrt{\frac{Height\ (cm)\ x\ Weight\ (kg)}{3600}}$ | 1 digit and 2 decimals |
| Temperature | Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors. | 4 digits and 3 decimals |
| Pulse | Enter the patient's pulse rate. | 4 digits and 3 decimals |
| Respiration Rate | Enter the patient's respiration rate. | 4 digits and 3 decimals |
| Systolic Blood Pressure | Enter the patient's systolic blood pressure. | 4 digits and 3 decimals |
| Diastolic Blood Pressure | Enter the patient's diastolic blood pressure. | 4 digits and 3 decimals |
| Pulse Oximetry | Enter the patient's pulse oximetry reading. | 3 digits |
| 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.<br>The MIS BSA formula is:<br>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.<br>The Mosteller BSA formula is:<br>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. |
| VIT16 | None of the Height and Weight were not entered. | Height or Weight should be entered. |
| VIT17 | BSA is not provided for Vital Signs inside Courses. | BSA is mandatory for Vital Signs inside Courses. |

# 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)

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# Appendices

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# Appendix I

# Conversion Tables

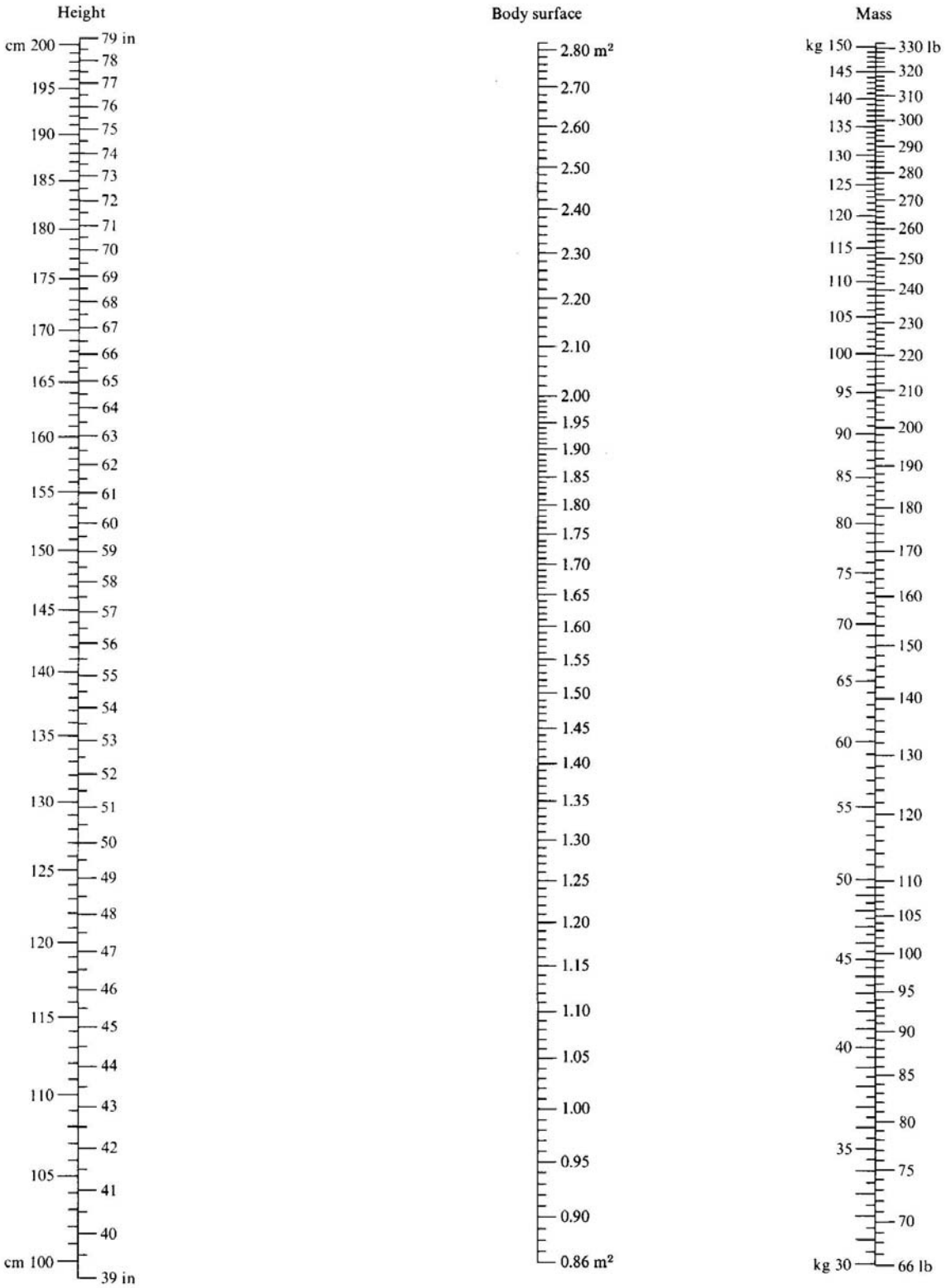
# Appendix I - Conversion Tables (cont'd)

## 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. | | |

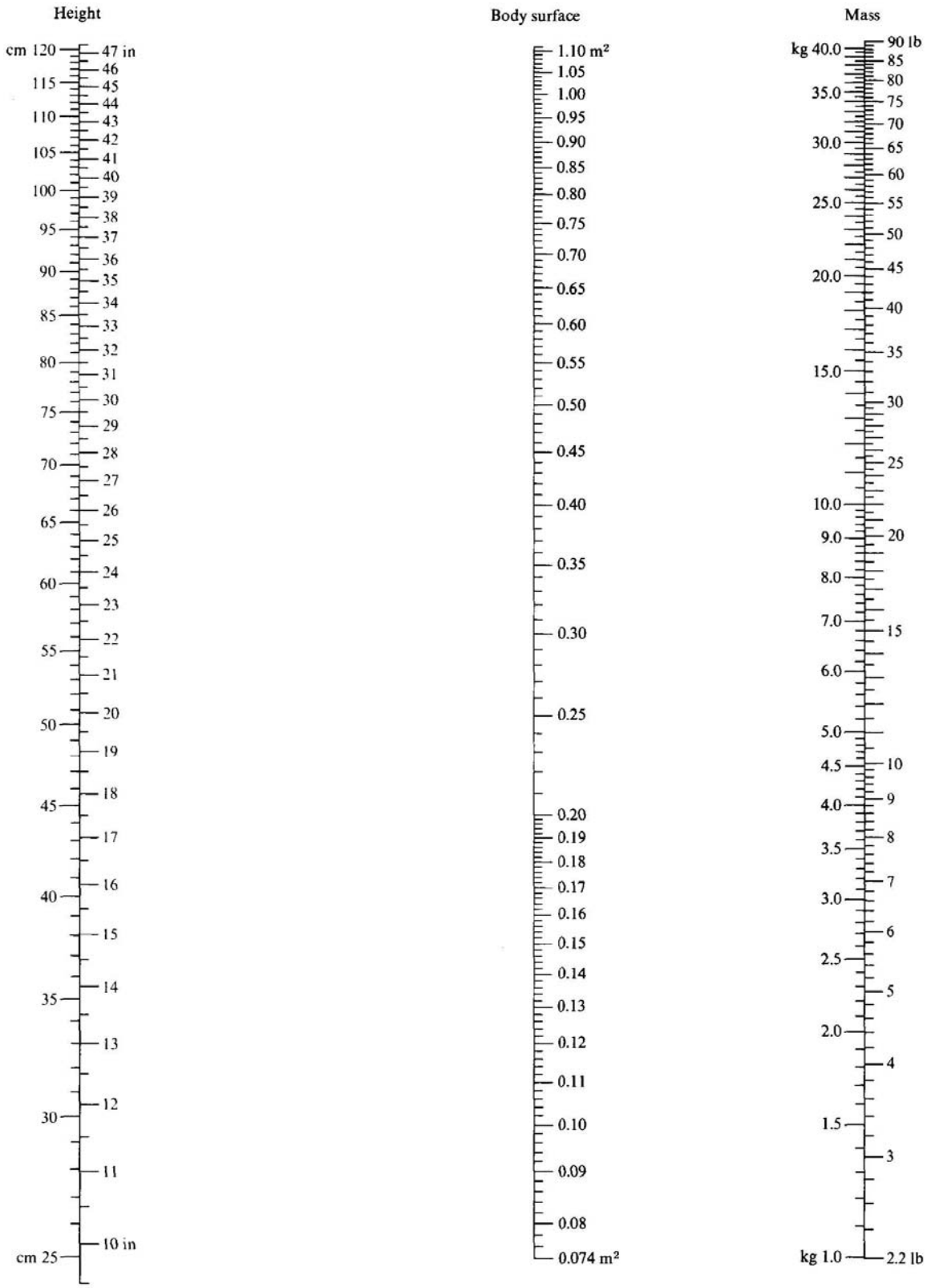
# Appendix I - Conversion Tables (cont'd)

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 |

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# Appendix II

# Useful References

# Appendix II - Useful References (cont'd)

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

# Appendix II - Useful References (cont'd)

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