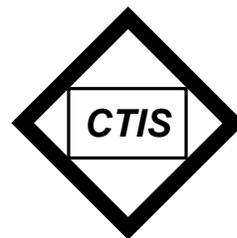


## **Clinical Data Update System (CDUS) v3.0**

### **Notice of Modifications**

**January 28, 2002**

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# SECTION 1: New Information to be Collected – Changes to Existing Tables

## 1.1 COLLECTIONS TABLE

### 1.1.1 Current Trial Status Date

The *Current\_Trial\_Status\_Date* field was added to the COLLECTIONS table to collect the date the current protocol status was effective. For example, if the current status is active, and the protocol became active on January 15, 2000, then 20000115 (format: YYYYMMDD) should be submitted as the status date.

**Reporting Requirements:** The *Current\_Trial\_Status\_Date* field is mandatory for all CDUS-Complete and CDUS-Abbreviated studies.

**Legacy Data:** The *Current\_Trial\_Status\_Date* field is required for all protocols.

To assist in determining the *Current\_Trial\_Status\_Date*, CTEP will include the current trial status and current trial status date with each site's quarterly *List of Expected Protocols*.

### 1.1.2 Current Funding Flag

The *Current\_Funding\_Flag* was added to the COLLECTIONS table to identify protocols that are currently funded under a CTEP grant or contract. The valid values for this field are (1) CTEP or (9) Other. Information in the PROTOCOL\_FUNDING table (see section 2.4) must be submitted when this flag is set to 1 (CTEP).

**Reporting Requirements:** The *Current\_Funding\_Flag* field is mandatory for all CDUS-Complete and CDUS-Abbreviated studies.

**Legacy Data:** The *Current\_Funding\_Flag* field is required for all protocols.

### 1.1.3 Technical Reporting Requirements

Each record associated with the COLLECTIONS table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Subm_Date</i>	<i>Date (YYYYMMDD)</i>
<i>CutOff_Date</i>	<i>Date (YYYYMMDD)</i>
<i>Current_Trial_Status_Code</i>	<i>Varchar2(2)</i>
 <i>Current_Trial_Status_Date</i>	<i>Date (YYYYMMDD)</i>
 <i>Current_Funding_Flag</i>	<i>Varchar2(1)</i> [valid values = (1) CTEP, or (9) Other]
<i>Completer_Name</i> <sup>1</sup>	<i>Varchar2(87)</i>
<i>Completer_Phone</i>	<i>Varchar2(20)</i>

<sup>1</sup> *Completer\_Name* should be submitted in the format Last name^First name^Middle initial (e.g., Public^John^Q). This information will be converted internally by CTEP during the Smart Loader data load into the three separate fields depicted on the data model.

\* Italicized items represent those elements that comprise the primary key.

Completer_FAX	Varchar2(20)
Completer_Email	Varchar2(50)
Change_Code	Varchar2(1)

A sample record associated with the COLLECTIONS table will appear as follows:

```
"COLLECTIONS", "<Protocol_ID>", <Subm_Date>, <CutOff_Date>, "<Current_Trial_Stat
us_Code>", <Current_Trial_Status_Date>, "<Current_Funding_Flag>", "<Completer_Name
>", "<Completer_Phone>", "<Completer_FAX>", "<Completer_Email>", "<Change_Code>"
```

## 1.2 CORRELATIVE\_STUDIES TABLE

Note: The reporting requirements for correlative study information were expanded to include protocols assigned to CDUS-Abbreviated reporting (formerly this information was only requested for protocols assigned to CDUS-Complete reporting).

### 1.2.1 Current Funding Flag

The Current\_Funding\_Flag was added to the CORRELATIVE\_STUDIES table to identify embedded correlative studies that are currently funded under a CTEP grant or contract. The valid values for this field are (1) CTEP or (9) Other. Information in the CORRELATIVE\_FUNDING table (see section 2.5) must be submitted when this flag is set to 1 (CTEP).

**Reporting Requirements:** The Current\_Funding\_Flag field is mandatory for all CDUS-Complete and CDUS-Abbreviated protocols that have embedded correlative studies.

**Legacy Data:** The Current\_Funding\_Flag is required for all protocols.

### 1.2.2 Number of Samples Collected

The Samples\_Collected field was added to the CORRELATIVE\_STUDIES table to collect the number of samples gathered across patients. For example, if three samples were collected for six patients on the correlative study, then 18 samples would be reported.

**Reporting Requirements:** The Samples\_Collected field is mandatory for all CDUS-Complete and CDUS-Abbreviated protocols that have embedded correlative studies.

**Legacy Data:** Samples\_Collected is required only for protocols that were activated on or after January 1, 2002.

### 1.2.3 Number of Samples Analyzed

The Samples\_Analyzed field was added to the CORRELATIVE\_STUDIES table to collect the number of samples analyzed across patients.

**Reporting Requirements:** The Samples\_Analyzed field is mandatory for all CDUS-Complete and CDUS-Abbreviated protocols that have embedded correlative studies.

**Legacy Data:** Samples\_Analyzed is required only for protocols that were activated on or after January 1, 2002.

### 1.2.4 Technical Reporting Requirements

Each record associated with the CORRELATIVE\_STUDIES table should consist of the following information:\*

\* Italicized items represent those elements that comprise the primary key.

	<i>Protocol_ID</i>	<i>Varchar2(35)</i>
	<i>Correlative_Study_ID</i>	<i>Varchar2(10)</i>
	Current_Funding_Flag	Varchar2(1)
	[valid values = (1) CTEP, or (9) Other]	
	Patients_Collected	Number(6)
	Patients_Analyzed	Number(6)
	Samples_Collected	Number(6)
	Samples_Analyzed	Number(6)
	Findings	Varchar2(2000)

A sample record associated with the CORRELATIVE\_STUDIES table will appear as follows:

"CORRELATIVE\_STUDIES", "<Protocol\_ID>", "<Correlative\_Study\_ID>", "<Current\_Funding\_Flag>", "<Patients\_Collected>", "<Patients\_Analyzed>", "<Samples\_Collected>", "<Samples\_Analyzed>", "<Findings>"

### 1.3 PATIENTS TABLE

#### 1.3.1 Ethnicity Flag

In accordance with the new requirements from the Office of Management and Budget, the Ethnicity\_Flag was added to the PATIENTS table to collect and identify patients with Hispanic or Latino culture or origin. This is defined as "a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race" (see section 2.1.4 and the table below for new Ethnicity values).

##### ***New Patient Ethnicity Codes***

<b>CODE</b>	<b>DESCRIPTION</b>	<b>DEFINITION</b>
1	Hispanic or Latino	A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
2	Non-Hispanic	A person NOT meeting the definition for Hispanic or Latino.
9	Unknown	Unknown

**Reporting Requirements:** The Ethnicity\_Flag is mandatory for all CDUS-Complete and CDUS-Abbreviated studies.

**Legacy Data:** The Ethnicity\_Flag is required for all protocols. Race and ethnicity information for protocols approved on or after January 1, 2002, must be both collected and reported according to the new guidelines (see section 2.1). Data for protocols approved prior to January 1, 2002, must be mapped according to section 2.1.

#### 1.3.2 Date of Last Treatment

The Last\_TX\_Date field was added to the PATIENTS table to collect the date of the patient's last treatment. This date is mandatory when the patient is reported as being off protocol treatment (in YYYYMMDD format).

**Reporting Requirements:** The Last\_TX\_Date field is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

\* Italicized items represent those elements that comprise the primary key.

**Legacy Data:** The Last\_TX\_Date is required for protocols activated on or after January 1, 2002.

### 1.3.3 Off Study Date

The Off\_Study\_Date field was added to the PATIENTS table to collect the date that the patient completed protocol-mandated follow-up.

**Reporting Requirements:** The Off\_Study\_Date field is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

**Legacy Data:** The Off\_Study\_Date is required for protocols activated on or after January 1, 2002.

### 1.3.4 Off Study Reason

The Off\_Study\_Reason field was added to the PATIENTS table to collect the reason that the patient went off study. The valid values for this field are listed below:

01 = Protocol-defined follow-up period completed

02 = Patient lost to follow-up

03 = Patient refused follow-up

04 = Death

05 = Toxicity/Side Effects/Complications

**Reporting Requirements:** The Off\_Study\_Reason field is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

**Legacy Data:** The Off\_Study\_Reason is required for protocols activated on or after January 1, 2002.

### 1.3.5 Baseline Abnormalities Flag

The Baseline\_Abnormalities\_Flag was added to the PATIENTS table to indicate whether baseline abnormalities were found during the patient's initial history and physical examination (see section 2.2 for additional details). The valid values for this field are (1) Yes, (2) No, and (9) Unknown.

**Reporting Requirements:** The Baseline\_Abnormalities\_Flag is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

**Legacy Data:** The Baseline\_Abnormalities\_Flag is required for protocols activated on or after January 1, 2002.

### 1.3.6 Race Code

The Race\_Code field was moved from the PATIENTS table and is now collected through the new PATIENT\_RACES table (see section 2.1 for additional details).

### 1.3.7 Eligibility Status

On review of CDU data, a problem has been noted with the information being submitted for the eligibility status field in the PATIENTS table. It has been identified that some sites

\* Italicized items represent those elements that comprise the primary key.

have submitted data as if the question were “Has the patient been declared **eligible**?” rather than “Has the patient been declared **ineligible**?” which is instructed in the CDUS Instructions and Guidelines version 2.0.

To more clearly reflect what is being collected for this field, the name of this column has been changed from Eligibility\_Status to Ineligibility\_Status.

CTEP is requesting that all sites review how they have interpreted this question in the past, and make corrections if it has been previously misinterpreted. An evaluation of the data submitted for this field is underway, and individual sites will be contacted to help ensure that the data is corrected.

### 1.3.8 Technical Reporting Requirements

Each record associated with the PATIENTS table should consist of the following information:\*

	<i>Protocol_ID</i>	Varchar2(35)	
	<i>Patient_ID</i>	Varchar2(20)	
	Zip_Code	Varchar2(10)	
	Country_Code	Varchar2(2)	
	Birth_Date	Date (YYYYMM)	
	Gender_Code	Varchar2(1)	
	<del><i>Race_Code</i></del>	<del>Varchar2(2)</del>	← Relocated
	<i>[Race_Code now collected through the PATIENT_RACES table]</i>		
→ NEW	Ethnicity_Flag	Varchar2(2)	
	[valid values = (1) Hispanic or Latino, (2) Non-Hispanic, or (9) Unknown]		
	Method_Of_Payment	Varchar2(2)	
	Date_Of_Entry	Date (YYYYMMDD)	
	Reg_Group_ID	Varchar2(6)	
	Reg_Inst_ID	Varchar2(6)	
	TX_On_Study	Varchar2(1)	
	Off_TX_Reason	Varchar2(2)	
→ NEW	Last_TX_Date	Date (YYYYMMDD)	
→ NEW	Off_Study_Reason	Varchar2(2)	
→ NEW	Off_Study_Date	Date (YYYYMMDD)	
	Subgroup_Code	Varchar2(10)	
	Ineligibility_Status	Varchar2(1)	← Name Change
	Baseline_PS_Code	Varchar2(1)	
	Prior_Chemo_Regs	Number(2)	
	Disease_Code	Number(10)	
	Resp_Eval_Status	Varchar2(1)	

\* Italicized items represent those elements that comprise the primary key.



Baseline\_Abnormalities\_Flag Varchar2(1)  
 [valid values = (1) Yes, (2) No, or (9) Unknown]

A sample record associated with the PATIENTS table will appear as follows:

"PATIENTS", "<Protocol\_ID>", "<Patient\_ID>", "<Zip\_Code>", "<Country\_Code>", "<Birth\_Date>", "<Gender\_Code>", "<Ethnicity\_Flag>", "<Method\_Of\_Payment>", "<Date\_Of\_Entry>", "<Reg\_Group\_ID>", "<Reg\_Inst\_ID>", "<TX\_On\_Study>", "<Off\_TX\_Reason>", "<Last\_TX\_Date>", "<Off\_Study\_Reason>", "<Off\_Study\_Date>", "<Subgroup\_Code>", "<Ineligibility\_Status>", "<Baseline\_PS\_Code>", "<Prior\_Chemo\_Regs>", "<Disease\_Code>", "<Resp\_Eval\_Status>", "<Baseline\_Abnormalities\_Flag>"

## 1.4 TABLE\_TREATMENT\_COURSES TABLE

### 1.4.1 Field Name Change

The following field name was changed to be consistent with CTEP terminology.

Original Field Name	New Field Name
Tox_Experience	AE_Experience

This is the only change to this table. All other information in this table remains the same.

## 1.5 ADVERSE\_EVENTS TABLE (Formerly The TOXIC\_EVENTS Table)

### 1.5.1 Table Name Change

The original name of the TOXIC\_EVENTS table was changed to the ADVERSE\_EVENTS table to be consistent with CTEP terminology.

### 1.5.2 Field Name Change

The following field names were changed to be consistent with CTEP terminology:

Original Field Name	New Field Name
Tox_Type_Code	AE_Type_Code
Tox_Grade_Code	AE_Grade_Code
Tox_Attribution_Code	AE_Attribution_Code

### 1.5.3 Adverse Event Other Specify

Each category in the Common Toxicity Criteria has an Other, Specify option for Adverse Events that are not listed in the available Adverse Event criteria (e.g., Gastrointestinal: Other, Specify; Blood/Bone Marrow: Other, Specify; etc.). The AE\_Other\_Specify field was added to the ADVERSE\_EVENTS table to collect the name of the Adverse Event when a toxicity type of Other, Specify is selected. For example, Hyperkeratosis is not a CTC term but is a very specific dermatologic manifestation associated with the use of a specific class of new agents. In this case, DERMATOLOGY/SKIN, Other, Specify is selected and Hyperkeratosis is entered as the actual Adverse Event term. All categories of the CTC allow for such specificity when the appropriate term is not included in the CTC.

**Reporting Requirements:** The AE\_Other\_Specify field is mandatory for all CDUS-Complete studies, but are not required for CDUS-Abbreviated studies.

\* Italicized items represent those elements that comprise the primary key.

**Legacy Data:** The AE\_Other\_Specify field is required for protocols activated on or after January 1, 2002.

### 1.5.4 New Reporting Requirement

Grade 3 Adverse Events with an attribution of Unrelated or Unlikely are now required to be reported. This is a new reporting requirement only.

**Reporting Requirements:** Grade 3 Adverse Event information is mandatory for all CDUS-Complete studies, but are not required for CDUS-Abbreviated studies.

**Legacy Data:** Grade 3 Adverse Event information is required for protocols activated on or after January 1, 2002.

The revised schema for CDU reporting requirements is as follows:

#### ***Routine Adverse Event Reporting Guidelines for CDUS***

<b>Attribution</b>	<b>Grade 1</b>	<b>Grade 2</b>	<b>Grade 3</b>	<b>Grade 4</b>	<b>Grade 5</b>
Unrelated			CDUS	CDUS	CDUS
Unlikely			CDUS	CDUS	CDUS
Possible	CDUS	CDUS	CDUS	CDUS	CDUS
Probable	CDUS	CDUS	CDUS	CDUS	CDUS
Definite	CDUS	CDUS	CDUS	CDUS	CDUS

### 1.5.5 Technical Reporting Requirements

Each record associated with the ADVERSE\_EVENTS table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Patient_ID</i>	<i>Varchar2(20)</i>
<i>Course_ID</i>	<i>Number6(1)</i>
<i>AE_Type_Code</i>	<i>Number(10)</i>
 <i>AE_Other_Specify</i>	<i>Varchar2(100)</i>
<i>AE_Grade_Code</i>	<i>Number(1)</i>
<i>AE_Attribution_Code</i>	<i>Number(1)</i>
<i>AER_Filed</i>	<i>Varchar2(1)</i>

A sample record associated with the ADVERSE\_EVENTS table will appear as follows:

"ADVERSE\_EVENTS", "<Protocol\_ID>", "<Patient\_ID>", <Course\_ID>, <AE\_Type\_Code>, "<AE\_Other\_Specify>", <AE\_Grade\_Code>, <AE\_Attribution\_Code>, "<AER\_Filed>"

\* Italicized items represent those elements that comprise the primary key.

## SECTION 2: New Information to be Collected – New Tables

### 2.1 PATIENT\_RACES TABLE

The Health and Human Services, Office of Management and Budget has revised the race and ethnicity reporting requirements. All NCI sponsored trials must comply with these new guidelines. In summary, the new standards include:

- The ability to classify patients under more than one racial category (see section 2.1.1),
- The separation of patient race and ethnicity into two data elements (see section 2.1.2),
- The modification of patient race codes and descriptions (see section 2.1.3), and
- The addition of patient ethnicity codes and descriptions (see section 2.1.4).

**Reporting Requirements:** Reporting Patient Race information is mandatory for all CDUS-Complete and CDUS-Abbreviated studies.

**Legacy Data<sup>2</sup>:** Race and ethnicity information is required for all protocols.

For protocols approved prior to January 1, 2002, race and ethnicity information can continue to be collected using the old guidelines, however, this information must be mapped and submitted according to the table below.

#### **Mapping of Legacy Data to Revised Race and New Ethnicity Codes**

LEGACY RACE AND ETHNICITY DATA		MAPPED TO REVISED CDUS 3.0 RACE AND ETHNICITY DATA			
CODE	DESCRIPTION	RACE CODE	ETHNICITY CODE	RACE DESCRIPTION	ETHNICITY DESCRIPTION
01	White, NOT of Hispanic origin	01	2	White	Non-Hispanic
02	Hispanic	99	1	Unknown	Hispanic or Latino
03	Black or African American, NOT of Hispanic origin	03	2	Black or African American	Non-Hispanic
04	Native Hawaiian or Other Pacific Islander	04	2	Native Hawaiian or Other Pacific Islander	Non-Hispanic
05	Asian	05	2	Asian	Non-Hispanic
06	American Indian or Alaska Native	06	2	American Indian or Alaska Native	Non-Hispanic
98	Other	99	9	Unknown	Unknown
99	Unknown	99	9	Unknown	Unknown

For protocols approved on or after January 1, 2002, race and ethnicity information must be both collected and reported according to the new guidelines.

#### 2.1.1 Multiracial Classification

The PATIENT\_RACES table was created to allow selection of multiple races when applicable to the patient. Patients may be classified as multiracial using one or more racial

<sup>2</sup> Protocols activated on or after January 1, 2002 and patients accrued to studies prior to January 1, 2002 are defined as Legacy.

\* Italicized items represent those elements that comprise the primary key.

categories. For example, a person of European and Chinese origins will be classified as (01) White and (05) Asian.

### 2.1.2 Separation of Race and Ethnicity

Under the new guidelines, patient race and ethnicity are now collected as two separate data elements.

### 2.1.3 Revised Race Values

The following racial categories are included in the updated standards as put forth by the Office of Management and Budget's guidelines.

#### ***Revised Patient Race Codes***

<b>CODE</b>	<b>DESCRIPTION</b>	<b>DEFINITION</b>
01	White	A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
03	Black or African American	A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
04	Native Hawaiian or Other Pacific Islander	A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
05	Asian	A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
06	American Indian or Alaska Native	A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
99	Unknown	Unknown

### 2.1.4 Ethnicity Values

With respect to ethnicity, the standards provide for the collection of data on whether a person is of "Hispanic or Latino" culture or origin. (The standards do not permit a multiple response that would indicate an ethnic heritage that is both Hispanic/Latino and non-Hispanic/non-Latino.) The new Patient Ethnicity Codes are listed below.

#### ***New Patient Ethnicity Codes***

<b>CODE</b>	<b>DESCRIPTION</b>	<b>DEFINITION</b>
1	Hispanic or Latino	A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
2	Non-Hispanic	A person NOT meeting the definition for Hispanic or Latino.
9	Unknown	Unknown

Ethnicity information will now be collected in the PATIENTS table (see section 1.3 for additional details).

\* Italicized items represent those elements that comprise the primary key.

## 2.1.5 Technical Reporting Requirements

Each record associated with the PATIENT\_RACES table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Patient_ID</i>	<i>Varchar2(10)</i>
<i>Race_Code</i>	<i>Varchar2(2)</i>

A sample record associated with the PATIENT\_RACES table will appear as follows:

"PATIENT\_RACES", "<Protocol\_ID>", "<Patient\_ID>", "<Race\_Code>"

## 2.2 BASELINE\_ABNORMALITIES TABLE

The BASELINE\_ABNORMALITIES table was created to collect baseline abnormality information found during the initial history and physical examination for the patient. This information must be submitted when the Baseline\_Abnormalities\_Flag in the PATIENTS table (see section 1.3) is set to 'Yes' and reported using the NCI Common Toxicity Criteria. Baseline abnormality information will provide CTEP with a baseline to use when analyzing treatment-related toxicities. If no baseline abnormalities were found during the patient's initial examination, the Baseline\_Abnormalities\_Flag is set to 'No.'

**Reporting Requirements:** Reporting baseline abnormality information is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

**Legacy Data:** Baseline abnormality information is required only for protocols activated on or after January 1, 2002.

### 2.2.1 Technical Reporting Requirements

Each record associated with the BASELINE\_ABNORMALITIES table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Patient_ID</i>	<i>Varchar2(10)</i>
<i>AE_Type_Code</i>	<i>Number(10)</i>
<i>AE_Other_Specify</i>	<i>Varchar2(100)</i>
<i>AE_Grade_Code</i>	<i>Number(1)</i>

A sample record associated with the BASELINE\_ABNORMALITIES table will appear as follows:

"BASELINE\_ABNORMALITIES", "<Protocol\_ID>", "<Patient\_ID>", "<AE\_Type\_Code>", "<AE\_Other\_Specify>", "<AE\_Grade\_Code>"

## 2.3 LATE\_ADVERSE\_EVENTS TABLE

In some cases, an Adverse Event is observed after a patient has completed treatment. Because these Adverse Events are not associated with a particular treatment course, they cannot be collected through the ADVERSE\_EVENTS table (see section 1.5), which is linked to the TREATMENT\_COURSES table. Under these circumstances, the Adverse Event is reported using the LATE\_ADVERSE\_EVENTS table. The Adverse Event is reported using the NCI Common Toxicity Criteria.

\* Italicized items represent those elements that comprise the primary key.

**Reporting Requirements:** Reporting late Adverse Event information is mandatory for all CDUS-Complete studies, but is not required for CDUS-Abbreviated studies.

**Legacy Data:** Late Adverse Event information is required only for protocols activated on or after January 1, 2002.

### 2.3.1 Technical Reporting Requirements

Each record associated with the LATE\_ADVERSE\_EVENTS table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Patient_ID</i>	<i>Varchar2(10)</i>
<i>AE_Type_Code</i>	<i>Number(10)</i>
<i>AE_Other_Specify</i>	<i>Varchar2(100)</i>
<i>AE_Grade_Code</i>	<i>Number(1)</i>
<i>AE_Start_Date</i>	<i>Date (YYYYMMDD)</i>

A sample record associated with the LATE\_ADVERSE\_EVENTS table will appear as follows:

"LATE\_ADVERSE\_EVENTS", "<Protocol\_ID>", "<Patient\_ID>", "<AE\_Type\_Code>", "<AE\_Other\_Specify>", "<AE\_Grade\_Code>", "<AE\_Start\_Date>"

## 2.4 PROTOCOL\_FUNDING TABLE

The PROTOCOL\_FUNDING table was created to collect grant or contract information on a protocol. The grant or contract number under which the protocol is funded is submitted in its entirety, including the Activity Code, Institution/Center/Division (ICD), and Serial Number. For example: U01 (Activity Code), CA (IC), 12345 (Serial Number). The *Status* and *Status Date* fields will indicate whether the protocol is actively funded under the reported grant or contract, and as of what date the study is actively funded. When the protocol is no longer funded through the reported grant or contract number, the *Status* field should be reported as 'IN' and the *Status Date* should reflect the date that the reported funding mechanism stopped. This information must be submitted when the *Current\_Funding\_Flag* in the COLLECTIONS table (see section 1.1) is set to (1) CTEP.

**Reporting Requirements:** Reporting protocol grant or contract information is mandatory for all CDUS-Complete and CDUS-Abbreviated studies that are funded under a CTEP grant or contract.

**Legacy Data:** Protocol funding information is required for all protocols.

### 2.4.1 Technical Reporting Requirements

Each record associated with the PROTOCOL\_FUNDING table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Activity_Code</i>	<i>Varchar2(3)</i>
<i>ICD</i>	<i>Varchar2(2)</i>
<i>Serial_Number</i>	<i>Number(6)</i>
<i>Status</i>	<i>Varchar2(2)</i>
[valid values = (AC) Active and (IN) Inactive]	

\* Italicized items represent those elements that comprise the primary key.

Status\_Date

Date (YYYYMMDD)

A sample record associated with the PROTOCOL\_FUNDING table will appear as follows:

"PROTOCOL\_FUNDING", "<Protocol\_ID>", "<Activity\_Code>", "<ICD>", "<Serial\_Number>", "<Status>", "<Status\_Date>

## 2.5 CORRELATIVE\_FUNDING TABLE

The CORRELATIVE\_FUNDING table was created to collect grant or contract information on a CTEP-funded correlative study. The grant or contract number under which the embedded correlative study is funded is submitted in its entirety, including the Activity Code, Institution/Center/Division (ICD), and Serial Number. For example: U01 (Activity Code), CA (IC), 12345 (Serial Number). The Status and Status Date fields will indicate whether the correlative study is actively funded under the reported grant or contract, and as of what date the study is actively funded. When a study is no longer funded through the reported grant or contract number, the Status field should be reported as 'IN' and the Status Date should reflect the date that the reported funding mechanism stopped. The information in this table must be submitted when the Current\_Funding\_Flag in the CORRELATIVE\_STUDIES table is set to (1) CTEP.

**Reporting Requirements:** Reporting correlative grant or contract information is mandatory for all CDUS-Complete and CDUS-Abbreviated protocols that have CTEP-funded embedded correlative studies.

**Legacy Data:** Correlative funding information is required for all protocols.

### 2.5.1 Technical Reporting Requirements

Each record associated with the CORRELATIVE\_FUNDING table should consist of the following information:\*

<i>Protocol_ID</i>	<i>Varchar2(35)</i>
<i>Correlative_Study_ID</i>	<i>Varchar2(10)</i>
<i>Activity_Code</i>	<i>Varchar2(3)</i>
<i>ICD</i>	<i>Varchar2(2)</i>
<i>Serial_Number</i>	<i>Number(6)</i>
Status	Varchar2(2)
[valid values = (AC) Active and (IN) Inactive]	
Status_Date	Date (YYYYMMDD)

A sample record associated with the CORRELATIVE\_FUNDING table will appear as follows:

"CORRELATIVE\_FUNDING", "<Protocol\_ID>", "<Correlative\_Study\_ID>", "<Activity\_Code>", "<ICD>", "<Serial\_Number>", "<Status>", "<Status\_Date>

\* Italicized items represent those elements that comprise the primary key.

## SECTION 3: CDUS Smart Loader Sample File

"COLLECTIONS","T95-0036",19970110,19961231,"AC",19961015, "1","Public^John^Q","(301)111-1212","(301)111-2323","public@med.com","1"  
"CORRELATIVE\_STUDIES","T95-0036","950036PK","1",40,40,80,70,"Study Findings"  
"CORRELATIVE\_STUDIES","T95-0036","950036QOL","9",40,35,70,60,"Study Findings"  
"CORRELATIVE\_FUNDING","T95-0036","950036PK","R01","CA","12345","AC",19961015  
"PROTOCOL\_FUNDING","T95-0036","U01","CA",12345,"CORRELATIVE\_FUNDING","T95-0036","950036PK","U01",,"CA",12233  
"PUBLICATIONS","T95-0036",1,"","Effectiveness of Taxol plus Cisplatin","Journal of the American Medical Association","50",1997,"McGraw Hill","10-20"  
"PUBLICATIONS","T95-0036",1,"99061487","","","","",""  
"AUTHORS","T95-0036",1,1,"CAREY"  
"AUTHORS","T95-0036",1,2,"SMITH"  
"PATIENTS","T95-0036","A5001","20595","",194206,"1","9","1",19960707,"NSABP","MD005","1","",,"SUBGROUP1","1","1",2,12345,"1","9"  
"PATIENTS","T95-0036","A5002","20595","",193608,"2","1","2",19960527,"NSABP","MD005","2","03",19960615,"04",19980819,"SUBGROUP1","1","2",2,12345,"1","1"  
"PATIENTS","T95-0036","A5003","20595","",194010,"1","2","3",19960605,"NSABP","MD005","1","",,"SUBGROUP2","1","1",0,23456,"2","2"  
"PATIENT\_RACES","T95-0036","A5001","01"  
"PATIENT\_RACES","T95-0036","A5002","01"  
"PATIENT\_RACES","T95-0036","A5003","03"  
"PATIENT\_RACES","T95-0036","A5003","01"  
"PRIOR\_THERAPIES","T95-0036","A5001",44544  
"PRIOR\_THERAPIES","T95-0036","A5001",77677  
"TREATMENT\_COURSES","T95-0036","A5001","1",19960710,"A1","MD005",170.5,61.3,"2"  
"TREATMENT\_COURSES","T95-0036","A5001","2",19960715,"A1","MD005",170.5,61.3,"1"  
"TREATMENT\_COURSES","T95-0036","A5002","1",19960605,"A1","MD005",152.4,73.6,"2"  
"TREATMENT\_COURSES","T95-0036","A5003","1",19960615,"A1","MD005",180.3,95.4,"2"  
"COURSE\_AGENTS","T95-0036","A5001","1","673089","2",258,"MG"  
"COURSE\_AGENTS","T95-0036","A5001","1","119875","2",375,"MG"  
"COURSE\_AGENTS","T95-0036","A5001","2","673089","2",258,"MG"  
"COURSE\_AGENTS","T95-0036","A5001","2","119875","2",375,"MG"  
"COURSE\_AGENTS","T95-0036","A5002","1","673089","2",245,"MG"  
"COURSE\_AGENTS","T95-0036","A5002","1","119875","2",350,"MG"  
"COURSE\_AGENTS","T95-0036","A5003","1","673089","2",278,"MG"  
"COURSE\_AGENTS","T95-0036","A5003","1","119875","2",380,"MG"  
"BASELINE\_ABNORMALITIES","T95-0036","A5002",455095,"",3  
"ADVERSE\_EVENTS","T95-0036","A5001",2,455095,"",4,4,"1"  
"LATE\_ADVERSE\_EVENTS","T95-0036","A5003",455095,"",4,20010815  
"BEST\_RESPONSES","T95-0036","A5001","05",19960730  
"BEST\_RESPONSES","T95-0036","A5002","04",19960530  
"BEST\_RESPONSES","T95-0036","A5003","06",19960715  
"TRIAL\_COMMENTS","T95-0036","SUBGROUP1","A1","","Response seen in one of two patients"  
"TRIAL\_COMMENTS","T95-0036","SUBGROUP2","A1","No Toxicity",""  
"PHASE1\_END\_POINTS","T95-0036","SUBGROUP1","A1"  
"PHASE1\_END\_POINT\_DLTS","T95-0036","SUBGROUP1","A1",455095

## SECTION 4: Value Revisions

### 4.1 OFF TREATMENT REASON

'Cytogenetic resistance' and 'Disease progression before active treatment' were added to the list of values for Off\_Treatment\_Reason.

'Patient Declared Ineligible' has been removed from the list of values for Off\_Treatment\_Reason.

### 4.2 PRIOR THERAPIES

The value associated with MedDRA Code 900114 was changed from 'Gene Therapy' to 'Gene Transfer.'

The following values were added to the list of values for Prior Therapies:

Added Value	MedDRA Code
Anti-retroviral Therapy	900126
Antisense	900120
Oncolytic Virotherapy	900124
Vaccine	900122
Chemotherapy non-cytotoxic	900128

### 4.3 DOSE UNIT CODE

The following values were added to the list of values for Unit\_Code:

Added Value	Description
billion pfu	Billion pfu
mcmol	Micromole
million IU	Million International Units
million pfu	Million pfu
mVP	Million Viral Particles
TCID	Tissue Culture Infectious Dose

### 4.4 PATIENT RACE AND PATIENT ETHNICITY

The Patient Race Codes were modified by removing the Hispanic (2) Code and adding the Patient Ethnicity Codes (see section 2.1 for additional details).

### 4.5 INTERNATIONAL MEDICAL TERMINOLOGY (IMT) AND MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MedDRA) TERMINOLOGY

All references to IMT Codes and terms have been replaced by references to Medical Dictionary of Regulatory Activities (MedDRA) Codes and terms. The International Conference on Harmonization has developed and extended the terminology (formerly referred to as IMT), and the "Implementable Version" of the new *Medical Dictionary for Regulatory Activities (MedDRA) Terminology* is intended for adoption internationally. Hence, what was formerly referred to as IMT is now referred to as MedDRA.

The codes and values used in the current version of CDUS will be upgraded to a more recent version of MedDRA. Additional information, including a mapping document from the current version to the new version, will be provided in a separate correspondence from CTEP to assist with this transition.

## **SECTION 5: Changes to Field Attributes**

### **5.1 DOSE\_AMOUNT**

The Dose\_Amount column in the COURSE\_AGENTS table was changed from Number (8) to Number (20,3) to allow for submission of up to three decimal places.

### **5.2 COURSE\_ID**

The Course\_ID field in the TREATMENT\_COURSES and ADVERSE\_EVENTS tables was changed to a numeric only field; non-numeric values will no longer be accepted for this field. Course\_ID information should be numbered sequentially; the CDUS Smart Loader will validate that the course information is provided in chronological order. For example, the start date for course 2 should be later than the start date for course 1.

### **5.3 UNIT\_CODE**

The Unit\_Code field in the TREATMENT\_COURSES table was changed from Varchar2(5) to Varchar2(12).

## SECTION 6: New and/or Revised Business Rules

### 6.1 NEW AND REVISED BUSINESS RULES (ALREADY IMPLEMENTED)

The table below describes added, removed, or modified business rules that have been implemented in previous releases of CDUS. They are listed here for documentation purposes only.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
COLLECTIONS	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be <= System Date
	SUBMISSION_DATE	Inappropriate Mandatory	REJECTION	Must be <= System Date
	LEAD_ORG_ID	Inconsistent Mandatory	REJECTION	Mandatory data not consistent with previous value
PUBLICATIONS	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be greater than or equal to the previous submission's CUTOFF_DATE
	YEAR	Inappropriate Requested	REJECTION	Invalid Value (Year must be > '0')
PATIENTS	BIRTH_DATE	Inappropriate Requested	REJECTION	Must be <= CUTOFF_DATE
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= CUTOFF_DATE
	OFF_TX_REASON	Incomplete Requested	REJECTION	OFF_TX_REASON must be NULL if TX_ON_STUDY = '1'
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Best Response for Progression is mandatory when OFF_TX_REASON = '02'
	OFF_TX_REASON	Inappropriate Mandatory	REJECTION	Must be NULL if TX_ON_STUDY = '1'
	RESP_EVAL_STATUS	Incomplete Mandatory	REJECTION	Best response record mandatory when RESP_EVAL_STATUS = '1'
TREATMENT_COURSES	ZIP_CODE	Incomplete Requested	CAUTION	Requested field is NULL (when COUNTRY_CODE is NULL and ZIP_CODE is NULL)
	TOX_EXPERIENCED	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value (Inactive)
ADVERSE_EVENTS	TOX_EXPERIENCED	Incomplete Mandatory	REJECTION	Toxic Event records mandatory when TOX_EXPERIENCED = '1'
	AER_FILED	Incomplete Mandatory	REJECTION	Toxic event record can only be submitted when TOX_EXPERIENCED = '1'
BEST_RESPONSES	GATEGORY	Incomplete Mandatory	REJECTION	Mandatory when RESP_EVAL_STATUS = '1'
	OBSERVED_DATE	Incomplete Mandatory	REJECTION	Mandatory when RESP_EVAL_STATUS = '1'
	CATEGORY	Inappropriate Mandatory	REJECTION	Treatment course record mandatory when BEST_RESPONSES record exists
	OBSERVED_DATE	Incomplete Mandatory	REJECTION	Mandatory when OFF_TX_REASON = '02'
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	Must be >= first COURSE_START_DATE
	OBSERVED_DATE	Incomplete Mandatory	REJECTION	BEST_RESPONSES records can only be submitted when RESP_EVAL_STATUS = '1'
TRIAL_COMMENTS	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	OBSERVED_DATE <= CUTOFF_DATE
	SUBGROUP_CODE	Incomplete Mandatory	REJECTION	Mandatory when TX_ASGNMT_CODE is NULL
	TX_ASGNMT_CODE	Incomplete Mandatory	REJECTION	Mandatory when SUBGROUP_CODE is NULL

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	GEN_RESPONSE_COMMENTS	Incomplete Mandatory	REJECTION	Mandatory when BEST_RESPONSES.CATEGORY = '98' (Other)
PHASE1_END_POINTS	TX_ASGNMT_CODE	Incomplete Requested	CAUTION	Requested when it is a Phase 1 trial with a DCTD-supplied investigational agent
PHASE1_END_POINT_DLTS	TOX_TYPE_CODE	Incomplete Mandatory	REJECTION	Mandatory when it is a Phase 1 trial with a DCTD-supplied investigational agent
	TX_ASGNMT_CODE	Incomplete Requested	CAUTION	Requested when it is a Phase 1 trial with a DCTD-supplied investigational agent

## 6.2 NEW AND REVISED BUSINESS RULES (FOR IMPLEMENTATION IN V3.0)

The table below provides new and revised business rules that will be implemented with the rest of the CDU version 3.0 changes (i.e., for the Quarter 2 2002 data load due July 31, 2002).

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
COLLECTIONS	CURRENT_TRIAL_STATUS_DATE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
CORRELATIVE_STUDIES	PATIENTS_COLLECTED	Inappropriate Requested	CAUTION	Value must not decrease over time
	PATIENTS_COLLECTED	Inappropriate Requested	CAUTION	Must be >= PATIENTS_ANALYZED
	PATIENTS_COLLECTED	Inappropriate Requested	CAUTION	Must be <= SAMPLES_COLLECTED
	PATIENTS_ANALYZED	Inappropriate Requested	CAUTION	Value must not decrease over time
	PATIENTS_ANALYZED	Inappropriate Requested	CAUTION	Must be <= SAMPLES_ANALYZED
	SAMPLES_COLLECTED	Inappropriate Requested	CAUTION	Value must not decrease over time
	SAMPLES_COLLECTED	Inappropriate Requested	CAUTION	Must >= SAMPLES_ANALYZED
	SAMPLES_ANALYZED	Inappropriate Requested	CAUTION	Value must not decrease over time
PATIENTS	BIRTH_DATE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be >= date where Protocol status became 'AC' (Active)
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= date where Protocol status became 'CL' (Closed to Accrual)
	GENDER_CODE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	LAST_TX_DATE	Incomplete Mandatory	REJECTION	Mandatory when TX_ON_STUDY = '2'
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Must be NULL if TX_ON_STUDY = '1'
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Must be >= DATE_OF_ENTRY
	LAST_TX_DATE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	BASELINE_ABNORMALITIES_FLAG	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	BASELINE_ABNORMALITIES_FLAG	Inappropriate Mandatory	REJECTION	Must be 'Yes' if PATIENT_ABNORMALITY information is entered and ABNORMALITY_TYPE = 'Baseline'
	BASELINE_ABNORMALITIES_FLAG	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
BASELINE_ABNORMALITIES	TOX_TYPE_CODE	Incomplete Mandatory	REJECTION	Mandatory when BASELINE_ABNORMALITIES_FLAG = 'Yes'

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	TOX_GRADE_CODE	Incomplete Mandatory	REJECTION	Mandatory when BASELINE_ABNORMALITIES_FLAG = 'Yes' (Mandatory when TOX_TYPE_CODE is not NULL)
	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when TOX_TYPE_CODE = 'other'
TREATMENT_COURSES	COURSE_START_DATE	Incomplete Mandatory	REJECTION	Mandatory data not submitted
ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when TOX_TYPE_CODE = 'other'
LATE_ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when TOX_TYPE_CODE = 'other'
PROTOCOL_FUNDING	IC	Incomplete Mandatory	REJECTION	Mandatory data not submitted
	SERIAL_NUMBER	Incomplete Mandatory	REJECTION	Mandatory data not submitted
	ACTIVITY_CODE	Incomplete Mandatory	REJECTION	Mandatory data not submitted
CORRELATIVE_FUNDING	IC	Incomplete Mandatory	REJECTION	Mandatory data not submitted
	SERIAL_NUMBER	Incomplete Mandatory	REJECTION	Mandatory data not submitted
	ACTIVITY_CODE	Incomplete Mandatory	REJECTION	Mandatory data not submitted

### 6.3 BUSINESS RULES WHERE A WARNING WILL CHANGE TO A CAUTION (FOR IMPLEMENTATION IN April 2002)

After receiving feedback from many sites, it has been decided that errors raised due to inconsistent mandatory data will be downgraded from WARNING errors to CAUTION errors. Sites will no longer need to provide CTEP with verification that the latest data is correct. However, as with all CAUTION errors, CTEP expects sites to review these errors to ensure that the data being submitted is correct and accurate. This change will be implemented with the Quarter 1 2002 data load (due April 30, 2002).

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
PATIENTS	DATE_OF_ENTRY	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	DISEASE_CODE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	OFF_TX_REASON	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	REG_GROUP_ID	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	REG_INST_ID	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
	SUBGROUP_CODE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
TREATMENT_COURSES	TX_ASGNMT_CODE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
ADVERSE_EVENTS	TOX_ATTRIBUTION_CODE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value
BEST_RESPONSES	OBSERVED_DATE	Inconsistent Mandatory	CAUTION	Mandatory data not consistent with previous value

## SECTION 7: Clarifications/New Instructions for Data Submissions

### 7.1 RESPONSE INFORMATION

- a. There have been several queries related to reporting response information for protocols that do not use traditional response criteria. If the protocol does not use the traditional response criteria provided in the list of values (e.g., where the response is based on serum level changes of a particular factor), then the value 'Other' should be submitted. If 'Other' is submitted, it is requested that information about the patient's response be submitted using the Gen\_Response\_Comments field as described in detail in the TRIAL\_COMMENTS table section of the CDUS Instructions and Guidelines.
- b. Progression should be reported even if it is experienced after a response (e.g., Less than Partial Response, Partial Response, Complete Response).
- c. The Observed\_Date from the BEST\_RESPONSES table is mandatory for all CDUS-Complete and CDUS-Abbreviated responses submitted, including Stable Disease. The Observed\_Date for Stable Disease is reported as the date that the test or procedure was performed that indicated that the patient had stable disease.

### 7.2 TREATMENT COURSES AE\_EXPERIENCED FLAG

The codes (1) Yes, (2) No, and (3) Too Early to Evaluate are the valid values available to indicate that a patient experienced an adverse event on the current course of therapy. This information is reported using the AE\_Experienced field in the TREATMENT\_COURSES table.

To accommodate all reporting situations, the definition of 'No' has been refined to indicate that the patient did not experience any adverse events *that are required to be reported via CDU*.

For example, if during a course of treatment a patient only experienced a Grade 1 adverse event with an attribution of 'Unlikely,' then the AE\_Experienced flag may be reported as 'No.' The site is not required to report the event.

However, although not required by CTEP, the site does have the option to choose to report these events. If a site chooses to report these cases to CTEP, then the AE\_Experienced flag should be reported as 'Yes.'

### 7.3 SUBGROUP AND TREATMENT ASSIGNMENT CODES AND DESCRIPTIONS

Subgroup and Treatment Assignment Codes and descriptions were previously created and submitted by the investigator to CTEP via the Protocol Submission Worksheet. This information is now abstracted from the protocol by CTEP staff. After a protocol is approved, the codes and descriptions assigned by CTEP are submitted to the investigator and CDU contact for review and acceptance. Additionally, this information is sent quarterly with the *List of Expected Protocols* for each site.

### 7.4 SMART LOADER REMINDER, WARNING, AND SUSPENSION PROCESS

The CDU data resubmission timeline was modified for files with rejection or warning errors. If no verification and/or resubmission is received by CTEP, the following correspondences will occur:

- 5 working days after a rejection notice is sent – reminder notice
- 10 working days after the rejection notice is sent – warning notice
- 15 working days after rejection notice is sent – suspension notice

The timeline for sending notices listed above will begin on the submission due date for the data.

If no file is received for an expected protocol, then notices are sent according to the following timeline:

- 1 working day after the due date – late notice
- 10 working days after the due date – warning notice
- 15 working days after the due date – suspension notice

## **7.5 REFERENCE REMOVED**

A footnote on page 11 of version 2.1 of the CDUS I&G stated "the final study report requirements for Phase 1-3 studies are posted on the CTEP Home Page at <http://ctep.info.nih.gov/PAMO/ProtocolInfOffice.htm>." This reference is invalid and was removed. Please contact the CTEP Protocol Information Office at (301) 496-1367 for questions about final study report requirements.

## **7.6 REGISTERING GROUP ID**

Collection of Reg\_Group\_ID from the PATIENTS table was expanded to include all trials with Group participation, not just Intergroup trials. For example, Registering Group information is collected for trials with John's Hopkins University as the lead, but with ECOG as a participating Group.

This information is mandatory for both CDUS-Complete and CDUS-Abbreviated studies.

## **7.7 REGISTERING INSTITUTION ID**

Because the lead Group on an Intergroup trial may have difficulty determining the correct Institution Code for patients registered outside the Lead Group, CTEP developed a Web site to assist in identifying the correct Reg\_Inst\_ID (see section 1.3 for information on the PATIENTS table). The institution names and codes for each Group can be found from the CTEP Home Page.

## **7.8 PHASE I END POINTS**

The instruction for the PHASE1\_END\_POINTS table was modified to include collecting either the recommended Phase 2 dose or the minimum effective dose depending on the protocol objectives.

## Appendix A: Summary List of Modifications

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
<b>New Information to be Collected: Modification to Existing Tables (CDUS Notice of Modifications, section 1)</b>				
<b>COLLECTIONS Table (CDUS Notice of Modifications, section 1.1)</b>				
<p>The COLLECTIONS table was modified by adding the following fields:</p> <ol style="list-style-type: none"> <li>The Current_Trial_Status_Date field was added to collect the date the current protocol status took effect (e.g., if the current status is active, and the protocol became active on January 15, 2000, then 20000115 [using the standard date format of YYYYMMDD] is submitted as the Current_Trial_Status_Date).</li> <li>The Current_Funding_Flag was added to identify protocols that are currently funded under a CTEP grant or contract.</li> </ol>	Mandatory	Mandatory	Required for all protocols.	To assist in determining the Current_Trials_Status_Date, CTEP will include the current protocol status and date with each site's quarterly <i>List of Expected Protocols</i> .
	Mandatory	Mandatory	Required for all protocols.	If Current_Funding_Flag is set to 'CTEP,' then grant or contract information must be submitted through the PROTOCOL_FUNDING table.  See section 2.4 for information on the PROTOCOL_FUNDING table.
<b>CORRELATIVE_STUDIES Table (CDUS Notice of Modifications, section 1.2)</b>				
<p>Correlative study information is now mandatory for all protocols with embedded correlative studies regardless of the monitoring method.</p> <p>The CORRELATIVE_STUDIES table was modified by adding the following fields:</p> <ol style="list-style-type: none"> <li>The Current_Funding_Flag was added to identify embedded correlative studies that are currently funded under a CTEP grant or contract.</li> <li>The Samples_Collected field was added to collect the number of samples collected across patients on the correlative study.</li> </ol>	Mandatory	Mandatory	Required for all protocols.	If Current_Funding_Flag is set to 'I' (CTEP) then grant or contract information must be submitted through the CORRELATIVE_FUNDING table.  See section 2.5 for information on the CORRELATIVE_FUNDING table.
	Mandatory	Mandatory	Required only for protocols activated on or after January 1, 2002.	

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
3. The Samples_Analyzed field was added to collect the number of samples analyzed across patients on the correlative study.	Mandatory	Mandatory	Required only for protocols activated on or after January 1, 2002.	
<b>PATIENTS Table (CDUS Notice of Modifications, section 1.3)</b>				
<p>The PATIENTS table was modified by adding or removing the following fields:</p> <p>1. The Ethnicity_Flag was added to identify whether a person is of Hispanic or Latino culture or origin.</p> <p>2. The Last_TX_Date field was added to indicate the date of the patient's last treatment.</p> <p>3. The Off_Study_Date field was added to collect the date a patient completed protocol-mandated follow-up.</p> <p>4. The Off_Study_Reason field was added to collect the reason that the patient went off study.</p> <p>5. The Baseline_Abnormalities_Flag was added to indicate whether baseline abnormalities were found during the patient's initial history and physical examination.</p> <p>6. The Gender_Code field is now mandatory for all protocols.</p> <p>7. The Birth_Date field is now mandatory for all protocols.</p> <p>8. The Race_Code field was moved to the PATIENT_RACES table. Race information is now submitted using the PATIENT_RACES table.</p>	Mandatory	Mandatory	Required for all protocols.	<p>Race and ethnicity information for protocols approved on or after January 1, 2002, must be both collected and reported according to the new guidelines (see section 2.1). Data for protocols approved prior to January 1, 2002, must be mapped according to section 2.1.</p> <p>See section 2.1.4 for a complete list of Ethnicity values.</p>
	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	The Last_TX_Date field must be submitted when the patient is reported as off protocol treatment (using the standard date format of YYYYMMDD).
	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	See section 1.3.4 for a complete set of valid values.
	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
	Mandatory	Mandatory	Not Applicable.	New reporting requirement only.
	Mandatory	Mandatory	Required only for protocols activated on or after January 1, 2002.	
	Not Applicable	Not Applicable	Not Applicable.	See section 2.1 for information on the PATIENT_RACES table.

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
<b>ADVERSE_EVENTS Table (Formerly the TOXIC_EVENTS Table) (CDUS Notice of Modifications, section 1.4)</b>				
<p>The TOXIC_EVENTS table name was changed and the table modified by adding the following field and reporting requirement:</p> <ol style="list-style-type: none"> <li>The TOXIC_EVENTS table name was changed to the ADVERSE_EVENTS table.</li> <li>The AE_Other_Specify field was added to collect Adverse Events when the option 'Other, Specify' is selected within a CTC category.</li> <li>Grade 3 Adverse Events with an attribution of Unrelated or Unlikely was added as a reporting requirement.</li> </ol>	<p>Not Applicable</p> <p>Mandatory</p> <p>Mandatory</p>	<p>Not Applicable</p> <p>Not Required</p> <p>Not Required</p>	<p>Required only for protocols activated on or after January 1, 2002.</p> <p>Required only for protocols activated on or after January 1, 2002.</p>	<p>New reporting requirement only.</p> <p>See section 1.5.4 for the complete Adverse Event Reporting Requirements.</p>
<b>New Information to be Collected: New Tables (CDUS Notice of Modifications, section 2)</b>				
<b>PATIENT_RACES Table (CDUS Notice of Modifications, section 2.1)</b>				
<p>The PATIENT_RACES table was created to collect multiracial patient classification.</p> <ul style="list-style-type: none"> <li>Patients are classified by all racial categories that apply (e.g., a patient of European and Chinese origin is classified as [01] White and [05] Asian).</li> <li>Revised Race Codes and descriptions and new Ethnicity Codes and descriptions are available.</li> <li>Race and ethnicity information are now addressed as separate data elements. Ethnicity information is collected in the PATIENTS table.</li> </ul>	Mandatory	Mandatory	<p>Required for all protocols.</p> <p>For protocols approved on or after January 1, 2002, race and ethnicity information must be both collected and reported according to the new guidelines.</p>	<p>Race and ethnicity information for protocols approved prior to January 1, 2002 can continue to be collected using the old guidelines, however this information must be mapped according to section 2.1.</p> <p>See section 1.3.6 for race code information, section 2.1.4 for ethnicity values, and section 1.3 for information on the PATIENTS table.</p>
<b>BASELINE_ABNORMALITIES Table (CDUS Notice of Modifications, section 2.2)</b>				
<p>The BASELINE_ABNORMALITIES table was created to collect baseline abnormalities found during a patient's initial history and physical examination.</p>	Mandatory	Not Required	<p>Required only for protocols activated on or after January 1, 2002.</p>	<p>Baseline abnormality information is submitted using the NCI CTC v3.0.</p> <p>Baseline abnormality information is mandatory when the Baseline_Abnormalities_Flag in the PATIENTS table is 'Yes.'</p>

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
<b>LATE_ADVERSE_EVENTS Table (CDUS Notice of Modifications, section 2.3)</b>				
The LATE_ADVERSE_EVENTS table was created to collect Adverse Events not associated with specific treatment courses (i.e., an adverse event observed in a patient that no longer receives treatment).	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
<b>PROTOCOL_FUNDING Table (CDUS Notice of Modifications, section 2.4)</b>				
The PROTOCOL_FUNDING table was created to collect grant or contract information of a protocol.	Mandatory	Mandatory	Required for all protocols.	Grant or contract numbers identifying the protocol's funding mechanisms are submitted using the Activity Code, ICD, and Serial Number.  Grant or contract information is mandatory when the COLLECTIONS.Current_Funding_Flag is 'Yes.'
<b>CORRELATIVE_FUNDING Table (CDUS Notice of Modifications, section 2.5)</b>				
The CORRELATIVE_FUNDING table was created to collect grant or contract information of a correlative study.	Mandatory	Mandatory	Required for all protocols.	Grant or contract numbers identifying the embedded correlative study's funding mechanism are submitted using the Activity Code, ICD, and Serial Number.  Grant or contract information is mandatory when the CORRELATIVE_STUDIES.Current_Funding_Flag is 'Yes.'
<b>Value Revisions (CDUS Notice of Modifications, section 4)</b>				
1. Off Treatment Reason – 'Cytogenetic resistance' and 'Disease progression before active treatment' were added to the Off_TX_Reason list of values. 'Patient declared ineligible' was removed from the Off_TX_Reason list of values.	Not Applicable	Not Applicable	Not Applicable.	
2. Prior Therapies – The value associated with MedDRA Code 900114 was changed from 'Gene Therapy' to 'Gene Transfer.' In addition, several new values have been added to the Prior Therapies list of values.	Not Applicable	Not Applicable	Not Applicable.	See section 4.2 for the added Prior Therapy Codes.
3. Dose Unit Code – several new values have been added to the Unit Code list of values.	Not Applicable	Not Applicable	Not Applicable.	See section 4.3 for the added Unit Codes.
4. Patient Race – The patient Race Code listing was revised.	Not Applicable	Not Applicable	Not Applicable.	See section 1.3.6 for Race Codes.

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
5. Patient Ethnicity – New codes were added for use with the Ethnicity_Flag.	Not Applicable	Not Applicable	Not Applicable.	See section 2.1.4 for Ethnicity values.
6. NCI Common Toxicity Criteria, v3.0 (NCI CTC v3.0) – CTEP is currently revising the NCI CTC and expects to release version 3.0 in April 2002.	Not Applicable	Not Applicable	Not Applicable.	All Adverse Events must be reported using the latest version of the NCI CTC. CTEP will provide mapping information to assist in this process.
7. Medical Dictionary for Regulatory Activities (MedDRA) Terminology: All references to International Medical Terminology (IMT) codes and terms were replaced with codes and terms from the Medical Dictionary of Regulatory Activities (MedDRA).	Not Applicable	Not Applicable	Not Applicable.	
<b>Changes to Field Attributes (CDUS Notice of Modifications, section 5)</b>				
1. The Dose_Amount field in the COURSE_AGENTS table was changed from Number(20) to Number(20,3) to submit up to three decimal places.	Not Applicable	Not Applicable	Not Applicable.	
2. The Course_ID field was made numeric. Non-numeric values will no longer be accepted for this field.	Not Applicable	Not Applicable	Not Applicable.	
3. The Unit_Code field in the TREATMENT_COURSES table was changed from Varchar2(5) to Varchar2(12).	Not Applicable	Not Applicable	Not Applicable.	
<b>New and/or Revised Business Rules (CDUS Notice of Modifications, section 6)</b>				
Please refer to Section 6 of the CDUS Notice of Modification for a complete list of all new and/or revised business rules.				
<b>Clarifications/New Instructions for Data Submissions (CDUS Notice of Modifications, section 7)</b>				
<b>Response Information (CDUS Notice of Modifications, section 7.1)</b>				
1. Patient response information is now requested when the value 'Other' is selected for the patient's therapy response ('Other' is generally selected for protocols that do not use traditional response criteria).	Clarification Only		Not Applicable.	Entry of response information is done using the TRIAL_COMMENTS table, Gen_Response_Comments field.
2. Progression is reported regardless of it occurring after a response (e.g., Less than Partial Response, Partial Response, Complete Response).	Clarification Only		Not Applicable.	

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
3. The Observed_Date field is mandatory for all CDUS-Complete responses submitted, including Stable Disease.	Mandatory	Not Required	Not Applicable.	The Observed_Date for Stable Disease is reported as the date the test or procedure was performed indicating the patient had Stable Disease.
<b>Treatment Courses AE Experienced Flag (CDUS Notice of Modifications, section 7.2)</b>				
1. The codes (1) Yes, (2) No, and (3) Too Early to Evaluate are the valid values available for the TREATMENT_COURSES AE_ Experienced field. The definition of 'No' has been refined to indicate that the patient did not experience any adverse events <i>that are required to be reported via CDU.</i>	Clarification Only		Not Applicable.	
<b>Subgroup and Treatment Assignment Codes and Descriptions (CDUS Notice of Modifications, section 7.3)</b>				
Subgroup and Treatment Assignment Codes and descriptions are now assigned by CTEP staff during protocol abstraction and review.	Clarification Only		Not Applicable.	After protocol approval, CTEP-assigned Subgroup and Treatment Assignment Codes and descriptions are submitted to the investigator and CDU contact for notification.  Subgroup and Treatment Assignment Codes are sent with each site's quarterly <i>List of Expected Protocols.</i>

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
<b>Smart Loader Reminder, Warning, and Suspension Process (CDUS Notice of Modifications, section 7.4)</b>				
<p>The CDU data resubmission timeline was modified to require verification and/or resubmission of files with rejection or warning errors. If no verification and/or resubmission is received by CTEP, the following correspondences will occur:</p> <ul style="list-style-type: none"> <li>• A reminder notice will be sent 5 working days after the rejection notice is sent.</li> <li>• A warning notice will be sent 10 working days after the rejection notice is sent.</li> <li>• A suspension notice will be sent 15 working days after the rejection notice is sent.</li> </ul> <p>The timeline for sending notices listed above will begin on the submission due date for the data.</p> <p>If no file is received for an expected protocol, then notices are sent according to the following timeline:</p> <ul style="list-style-type: none"> <li>• A late notice will be sent 1 working day after the due date.</li> <li>• A warning notice will be sent 10 working days after the due date.</li> <li>• A suspension notice will be sent 15 working days after the due date.</li> </ul>	Clarification Only		Not Applicable.	
<b>Reference Removed (CDUS Notice of Modifications, section 7.5)</b>				
An invalid footnote was removed from page 11 of the <i>CDUS Instructions and Guidelines</i> .	Clarification Only		Not Applicable.	
<b>Registering Group ID (CDUS Notice of Modifications, section 7.6)</b>				
Collection of the Reg_Group_ID was expanded beyond Intergroup trials to include all trials with Cooperative Group participation.	Mandatory	Mandatory	Required for all protocols.	
<b>Registering Institution ID (CDUS Notice of Modifications, section 7.7)</b>				
A Web site will be available to assist lead Groups in identifying the correct Reg_Inst_ID for patients registered outside the lead Group on Intergroup trials.	Clarification Only		Not Applicable.	
<b>Phase I End Points (CDUS Notice of Modifications, section 7.8)</b>				
Instruction for the PHASEI_END_POINTS table was modified to include collecting either the recommended Phase 2 dose or the minimum effective dose depending on protocol objectives.	Clarification Only		Not Applicable.	