

Procedures

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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

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. <div><div><div>Note: For CTMS monitored protocols, these are the only Procedures sent:</div><div>EKG Electrocardiogram CXR Chest X-ray BRNCHGRM Bronchogram UPGISER Upper GI Series LOGISER Lower GI Series SKELSURV Skeletal Survey HOLTMON Holter Monitor BONESCAN Bone Scan EEG Electroencephalogram BMCELLUTY Bone Marrow Cellularity UCASTS Urine Casts MUGASCAN Muga Scan ULTRASND Ultrasound CATSCAN CAT Scan MRI MRI X-RAY X-ray PETSCAN PET Scan CULTURE Culture</div></div></div>	Use pick list.

Body Site ^(m)	Select the body site from the pick list. In the case of tests such as CATSCAN, MRI, and X-RAY record the applicable body site. For CAT Scan and MRI use thorax, abdomen, pelvis or brain.	Use pick list.
Abnormal Result? ^(m)	Select whether the finding results for the particular procedure / body site were either: A - Abnormal N - Normal	Use pick list.
Findings	If abnormal, enter as summary of the abnormal findings.	128 characters 200 characters for non-CTEP sponsored studies.



Legend: ^(d) derived field, ^(m) RDC mandatory, ^(c) for CTEP reporting only.

Validations

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

Derivations

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