

# BTTC Physical Exams - Simplified

Neurological Assessment Screenshot.PNG

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## Purpose

This CRF will record physical exam results during treatment. It will also record the vital signs data and neurological exam data obtained at time of the physical exam. Note: Some BTTC protocols will not require specific physical exam data to be captured.

## Physical Exams - Courses eCRF

The screenshot shows the BTTC Physical Exams - Courses eCRF form. It includes sections for Patient Information, Physical Exam, Vital Signs - PE, and Neurological Assessment. The Physical Exam section has fields for PE Done, Date of Examination, Change from Baseline, and Change from Previous Evaluation. The Vital Signs - PE section has a table for recording vital signs (HR, BP, RR, SpO2, Temp, etc.) for multiple patients. The Neurological Assessment section has fields for Date of Exam, Exam Site, and Exam Date.

Field Name	Description / Instructions	Format
Visit Date <sup>(m)</sup>	Enter the date the physical examination took place.	DD-MM-YYYY
PE Done? <sup>(m)</sup>	Indicate whether the physical examination was performed: YES - Yes NO - No	Use pick list.
Date of Examination	Enter the date the physical examination took place.	DD-MM-YYYY
Day in Course <sup>(d)</sup>	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	Use pick list.
Change from Previous Evaluation?	Indicate whether the finding results were changed compared with that of previous evaluation: Y - Yes N - No	Use pick list.
Course# <sup>(d)</sup>	Indicates the course number that this physical exam was performed as derived from the course initiation start date.	5 digits
Day in Course <sup>(d)</sup>	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 <sup>(m)</sup>	Enter the date the vital signs were taken.	DD-MMM-YYYY

Time	Enter the time the vital signs were taken.	HH(24): MM
Notes	If necessary, enter some brief notes.	200 characters
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 <sup>(m)</sup>	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 <sup>(m)</sup>	Enter the patient's height only in centimeters, to one decimal place. See Appendix 1 for conversion factors.	5 digits and 2 decimals
BSA <sup>(m)</sup>	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 (C)	Enter the patient's temperature only in Celsius, to one decimal place.	4 digits and 1 decimals
Temperature (F)	Enter the patient's temperature only in Fahrenheit , to one decimal place.	3 digits and 1 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
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 <sup>(d)</sup> <sup>(m)</sup>	Enter the date the vital signs were taken.	DD-MMM-YYYY



Legend: <sup>(d)</sup> derived field, <sup>(m)</sup> RDC mandatory

## Validations TBD

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 TBD

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.