

# 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 CBIIT) 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 Enrollment 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

<b>Field Name</b>	<b>Description/Instructions</b>	<b>Format</b>	<b>CDE Public ID</b>
Arm	Text term to capture protocol arm(s) available as described in a protocol for subject assignment at the time of eligibility	Free Text	2454528v.1
Intergroup Patient ID	A numeric sequent used to uniquely identify an individual participating in an intergroup clinical protocol.	Free Text	2465308v.1
Enrollment Date	The date the Participant is accepted into the study. The study site may also be notified of the treatment arm and Study Participant Identifier on this date.	Use MM/DD/YYYY date format.	2746541v.1
Pt ID#	The unique numeric or alphanumeric identification assigned to a participant in a	Free Text	2003301v.3
Registrar	The name of the individual responsible for registering a patient for participation in a clinical trial.	Free Text	2172v.3