

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 was developed which is comprised of a set of components including questions representing data items. The eCRF instruction manual is a set of instructions 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).

Participant Identification Module

Field Descriptions and Instructions

Field Name/Status	Description/Instructions	Format
Participant Last Name (m)	Character String identifying Last (Family) name	Free text
Participant First Name (m)	Character String identifying First (Personal or Given) name	Free text
Participant Middle Name (o)	Character String identifying Middle name or Initial	Free text
Participant Home Street Address (o)	Primary roadway name and building number of participant's residence	Free text
Participant City (o)	Primary municipality of participant's residence	Free text
Participant State (o)	Primary state or province of a country (if applicable)	Enumerated Values Use choice list
Participant Postal Code (o)	Character string identifier for an address	Free text
Participant Telephone Number (o)	Character string identifier designating the primary telephone number	Free text
Participant Initials (o)	Character String identifying First, Middle and Last Name initials	Free text Use prescribed entry format, FML

NCI Standard Participant Identification Module Template

Mandatory Questions

Participant Last Name

Text Field – Maximum Length = 35

[CDE Public ID and Version 2179591v2.0: A means of identifying an individual by using a word or group of words indicating a person's last (family) name. Synonym = Last Name, Surname.]

Participant First Name

Text Field – Maximum Length = 35

[CDE Public ID and Version 2179591v2.0: A word or group of words indicating a person's first (personal or given) name; the name that precedes the surname. Synonym = Given Name.]

Optional Questions

Participant Middle Name

Text Field – Maximum Length = 35

[CDE Public ID and Version 2179590v2.0: A means of identifying an individual by using a word or group of words indicating a person's middle name.]

Participant Street Address

Text Field – Maximum Length = 60

[CDE Public ID and Version 62587v3.0: The street location or other designation, such as an internal code, for the address. This can be for either a person or organization.]

Participant City

Text Field – Maximum Length = 30

[CDE Public ID and Version 2179601v1.0: A component of an address that specifies a location by identification of a city, town, or village.]

Participant State or Province

Aguascalientes	Alabama	Alaska	Alberta	American Samoa
Arizona	Arkansas	Baja California	Baja California Sur	British Columbia
California	Campeche	Chiapas	Chihuahua	Coahuila de Zaragoza
Colima	Colorado	Connecticut	Delaware	District of Columbia

Distrito Federal	Durango	Florida	Georgia	Guam
Guanajuato	Guerrero	Hawaii	Hidalgo	Idaho
Illinois	Indiana	Iowa	Jalisco	Kansas
Kentucky	Louisiana	Maine	Manitoba	Marshall Islands
Maryland	Massachusetts	Mexico	Michigan	Michoacán de Ocampo
Micronesia	Minnesota	Mississippi	Missouri	Montana
Morelos	Nayarit	Nebraska	Nevada	New Brunswick
New Hampshire	New Jersey	New Mexico	New York	Newfoundland
North Carolina	North Dakota	Northern Mariana Islands	Northwest Territories	Nova Scotia
Nuevo Leon	Nunavut	Oaxaca	Ohio	Oklahoma
Ontario	Oregon	Palau	Pennsylvania	Prince Edward Island
Puebla	Puerto Rico	Quebec	Queretaro de Arteaga	Quintana Roo
Rhode Island	San Luis Potosi	Saskatchewan	Sinaloa	Sonora
South Carolina	South Dakota	Tabasco	Tamaulipas	Tennessee
Texas	Tlaxcala	US Minor Outlying Islands	Utah	Veracruz-Llave
Vermont	Virgin Islands of the US	Virginia	Washington	West Virginia
Wisconsin	Wyoming	Yucatan	Yukon Territory	Zacatecas

[CDE Public ID and Version 2179603v2.0: A component of an address that specifies a location by identification of a principal administrative unit of a country.]

Participant Postal Code

Text Field – Maximum Length = 15

[CDE Public ID and Version 2179606v2.0: The string of characters used to identify the five-digit Zone Improvement Plan (ZIP) code and the four-digit extension code (if available) that represents the geographic segment that is a subunit of the ZIPcode, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery; or the postal zone specific to the country, other than the U.S., where the mail is delivered]

Participant Telephone Number

Text Field – Maximum Length = 25

The preferred format for telephone number is +CCC(AAA)LLLLLLLL/XXXXX where +CCC is the country code, (AAA) is the area code, LLLLLLLL is the local code and XXXXX is the extension number. Partial numbers may be filled from the left, e.g., + (AAA)LLLLLLLL/XXXXX (country code unknown or not necessary), + ()LLLLLLLL/, (country code, area code, and extension unknown or not necessary), etc.

[CDE Public ID and Version 2179593v3.0: The number that identifies a particular telephone connection.]

Participant Initials

Text Field – Maximum Length = 25

[CDE Public ID and Version 2001039v4.0: The initial letters of the first, middle, and last names of the patient or participant registered on the clinical trial.]

End of Participant Identification Module