BTTC Physical Exams - Courses

Neurological Assessment Screenshot.PNG

Contents

Purpose

This CRF will record physical exam results during treatment. Note: Some BTTC protocols will not require specific physical exam data to be captured.

Physical Exams - Courses eCRF

Field Name	Description / Instructions	Format
Visit Date [(m)]	Enter the date the physical examination took place.	DD-MM-YYYY
PE Done? [(m)]	Indicate whether the physical examination was performed: YES - Yes NO - No ⓘ Note: not applicable for CTMS.	Use pick list.
Date of Examination	Enter the date the physical examination took place.	DD-MM-YYYY
Day in Course [(d)]	Number of days since the beginning of the course is derived from the course initiation start date and examination date.	5 digits
Change from Baseline?	Indicate whether the finding results were changed compared with that of baseline: Y - Yes N - No ⓘ Note: not applicable for CTMS.	Use pick list.

Change from Previous Evaluation?	Indicate whether the finding results were changed compared with that of previous evaluation: Y - Yes N - No ⓘ Note: not applicable for CTMS.	Use pick list.
Body System	Predefined Body System. It cannot be changed.	text
Finding Results	Indicate whether the finding results for the particular body system were either: N - Normal A - Abnormal X - Not Examined L - Not Applicable Comments are required for abnormal finding results. ⓘ Note: Do not select "Normal" if the body system was not specifically assessed during the physical exam (i.e.: not mentioned in the progress note in the medical record). Any baseline body system with "Abnormal" Finding Results that remained unchanged must be re-entered in this case report form. ⓘ For CTMS reporting studies, L is reported as X.	Use pick list.
Comments	If the finding results of a particular body system have changed from baseline, give a brief description of the change. If choosing "Other", indicate the body or organ system missing from the list in the comment and include this for subsequent exams.	200 characters (128 reported)

✓ Legend: (d) derived field, (m) RDC mandatory

Validations

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

Derivations

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

Physical Exams - Courses eCRF (Vital Signs tab)

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 that this physical exam was performed as derived from the course initiation start date.	5 digits
Day in Course (d)	Indicates the day since the beginning of course the vital signs are related to based on their date and time.	5 digits
Date of Vitals (m)	Enter the date the vital signs were taken.	DD-MMM-YYYY
Time	Enter the time the vital signs were taken.	HH(24):MM
Notes	If necessary, enter some brief notes. ⓘ Note: This information is not sent to the reporting agency.	200 characters
Performance Status (Karnofsky)	Select a value from the Karnofsky performance status scale. 0 - Dead 10 - Moribund 20 - Very Sick 30 - Hospitalized 40 - Disabled 50 - Frequent Assistance 60 - Occasional Assistance 70 - Self Care 80 - Effort 90 - Able 100 - Normal	Use pick list.
Status (Zubrod)	Select a value from the Zubrod/ECOG performance status scale. 0. Asymptomatic 1. Symptomatic, fully ambulatory 2. Symptomatic, in bed less than 50% of day 3. Symptomatic, in bed more than 50% of the day, but not bedridden 4. Bedridden	Use pick list.
Performance Status (Lansky)	Select a value from the Lansky performance status scale. 0 - Unresponsive 10 - No play; does not get out of bed 20 - Often sleeping; play entirely limited to very passive activities 30 - In bed; needs assistance even for quiet play 40 - Mostly in bed; participates in quiet activities 50 - Gets dressed but lies around much of the day; no active play; able to participate in all quiet play 60 - Up and around; but minimal active play; keeps busy with quieter activities 70 - Both greater restriction of and less time spent in play activity 80 - Active; but tires more quickly 90 - Minor restrictions in physically strenuous activity 100 - Fully active, normal	Use pick list.
Body Weight (m)	Enter the patient's weight only in kilograms. Use decimal places only for patients under 10kg. See Appendix 1 for conversion factors.	5 digits and 2 decimals
Height (m)	Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors.	5 digits and 2 decimals

BSA (m)	Enter the patient's body surface area in m2 (to two decimal places) if needed for the calculation of study medication dose level. A nomogram for children's and adult's body surface area calculation can be found in Appendix 1. The following simple approximation may be used for persons of "normal" height and weight:	4 digit and 2 decimals
Temperature	Enter the patient's temperature only in Celsius, to one decimal place. See Appendix 1 for conversion factors.	8 digits and 3 decimals
Pulse	Enter the patient's pulse rate.	8 digits and 3 decimals
Respiration Rate	Enter the patient's respiration rate.	8 digits and 3 decimals
Systolic Blood Pressure	Enter the patient's systolic blood pressure.	8 digits and 3 decimals
Diastolic Blood Pressure	Enter the patient's diastolic blood pressure.	8 digits and 3 decimals
Pulse Oximetry	Enter the patient's pulse oximetry reading.	3 digits and 2 decimals

✅ Legend: (d) derived field, (m) RDC mandatory

Validations

Code	Description	Resolutions
VIT01	Systolic Blood Pressure is less than Diastolic Blood Pressure.	Systolic Blood Pressure must be greater than Diastolic Blood Pressure.
VIT02	Two Vital Signs entries have the same Date and Time.	Correct the date and/or time.
VIT03	Entered BSA is not within 10% accuracy of the calculated BSA using the MIS formula.	Correct the BSA. The MIS BSA formula is: BSA (m²) = Height(cm)^0.725 x Weight(kg)^0.425 / 139.315
VIT04	Entered BSA is not within 10% accuracy of the calculated BSA using the Mosteller formula.	Correct the BSA. The Mosteller BSA formula is: BSA (m²) = (CCRClinicalIT2: Height(cm) x Weight(kg) / 3600)^½
VIT05	Vitals Date is in the future.	Enter a date that is equal to or prior to the current date.
VIT06, VIT07, VIT08, VIT09, VIT10, VIT11, VIT12, VIT13	Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic and/or Diastolic Blood Pressure are/is less than zero.	Height, Weight, BSA, Temperature, Pulse, Respiration Rate, Systolic Blood Pressure and Diastolic Blood Pressure must be greater than zero.
VIT14	Pulse Oximetry is out of range.	Pulse Oximetry must be an integer number between 0 and 100.
VIT15	Vitals (on cycle sections) have Date of Vitals outside the range of the cycle start and stop date.	Enter an appropriate date. Note: this does not apply for all protocol.

Derivations

Code	Field Name	Description
VIT1002	Day in Course	Number of days since the beginning of the course is derived from the course initiation start date and the vital signs date.

Physical Exams - Courses eCRF (Neurological Assessment tab)

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
Data Collected	To indicate whether the data was collected for this assessment and time-point YES - Yes NO - No	Use pick list.
Reason if No	If necessary, enter text reason that data is not collected for an identified assessment at this assessment and time point .	200 characters
Evaluation Date [(m)]	Enter the date the vital signs were taken.	DD-MMM-YYYY
Neurological Assessment	Select the patient's results or findings of neurological assessment. This determination must be adequately documented in the patient's medical record. DEFINITELY BETTER DEFINETELY WORSE POSSIBLY BETTER POSSIBLY WORSE STABLE BASELINE	Use pick list.
Preference Hand	Select relating to the subject's identification of the preference or dominant hand. Preference hand can be defined as right, left, or both (bilateral).	Use pick list.

> Legend: [(d)] derived field, [(m)] RDC mandatory

Validations

Code	Description	Resolutions
TBD		