

Manual for the Completion of caBIG™ Case Report Form (CRF) Modules

Introduction

In 2006, members of the Cancer Biomedical Informatics Grid or caBIG™ in conjunction with the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBII) initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into three categories:

Mandatory – must be included when this data is collected for reporting

Conditional – there are business rules to indicate situations under which this element should be used on a CRF

Optional – no requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data, this is the element to include on the CRF

A template form with modules that contain questions or variables representing data to be collected was developed. The companion eCRF instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc.

Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

NCI Standard Physical Examination Module Template Instructions

Field Descriptions and Instructions

Field Name Status	Description/Instructions	Format	CDE Public ID
Evaluation Date (m)	Enter the date the physical examination is performed.	Use prescribed date entry format.	2004170v.3
Body System Type (c)	Enter the body system (Condition 1: For conventional physical exam CRF, Body System, and Finding Description are Mandatory).	Use choice list	2002895v.4
Other Body System/Site Text (c)	Enter description of other body system/site.	Enter the name of the other body system/site.	2182671v.1
Patient Abnormal Physical Examination Specify (c)	Specify the abnormal physical examination results.	Enter the abnormal physical examination results.	2201880v.1
Patient Physical Examination Ind-2 (c)	Enter whether the overall physical exam is performed. If Yes, report all abnormal findings on Medical History CRF. (Condition 2: Per CDASH alternate recommendation	Use choice list	2201750v.1

	for physical exam, Overall Physical Exam Performed is preferred.		
Finding Result ¹ (o)	Enter the result of the assessment for a particular body system.	Use choice list	2003876v.1

NCI Standard Physical Examination Module Template

Mandatory Questions

Evaluation Date

Exchange Format: YYYYMMDD

[CDE Public ID and Version 2004I70v3.0: The date of the evaluation, procedure or visit that yielded data.]

Conditional Questions

Body System

Abdomen
 AllergyDrug Sensitivity
 Appearance
 Body as a Whole
 Breasts
 Cardiovascular
 Central Nervous System
 Chest Constitutional
 Dermatologic
 Endocrine
 EndocrineMetabolic
 Extremities
 Gastrointestinal
 Genitalia
 Genitourinary
 HIEIEINIT
 Hematologic
 HematopoieticLymph
 Hepatic
 Immune
 IntegumentaryHair
 Musculoskeletal
 Neck
 Neurologic
 Other
 Pelvis
 Peripheral Vascular
 Psychiatric
 Psychologic
 Pulmonary
 Rectal
 Renal
 Reproductive History

¹ In CDISC SDTM the indication of normal or abnormal is considered to be a single result with either the word 'normal' or the abnormality described.

Respiratory
Spleen
Substance abuse/Dependency
Transfusion History
Urinary

[CDE Public ID and Version 2002895v4.0: An anatomic structure that consists of all members of one or more organ subclasses; these members are interconnected by anatomical structures or body substances.]

Other Body System Site

Text field – Maximum length = 200

[CDE Public ID and Version 2182671v1.0: The text that describes the other specific organ system or body site.]

Patient Abnormal Physical Examination Specify

Text field – Maximum length = 200

[CDE Public ID and Version 2201880v1.0: The free text field to specify the abnormal physical examination or systemic evaluation of the body and its functions using visual inspection, palpation, percussion, and auscultation, aimed to determine the presence or absence of physical signs of disease or abnormality for individual's health assessment.]

Overall Physical Exam Performed

Yes
No

[CDE Public ID and Version 2201750v1.0: The yes/no indicator whether a physical examination has been performed.]

Optional Questions

Finding Result

A = Abnormal
C = No Change
E = Equivocal
G = Negative
I = Improving
L = Not Applicable
N = Normal
O = No Source Data
P = Positive
S = Stable
U = Unstable
V = Not Evaluable
W = Worse
X = Not Examined
Z = Not Assessed

[CDE Public ID and Version 2003876v3.1: Response represents summary findings for the evaluation of a body system/site as normal (N), abnormal (A), not examined (X), or other enumerated values.]

End of Physical Examination Module