

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 CBIIIT) 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 Registration Module Template Instructions

The CTMS WS Registration/Enrollment workgroup has envisioned enrolling a participant into a clinical trial as a two step process. The first process step, Registration, consists of the registering institution applying for entry of a consented participant into a specific research study by conveying designated registration information to a central facility (e.g., coordinating center) that is in charge of accepting participants into the study. In the second process step, Enrollment, typically the center's registrar receives and reviews the registration information and makes a determination to accept or not accept the application. If the participant is deemed acceptable, the center enrolls the participant in the study and the coordinating center returns a notification to the registering institution indicating that the proposed participant is enrolled.

Field Descriptions and Instructions

Field Name/Status	Description/Instructions	Format
Study Identifier (m)	Enter the numeric or alphanumeric identification assigned to the study.	Free Text
Prior Study Participation (c)	Enter Yes, No, or Unknown to indicate if the participant was on a prior study.	Use choice list
Prior Participant Identifier (c)	If the participant was on a prior study, enter the identifier that was assigned to the participant.	Free Text
Registering Institution Code (c)	Enter the organization code of the Registering Institution.	Free Text
Treating Physician Name (c)	Enter the name of the physician that has primary responsibility for the care of the participant.	Free Text
Registration Date (c)	Enter the date the participant's information was sent to the Coordinating Center	Use MM/DD/YYYY date format.
Person Completing Form Name(c)	Enter the first initial and last name of the person who completed the documentation.	Free Text
Person Completing Form Phone (c)	Enter the telephone number of the person who completed the documentation.	Free Text
Person Completing Form FAX (c)	Enter the fax machine number of the person who completed the documentation.	Free Text
Responsible CRA (c)	Enter the name of the clinical research associate who documented information.	Free Text
CRA Phone (c)	Enter the telephone number of the clinical research associate.	Free Text
CRA Fax (c)	Enter the fax number of the clinical research associate.	Free Text
Projected Start Date of Treatment (c)	Enter the text that represents the day, month and year the treatment is anticipated to begin.	Use MM/DD/YYYY date format.
Stratification Factors (c)	Enter the specific factors by which participants are segregated before randomization to intervention arms of a protocol.	Free Text

Participant Subgroup Code (c)	Enter the CTEP code designating the strata specifying a subgroup that defines the stratum for a participant as compared to the question 'Stratification Factor.' Both questions are NOT needed in the same module.	Free Text
Local Participant Identifier (o)	Enter the identifier assigned by a healthcare facility used to link to the participant's medical record.	Free Text
Specialist Physician Name (o)	Enter the name of the Radiation Therapist, Medical Oncologist, Surgeon, etc.	Free Text

NCI Standard Registration Module Template

Mandatory Questions

Study Identifier

Text Field - Maximum length = 12

[CDE Public ID and Version 2016937v3.0: Definition: The numeric or alphanumeric identification assigned to the study.]

Conditional Questions

Was the participant on a prior study with this group?

Yes
No
Unknown

[CDE Public ID and Version 2746466v1.0: The yes/no/unknown indicator that asks whether the participant was on a prior protocol with this group.]

What was the prior study participant identifier?

Text Field – Maximum length = 35

[CDE Public ID and Version 2181976v1.0: Definition: The unique numeric or alphanumeric identification that was assigned to a participant from a previous study.]

Registering Institution Code

Text Field – Maximum length = 10

[CDE Public ID and Version 2003307v4.0: Definition: Code that uniquely identifies the institution where the research participant was registered in a clinical trial.]

Treating Physician Name

Text Field – Maximum length = 35

[CDE Public ID and Version 62749v3.0: Definition: The name of the physician having primary responsibility for the care of this study's participant in accordance with this protocol.]

Registration Date

Display Format = MM/DD/YYYY

[CDE Public ID and Version 2171v4.0: Definition: The date the research participant's information was submitted to the coordinating entity for the purpose of evaluating for acceptance on a clinical trial.]

Person Completing Form Name

Text Field [First Initial, Last Name] – Maximum length = 35

[CDE Public ID and Version 2006163v1.0: Definition: The name of the person who documented information on the registration form or other document.]

Person Completing Form, Phone

Text Field – Maximum length = 20

[CDE Public ID and Version 2175v3.0: Definition: The telephone number to use to contact the person who documented the information on the case report form.]

Person Completing Form, Fax

Text Field – Maximum length = 14

[CDE Public ID and Version 2176v5.0: Definition: The telephone number to reach a fax machine for the person who documented the information on the case report form]

Responsible CRA

Text Field – Maximum length = 14

[CDE Public ID and Version 2452692v1.0: Definition: The name of the person who provides the participant's data on the study.]

CRA Phone Number

Text Field – Maximum length = 20

[CDE Public ID and Version 2661003v1.0: Definition: The telephone number of the person who provides the participant's data on the study.]

CRA Fax Number

Text Field – Maximum length = 14

[CDE Public ID and Version 2661012v3.0: Definition: The Fax number of the person who provides the participant's data on the study.]

Projected Start Date of Treatment

Display Format = mm/dd/yyyy

[CDE Public ID and Version 657v3.0: Definition: The month, day, and year on which protocol treatment is anticipated to begin.]

Stratification Factors (protocol specific)

Text Field – Maximum length = 100

[CDE Public ID and Version 3608v4.0: Definition: Study specific factors by which research participants are segregated to assure balance of these factors before randomization to the intervention arms of a clinical protocol.]

Participant Subgroup Code

Text Field – Maximum length = 10

[CDE Public ID and Version 1925v42.31: Definition: The CTEP code designating the strata for a research participant.]

Optional Questions

Participant Local Identifier

Text Field – Maximum length = 10

[CDE Public ID and Version 2746468v1.0: Definition: The unique numeric or alphanumeric designation assigned by a healthcare facility used to link to the participant's medical record.]

Specialist Physician Name

Text Field – Maximum length = 35

[CDE Public ID and Version 2746480v1.0: Definition: The physician involved in the protocol treatment working with the treating physician specializing in a treatment. For example, Radiation Therapist, Medical Oncologist, Surgeon, etc.]

End of Registration Module