CTMS

3.12 -› 3.13

REVISIONS TO

MANUAL FOR THE COMPLETION

OF THE
NCI/DCTD/CTEP
CLINICAL TRIALS MONITORING SERVICE

CASE REPORT FORMS

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INTRODUCTION

In March 2005 the Manual for the Completion of the CTMS Case Report Forms (version 3.12) was updated to version 3.13. This document contains the revised sections, which may be used to update a copy of the 3.12 Manual.

No CRFs were revised, only the first page of the accompanying commentary for:

Adverse Events

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ADVERSE EVENTS

Complete a separate Adverse Event case report form for each course.

All adverse events, including laboratory abnormalities, regardless of severity or relationship to treatment, must be reported to CTMS - *with the following exception:*

> *If the patient is on a multi-agent protocol which includes a commercially available agent, then grades 1 and 2 AEs which are "unrelated" or "unlikely related" to the investigational agent and "possibly", "probably", or "definitely" related to the commercial agent, and which are listed on the commercial agent's product label, need not be reported. They should, however, be documented in the patient's medical/research records as meeting these criteria. Grades 3, 4, and 5 AEs must be reported regardless of cause, but if attributable to the commercial agent they should be coded as "unrelated" or "unlikely related" (to the investigational agent).*

Relation to IND agent	**Must AE be reported ?**				
	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**
Unrelated	Yes – *unless related to commercial agent(s) on multi-agent protocol*		Yes	Yes	Yes
Unlikely			Yes	Yes	Yes
Possible	Yes	Yes	Yes	Yes	Yes
Probable	Yes	Yes	Yes	Yes	Yes
Definite	Yes	Yes	Yes	Yes	Yes

Start Date of Course: State the date, in dy/mth/yr format, on which the course was started, i.e., the date on which a protocol stipulated drug was first administered. This date must match the date recorded on the corresponding Course Initiation and Course Assessment forms.

Adverse Event Description: Record a **succinct clinical description** of the adverse event. Extended relevant clinical observations and evaluations may be recorded in the Comments form, correctly identified and dated.

Note that entering verbatim CTC category terms is discouraged since the clinical description may contain additional useful details. Use of "Other" terms is particularly inappropriate.

CTEP Toxicity Type Code: Using the Common Toxicity Criteria (CTC) appropriate for the protocol, select the appropriate CTEP/CDUS Code for the adverse event listed above.

In the absence of a specific CTC term, choose the "Other" term from the appropriate general category and be sure a meaningful "description" is entered.

Condensed lists of the CTC codes are provided in Appendix II. For more complete descriptions of the CTC terms refer to the CTC manuals available on the CTEP Internet Web site.