Clinical Data Update System (CDUS) v3.0

Notice of Modifications

May 3, 2002

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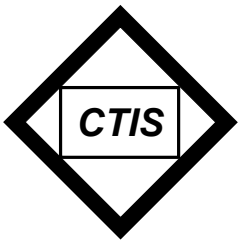

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Updates and Clarifications Made to the January 28, 2002 Notice of Modifications

Funding Information

All references to the collection of funding information were removed. This includes references made to the Current_Funding_Flag in the COLLECTIONS and CORRELATIVE_STUDY tables, the PROTOCOL_FUNDING and CORRELATIVE_FUNDING tables, the CDUS Smart Loader Sample File, the New and/or Revised Business Rules, and the Summary. The following provides the specific sections affected in the January 28, 2002 Notice of Modifications and the type of revision.

Original Section Name and Number		Revision
1.1.2	Current Funding Flag	Removed
1.2.1	Current Funding Flag	Removed
2.4	PROTOCOL_FUNDING_TABLE	Removed
2.5	CORRELATIVE_FUNDING_TABLE	Removed
3	CDUS Smart Loader Sample File	Revised
6	New and/or Revised Business Rules	Revised
Appendix A: Summary List of Modifications		Revised

Clarifications and Editorial Modifications

1.3.3 Off Study Date and 1.3.4 Off Study Reason, pg. 4: These sections were switched to reflect their placement within the PATIENTS Table (the sections are now numbered **1.3.3 Off Study Reason** and **1.3.4 Off Study Date**).

1.4 TREATMENT_COURSES TABLE, pg. 6: The word "Table" appearing first in the section title was removed.

1.6.3 Adverse Event - Other, Specify, pg. 7: Minor typographical revisions were made for consistency.

2.2. BASELINE_ABNORMALITIES TABLE, pg. 12: The word "toxicities" was changed to "Adverse Events" in the following sentence: Baseline abnormality information will provide CTEP with a baseline to use when analyzing treatment-related **toxicities**.

4.1 OFF TREATMENT REASON, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **OFF_TREATMENT_REASON FROM THE PATIENTS TABLE**).

4.1 OFF TREATMENT REASON, pg. 16: The new and removed values were formatted as columns to be consistent with Sections 4.2 and 4.3.

4.2 PRIOR THERAPIES, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **THERAPY_CODE FROM THE PRIOR_THERAPIES TABLE**).

4.3 DOSE UNIT CODE, pg. 16: This section title was renamed to reflect both the field and table name (the section is now named **UNIT_CODE FROM THE COURSE_AGENTS TABLE**). The value "mVP" was updated to "MVP."

4.4 PATIENT RACE AND PATIENT ETHNICITY, pg. 17: This section title was renamed to reflect both the field and table name (the section is now named **RACE_CODE FROM THE PATIENT RACES TABLE AND ETHNICITY_FLAG FROM THE PATIENTS TABLE**).

4.5 INTERNATIONAL MEDICAL TERMINOLOGY (IMT) AND MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MedDRA) TERMINOLOGY, pg. 17: This section was updated to specify the field names and tables affected by the change from IMT to MedDRA codes.

4.4 PATIENT RACE AND PATIENT ETHNICITY, pg. 17: The Hispanic Race Code was updated from (2) to (02).

5.1 DOSE_AMOUNT, pg. 18: This section was updated to clarify that the total number of spaces available for entry as 20. If needed, 17 spaces can be used for digits with an additional three spaces available for decimal places.

Updates to Section 1: New Information to be Collected – Changes to Existing Tables

1.3.3 Off Study Reason, pg. 4: The word "period" was removed from the following valid value description:
01 = Protocol-defined follow-up **period** completed

1.3.3 Off Study Reason, pg. 4: The word "toxicity" was replaced with "Adverse Event" for the following valid value description: 05 = **Toxicity**/Side Effects/Complications

1.3.3 Off Study Reason, pg. 4: "Other" (98) was added to the list of Off_Study_Reason valid values.

1.3.4 Off Study Date, pg. 4: The section was updated to clarify that any value given for Off_Study_Reason would require entry of the Off_Study_Date.

1.3.8 Technical Reporting Requirements, pg. 5: The attribute for the Ethnicity_Flag was updated fromVarchar2(2) to Varchar2(1).

1.4.1 Field Name and Attribute Change, pg. 6: The original field name (Tox_Experience) and the new field name (AE_Experience) were changed to past tense (Tox_Experienced and AE_Experienced). The section was updated to better reflect the change to the Course_ID field.

1.5 COURSE_AGENTS TABLE, pg. 6: The section was updated to better reflect the change to the Course_ID field.

1.6.2 Field Name and Attribute Change, pg. 6: The section was updated to better reflect the change to the Course_ID field.

1.6.3 Adverse Event – Other, Specify, pg. 7: The term "toxicity type" was replaced with "AE_Type_Code" in the following sentence: 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.

1.6.5 Technical Reporting Requirements, pg. 8: The placement of the AE_Other_Specify element within the ADVERSE_EVENTS table was modified to group the primary key elements together.

1.6.5 Technical Reporting Requirements, pg. 8: The Course_ID field was updated from "Number6(1)" to "Number(6)."

1.7 TRIAL_COMMENTS TABLE, pg. 8: This section was added to reflect a field name change.

1.8 PHASE1_END_POINT_DLTS TABLE, pg. 8: This section was added to reflect a field name change.

Updates to Section 1: New Information to be Collected – New Tables

2.1.5 Technical Reporting Requirements, pg. 12: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

2.2.1 Technical Reporting Requirements, pg. 12: The placement of AE_Other_Specify element within the BASELINE_ABNORMALITIES table was modified to group the primary key elements together.

2.2.1 Technical Reporting Requirements, pg. 12: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

2.3.1 Technical Reporting Requirements, pg. 13: The placement of AE_Other_Specify element within the LATE_ADVERSE_EVENTS table was modified to group the primary key elements together.

2.3.1 Technical Reporting Requirements, pg. 13: The attribute for the Patient_ID column was updated from Varchar2(10) to Varchar2(20).

Updates to Section 3: CDUS Smart Loader Sample File, pg. 15

The PATIENTS table was updated to reflect a varchar field (with quotation marks) for Off_Study_Reason.

The COURSE_AGENTS table was updated to reflect a number field (without quotation marks) for Course_ID and to reflect the Unit_Code as lower case.

The sample file was updated to reflect the placement changes described above for the ADVERSE_EVENTS, BASELINE_ABNORMALITIES, and LATE_ADVERSE_EVENTS tables.

Several data examples were updated to more accurately reflect "live" data.

Updates to Section 4: Value Revisions, pg. 16

4.1 OFF TREATMENT REASON, pg. 16: The word "toxicity" was changed to "Adverse Event" for the following valid value description: 03 = **Toxicity**/Side Effects/Complications

4.2 Therapy_Code from the PRIOR_THERAPIES Table, pg. 16: MedDRA v5.0 codes were added to the list of new values.

4.3 DOSE UNIT CODE, pg. 16: A value was added to accommodate dose units that are measured as cells.

Updates to Section 5: Changes to Field Attributes, pg. 18

5.2 COURSE_ID, pg. 18: This section was updated to reflect the change of the Course_ID field in the COURSE_AGENTS table as well as the TREATMENT_COURSES and ADVERSE_EVENTS tables. This section was also clarified to provide specific attribute information regarding Course_ID.

5.3 UNIT CODE, pg. 18: The table named in this section was updated to the COURSE_AGENTS table.

Updates to Section 6: New and/or Revised Business Rules, pg. 19

Business rules were updated to more accurately reflect the modifications made to the CDUS v3.0. Please refer to this version of the business rules; all previous versions are now obsolete.

Updates to Section 7: Clarifications/New Instructions for Data Submissions, pg. 24

7.1 RESPONSE INFORMATION, pg. 24, Item a: The word "requested" was changed to "mandatory" in the following sentence: 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.

7.1 RESPONSE INFORMATION, pg. 24, Item c: The reference to the CDUS Abbreviated monitoring method was removed from the following sentence: The Observed_Date from the BEST_RESPONSES table is mandatory for all CDUS-Complete and **CDUS-Abbreviated** responses submitted, including Stable Disease.

7.3 SUBGROUP AND TREATMENT ASSIGNMENT CODES AND DESCRIPTIONS, pg. 24: This section was updated to include Correlative Study IDs.

7.4 SMART LOADER REMINDER, WARNING, AND SUSPENSION PROCESS, pg. 24: The word "warning" was removed from the following sentence: The CDU data resubmission timeline was modified for files with rejection or **warning** errors.

Updates to Appendix A: Summary List of Modifications

The summary was updated to reflect all clarifications described in this section. The following identifies specific updates made to the summary that are not reflected in any other section of this document.

CORRELATIVE_STUDIES Table, pg. A-1: A comment as added to clarify that correlative study information is mandatory *only* for protocols with embedded correlative studies.

PATIENTS Table, pg. A-2, Item 6: The Legacy Data Requirements column was updated to reflect that the Gender_Code field is required for all protocols.

PATIENTS Table, pg. A-2, Item 7: The Legacy Data Requirements column was updated to reflect that the Birth_Date field is required for all protocols. The Comments column was updated to reflect that this is a new reporting requirement.

PATIENTS Table, pg. A-2, Item 9: The column name change was added to the summary.

BASELINE_ABNORMALITIES Table, pg. A-4, Item 7: The Comments column was updated to remove the reference to version 3.0 of the NCI Common Toxicity Criteria (CTC).

Value Revisions, pg. A-5, Item 6: The reference to the NCI Common Toxicity Criteria (CTC), v3.0 was removed. CTEP is currently revising the NCI CTC, however the expected release date is undetermined at this time.

Response Information, pg. A-6, Item 1: The Reporting Requirements and Legacy Data Requirements columns were updated to provide specific requirements for response information.

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 Technical Reporting Requirements

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

	Protocol_ID	*Varchar2(35)*
	Subm_Date	*Date (YYYYMMDD)*
	CutOff_Date	*Date (YYYYMMDD)*
	Current_Trial_Status_Code	Varchar2(2)
NEW	Current_Trial_Status_Date	Date (YYYYMMDD)
	Completer_Name[1]	Varchar2(87)
	Completer_Phone	Varchar2(20)
	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_Status_Code>",<Current_Trial_Status_Date>,"<Completer_Name>","<Completer_Phone>","<Completer_FAX>","<Completer_Email>","<Change_Code>"

[1] 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.

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 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.

1.2.2 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.

1.2.3 Technical Reporting Requirements

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

	Protocol_ID	*Varchar2(35)*
	Correlative_Study_ID	*Varchar2(10)*
	Patients_Collected	Number(6)
	Patients_Analyzed	Number(6)
NEW	Samples_Collected	Number(6)
NEW	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>",<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

* Italicized items represent those elements that comprise the Primary Key.

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

CODE	DESCRIPTION	DEFINITION
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.

Legacy Data: The Last_TX_Date is required for protocols activated on or after January 1, 2002.

1.3.3 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 completed

02 = Patient lost to follow-up

03 = Patient refused follow-up

04 = Death

05 = Adverse Event/Side Effects/Complications

98 = Other

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.

* Italicized items represent those elements that comprise the Primary Key.

1.3.4 Off Study Date

The Off_Study_Date field was added to the PATIENTS table to collect the date that the patient went off study due to one of the reasons provided from the valid values in Section 1.3.3.

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.

1.3.5 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 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:*

Protocol_ID	*Varchar2(35)*
Patient_ID	*Varchar2(20)*
Zip_Code	Varchar2(10)
Country_Code	Varchar2(2)
Birth_Date	Date (YYYYMM)

* Italicized items represent those elements that comprise the Primary Key.

	Gender_Code	Varchar2(1)
	~~*Race_Code*~~	~~*Varchar2(2)*~~ Relocated
	[Race_Code now collected through the PATIENT_RACES table]	
NEW	Ethnicity_Flag	Varchar2(1)
	[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)
NEW	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 TREATMENT_COURSES TABLE

1.4.1 Field Name and Attribute Change

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

Original Field Name	New Field Name
Tox_Experienced	AE_Experienced

The attribute for the Course_ID field was changed to the following (see Section 5.2 for additional information):

* Italicized items represent those elements that comprise the Primary Key.

Original Field Attribute	New Field Attribute
Varchar2(10)	Number(6)

These are the only changes to this table. All other information in this table remains the same.

1.5 COURSE_AGENTS TABLE

1.5.1 Attribute Change

The attribute for the Course_ID field was changed to the following (see Section 5.2 for additional information):

Original Field Attribute	New Field Attribute
Varchar2(10)	Number(6)

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

1.6 ADVERSE_EVENTS TABLE (Formerly The TOXIC_EVENTS Table)

1.6.1 Table Name Change

The original name of the TOXIC_EVENTS table was changed to the ADVERSE_EVENTS table to be consistent with CTEP terminology.

1.6.2 Field Name and Attribute 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

The attribute for the Course_ID field was changed to the following (see Section 5.2 for additional information):

Original Field Attribute	New Field Attribute
Varchar2(10)	Number(6)

1.6.3 Adverse Event - Other, Specify

Each category in the Common Toxicity Criteria (CTC) 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 the AE_Type_Code 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 in the AE_Other_Specify field. All categories of the CTC allow for such specificity when the appropriate term is not included in the CTC.

* Italicized items represent those elements that comprise the Primary Key.

Reporting Requirements: The AE_Other_Specify field is mandatory for all CDUS-Complete studies, but are not required for CDUS-Abbreviated studies.

Legacy Data: The AE_Other_Specify field is required for protocols activated on or after January 1, 2002.

1.6.4 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

Attribution	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
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

1.6.5 Technical Reporting Requirements

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

	Protocol_ID	*Varchar2(35)*
	Patient_ID	*Varchar2(20)*
	Course_ID	*Number(6)*
	AE_Type_Code	*Number(10)*
	AE_Grade_Code	*Number(1)*
	AE_Other_Specify	Varchar2(100)
	AE_Attribution_Code	Number(1)
	AER_Filed	Varchar2(1)

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_Grade_Code>,"<AE_Other_Specify>",<AE_Attribution_Code>,"<AER_Filed>"

* Italicized items represent those elements that comprise the Primary Key.

1.7 TRIAL_COMMENTS TABLE

1.7.1 Field Name Change

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

Original Field Name	New Field Name
Gen_Tox_Comments	Gen_AE_Comments

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

1.8 PHASE1_END_POINT_DLTS TABLE

1.8.1 Field Name Change

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

Original Field Name	New Field Name
Tox_Type_Code	AE_Type_Code

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

* 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[2]**:** 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

[2] 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

CODE	DESCRIPTION	DEFINITION
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

CODE	DESCRIPTION	DEFINITION
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:*

Protocol_ID	*Varchar2(35)*
Patient_ID	*Varchar2(20)*
Race_Code	*Varchar2(2)*

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 Adverse Events. If no baseline abnormalities were found during the patient's initial examination, the Baseline_Abnormalities_Flag it 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:*

Protocol_ID	*Varchar2(35)*
Patient_ID	*Varchar2(20)*
AE_Type_Code	*Number(10)*
AE_Grade_Code	*Number(1)*
AE_Other_Specify	Varchar2(100)

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

"BASELINE_ABNORMALITIES","<Protocol_ID>","<Patient_ID>",<AE_Type_Code>, <AE_Grade_Code>, "<AE_Other_Specify>"

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 Section1.6), 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:*

Protocol_ID	*Varchar2(35)*
Patient_ID	*Varchar2(20)*
AE_Type_Code	*Number(10)*
AE_Grade_Code	*Number(1)*
AE_Other_Specify	Varchar2(100)
AE_Start_Date	Date (YYYYMMDD)

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_Grade_Code>,"<AE_Other_Specify>",<AE_Start_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,"Public^John^Q","(301)111-1212","(301)111-2323","public@med.com","1"
"CORRELATIVE_STUDIES","T95-0036","950036PK",40,40,80,70,"Study Findings"
"CORRELATIVE_STUDIES","T95-0036","950036QOL",40,35,70,60,"Study Findings"
"PUBLICATIONS","T95-0036",1,"","Effectiveness of Taxol plus Cisplatin","Journal of the American Medical Association","50",1997,"McGraw Hill","10-20"
"PUBLICATIONS","T95-0036",2, "99061487","","","",,"","",""
"AUTHORS","T95-0036",1,1,"CAREY"
"AUTHORS","T95-0036",1,2,"SMITH"
"PATIENTS","T95-0036","A5001","20595","",194206,"1","9","1",19961015,"NSABP","MD005","1","",,"",,"SUBGROUP1","2","1",2,12345,"1","9"
"PATIENTS","T95-0036","A5002","20595","",193608,"2","1","2",19961018,"NSABP","MD005","2","02",19961105,"04",19980819,"SUBGROUP1","2","2",2,12345,"1","1"
"PATIENTS","T95-0036","A5003","20595","",194010,"1","2","3",19961018,"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",1,19961015,"A1","MD005",170.5,61.3,"2"
"TREATMENT_COURSES","T95-0036","A5001",2,19961021,"A1","MD005",170.5,61.3,"1"
"TREATMENT_COURSES","T95-0036","A5002",1,19961018,"A1","MD005",152.4,73.6,"2"
"TREATMENT_COURSES","T95-0036","A5003",1,19961018,"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","A5002",455095,4,"",19980710
"BEST_RESPONSES","T95-0036","A5001","02",19961120
"BEST_RESPONSES","T95-0036","A5002","05",19960530
"BEST_RESPONSES","T95-0036","A5003","06",19961130
"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 FROM THE PATIENTS TABLE

The value associated with code 03 was changed from 'Toxicity/Side Effects/Complications' to 'Adverse Event/Side Effects/Complications.'

The following values were added to the list of values for Off_TX_Reason:

Added Value	Code
Cytogenetic Resistance	11
Disease Progression before Active Treatment	12

The following value was removed from the list of values for Off_TX_Reason:

Value Removed	Code
Patient Declared Ineligible	09

4.2 THERAPY_CODE FROM THE PRIOR_THERAPIES TABLE

The value associated with MedDRA Code 900114 was changed from 'Gene Therapy' to 'Gene Transfer' (MedDRA v5.0 Code 90003004).

The following values were added to the list of values for Therapy_Code:

Added Value	MedDRA Code	MedDRA v5.0 Code*
Anti-retroviral Therapy	900126	90003000
Antisense	900120	90003002
Chemotherapy non-cytotoxic	900128	90003018
Oncolytic Virotherapy	900124	90003008
Vaccine	900122	10036903

*It is recommended that MedDRA v5.0 codes be used.

4.3 UNIT_CODE FROM THE COURSE_AGENTS TABLE

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
cells	Cells

4.4 RACE_CODE FROM THE PATIENT_RACES TABLE AND ETHNICITY_FLAG FROM THE PATIENTS TABLE

The Patient Race Codes were modified by removing the Hispanic (02) 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 MedDRA version 5.0. 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. The following fields are affected:

Table Name	Field Name
PATIENTS	Disease_Code
PRIOR_THERAPY	Therapy_Code
ADVERSE_EVENTS	AE_Type_Code
PHASE1_END_POINT_DLTS	AE_Type_Code
BASELINE_ABNORMALITIES	AE_Type_Code
LATE_ADVERSE_EVENTS	AE_Type_Code

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 17 digits and three decimal places (a total of 20 digits can be entered).

5.2 COURSE_ID

The Course_ID field in the TREATMENT_COURSES, COURSE_AGENTS, and ADVERSE_EVENTS tables was changed from Varchar2(10) to Number(6); 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 COURSE_AGENTS table was changed from Varchar2(5) to Varchar2(12).

SECTION 6: New and/or Revised Business Rules

Please use this version (May 3, 2002) of the business rules to make adjustments in your processes. All previous versions are now obsolete.

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	SUBMISSION_DATE	Inappropriate Mandatory	REJECTION	Must be <= System Date
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be <= System Date
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be greater than or equal to the previous submission's CUTOFF_DATE
	~~LEAD_ORG_ID~~	~~Inconsistent Mandatory~~	~~REJECTION~~	~~Mandatory data not consistent with previous value~~
PUBLICATIONS	YEAR	Inappropriate Requested	REJECTION	Invalid Value (Year must be > '0')
PATIENTS	ZIP_CODE	Incomplete Requested	CAUTION	ZIP_CODE is NULL (when COUNTRY_CODE is NULL and ZIP_CODE is NULL)
	BIRTH_DATE	Inappropriate Requested	REJECTION	Must be <= CUTOFF_DATE
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= CUTOFF_DATE
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Best Response for Progression is mandatory when OFF_TX_REASON = '02'
	OFF_TX_REASON	Inappropriate Mandatory	REJECTION	OFF_TX_REASON must be NULL if TX_ON_STUDY = '1'
	~~OFF_TX_REASON~~	~~Inappropriate Mandatory~~	~~REJECTION~~	~~Must be NULL if TX_ON_STUDY = '1'~~
	RESP_EVAL_STATUS	Incomplete Mandatory	REJECTION	BEST_RESPONSES record mandatory when RESP_EVAL_STATUS = '1'
PRIOR_THERAPIES	THERAPY_CODE	Incomplete Mandatory	REJECTION	Primary Key is NULL
TREATMENT_COURSES	AE_EXPERIENCED	Incomplete Mandatory	REJECTION	Adverse Event records mandatory when AE_EXPERIENCED = '1'
	~~TOX_EXPERIENCED~~	~~Inconsistent Mandatory~~	~~WARNING~~	~~Mandatory data not consistent with previous value (Inactive)~~
ADVERSE_EVENTS	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Adverse Event records can only be submitted when AE_EXPERIENCED = '1'
BEST_RESPONSES	CATEGORY	Incomplete Mandatory	REJECTION	Best Response for Progression is mandatory when OFF_TX_REASON = '02'
	CATEGORY	Inappropriate Mandatory	REJECTION	TREATMENT_COURSES record mandatory when BEST_RESPONSES record exists
	OBSERVED_DATE	Incomplete Mandatory	REJECTION	Mandatory Column is NULL
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	Must be >= first COURSE_START_DATE
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	OBSERVED_DATE <= CUTOFF_DATE
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Mandatory when RESP_EVAL_STATUS = '1'

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	BEST_RESPONSES records can only be submitted when RESP_EVAL_STATUS = '1'
~~TRIAL_COMMENTS~~	~~SUBGROUP_CODE~~	~~Incomplete Mandatory~~	~~REJECTION~~	~~Mandatory when TX_ASGNMT_CODE is NULL~~
	~~TX_ASGNMT_CODE~~	~~Incomplete Mandatory~~	~~REJECTION~~	~~Mandatory when SUBGROUP_CODE is NULL~~
~~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
	CURRENT_TRIAL_STATUS_DATE	Inappropriate Mandatory	REJECTION	Must be <= System Date
CORRELATIVE_STUDIES	PATIENTS_COLLECTED	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	PATIENTS_COLLECTED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	PATIENTS_COLLECTED	Inappropriate Mandatory	REJECTION	Must be >= PATIENTS_ANALYZED
	PATIENTS_COLLECTED	Inappropriate Mandatory	REJECTION	Must be <= SAMPLES_COLLECTED
	PATIENTS_ANALYZED	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	PATIENTS_ANALYZED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	PATIENTS_ANALYZED	Inappropriate Mandatory	REJECTION	Must be <= SAMPLES_ANALYZED
	SAMPLES_COLLECTED	Incomplete Mandatory	REJECTION	Mandatory for all studies Activated on or after 01/01/2002
	SAMPLES_COLLECTED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	SAMPLES_COLLECTED	Inappropriate Mandatory	REJECTION	Must >= SAMPLES_ANALYZED
	SAMPLES_ANALYZED	Incomplete Mandatory	REJECTION	Mandatory for all studies Activated on or after 01/01/2002
	SAMPLES_ANALYZED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Correlative Study information Mandatory if Correlative ID abstracted
PATIENTS	BIRTH_DATE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	BIRTH_DATE	Inappropriate Mandatory	REJECTION	Patient age must be <=100 at Date of Entry
	GENDER_CODE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	ETHNICITY_FLAG	Incomplete Mandatory	REJECTION	Mandatory field is NULL

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	~~RACE_CODE~~	~~Inconsistent Requested~~	~~CAUTION~~	~~Data not consistent with previous value~~
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be >= date when the CURRENT_TRIAL_STATUS_CODE = 'AC' (Active)
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= date when the CURRENT_TRIAL_STATUS_CODE = 'CL' (Closed to Accrual)
	LAST_TX_DATE	Incomplete Mandatory	REJECTION	Mandatory when TX_ON_STUDY = '2'; CDUS-Complete; and study Activated on or after 01/01/2002
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Must be NULL if TX_ON_STUDY = '1'; CDUS-Complete; and study Activated on or after 01/01/2002
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Must be >= DATE_OF_ENTRY
	LAST_TX_DATE	Inconsistent Mandatory	CAUTION	Data not consistent with previous value
	OFF_STUDY_REASON	Incomplete Mandatory	REJECTION	Mandatory if OFF_STUDY_DATE is NOT NULL
	OFF_STUDY_DATE	Incomplete Mandatory	REJECTION	Mandatory if OFF_STUDY_REASON is NOT NULL
	BASELINE_ABNORMALITIES_FLAG	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete and Activated on or after 01/01/2002
	BASELINE_ABNORMALITIES_FLAG	Incomplete Mandatory	REJECTION	Baseline Abnormalities information Mandatory if BASELINE_ABNORMALITIES_FLAG = 'Yes'
	BASELINE_ABNORMALITIES_FLAG	Inconsistent Mandatory	CAUTION	Data not consistent with previous value
	~~BASELINE_ABNORMALITIES_FLAG~~	~~Inappropriate Mandatory~~	~~REJECTION~~	~~Must be 'Yes' if PATIENT_ABNORMALITY information is entered and ABNORMALITY_TYPE = 'Baseline'~~
PATIENT_RACES	RACE_CODE	Incomplete Mandatory	REJECTION	Primary Key is NULL
	~~RACE_CODE~~	~~Inconsistent Mandatory~~	~~CAUTION~~	~~Data not consistent with previous value~~
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	PATIENT_RACES information Mandatory if patient record exists
TREATMENT_COURSES	COURSE_START_DATE	Incomplete Mandatory	REJECTION	Mandatory data not submitted
BASELINE_ABNORMALITIES	~~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 AE_TYPE_CODE = 'other'
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Mandatory when BASELINE_ABNORMALITIES_FLAG = 'Yes'
	ALL COLUMN NAMES	Inappropriate Mandatory	REJECTION	Baseline Abnormality Records may only be submitted if BASELINE_ABNORMALITIES_FLAG = 'Yes'
ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'other'; CDUS-Complete; and Activated on or after 01/01/2002
LATE_ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'other'
TRIAL_COMMENTS	GEN_RESPONSE_COMMENTS	Incomplete Mandatory	REJECTION	Mandatory when BEST_RESPONSES.CATEGORY = '98' (Other) ; CDUS-Complete ; and Activated on or after 01/01/2002

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 mandatory 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 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 TABLE, 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, TREATMENT ASSIGNMENT CODES AND CORRELATIVE STUDY IDS AND DESCRIPTIONS

Subgroup Codes, Treatment Assignment Codes, and Correlative Study IDs and their descriptions were previously created and submitted by the investigator to CTEP via the Protocol Submission Worksheet (PSW). 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 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		
New Information to be Collected: Modification to Existing Tables (*CDUS Notice of Modifications, Section 1)*				
COLLECTIONS Table (*CDUS Notice of Modifications, Section 1.1)*				
The COLLECTIONS table was modified by adding the following fields: 1. 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).	Mandatory	Mandatory	Required for all protocols.	To assist in determining the Current_Trial_Status_Date, CTEP will include the current protocol status and date with each site's quarterly *List of Expected Protocols*.
CORRELATIVE_STUDIES Table (*CDUS Notice of Modifications, Section 1.2)*				
Correlative study information is now mandatory for all protocols with embedded correlative studies regardless of the monitoring method. The CORRELATIVE_STUDIES table was modified by adding the following fields: 1. The Samples_Collected field was added to collect the number of samples collected across patients on the correlative study.	Mandatory	Mandatory	Required only for protocols activated on or after January 1, 2002.	Mandatory ONLY for protocols with embedded correlative studies.
2. 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.	
PATIENTS Table (*CDUS Notice of Modifications, Section 1.3)*				
The PATIENTS table was modified by adding or removing the following fields:				
1. The Ethnicity_Flag was added to identify whether a person is of Hispanic or Latino culture or origin.	Mandatory	Mandatory	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. See Section 2.1.4 for a complete list of Ethnicity values.

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
2. The Last_TX_Date field was added to indicate the date of the patient's last treatment.	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).
3. The Off_Study_Reason field was added to collect the reason that the patient went off study.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	See Section 1.3.3 for a complete set of Off_Study_Reason valid values.
4. The Off_Study_Date field was added to collect the date a patient went off study.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
5. The Baseline_Abnormalities_Flag was added to indicate whether baseline abnormalities were found during the patient's initial history and physical examination.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
6. The Gender_Code field is now mandatory for all protocols.	Mandatory	Mandatory	Required for all protocols.	New reporting requirement only.
7. The Birth_Date field is now mandatory for all protocols.	Mandatory	Mandatory	Required for all protocols.	New reporting requirement only.
8. The Race_Code field was moved to the PATIENT_RACES table. Race information is now submitted using the PATIENT_RACES table.	Not Applicable	Not Applicable	Not Applicable.	See Section 2.1 for information on the PATIENT_RACES table.
9. The Eligibility_Status field was renamed to Ineligibility_Status.	Not Applicable	Not Applicable	Not Applicable.	
TREATMENT_COURSES Table (*CDUS Notice of Modifications, Section 1.4*)				
1. The Tox_Experienced field name was changed to AE_Experienced to be consistent with CTEP terminology.	Not Applicable	Not Applicable		
2. The attribute for the Course_ID field was changed from Varchar2(10) to Number(6).	Not Applicable	Not Applicable		See Section 5.2 for additional information.
COURSE_AGENTS Table (*CDUS Notice of Modifications, Section 1.5*)				
The attribute for the Course_ID field was changed from Varchar2(10) to Number(6).	Not Applicable	Not Applicable		See Section 5.2 for additional information.
ADVERSE_EVENTS Table (Formerly the TOXIC_EVENTS Table) (*CDUS Notice of Modifications, Section 1.6*)				
The TOXIC_EVENTS table name was changed and the table modified by adding the following field and reporting requirement: 1. The TOXIC_EVENTS table name was changed to the ADVERSE_EVENTS table.	Not Applicable	Not Applicable		

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
2. The Tox_Type_Code field name was changed to AE_Type_Code, the Tox_Grade_Code field name was changed to AE_Grade_Code, and the Tox_Attribution_Code field name was changed to AE_Attribution_Code to be consistent with CTEP terminology.	Not Applicable	Not Applicable		
3. The attribute for the Course_ID field was changed from Varchar2(10) to Number(6).	Not Applicable	Not Applicable		See Section 5.2 for additional information.
4. The AE_Other_Specify field was added to collect Adverse Events when the option 'Other, Specify' is selected within a CTC category.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	
5. Grade 3 Adverse Events with an attribution of Unrelated or Unlikely was added as a reporting requirement.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	New reporting requirement only. See Section 1.6.4 for additional information on Adverse Event Reporting Requirements.
TRIAL_COMMENTS Table (*CDUS Notice of Modifications, Section 1.7)*				
The Gen_Tox_Comments field name was changed to Gen_AE_Comments to be consistent with CTEP terminology.	Not Applicable	Not Applicable		
PHASE1_END_POINTS Table (*CDUS Notice of Modifications, Section 1.8)*				
The Tox_Type_Code field name was changed to AE_Type_Code to be consistent with CTEP terminology.	Not Applicable	Not Applicable		
New Information to be Collected: New Tables (*CDUS Notice of Modifications, Section 2)*				
PATIENT_RACES Table (*CDUS Notice of Modifications, Section 2.1)*				
The PATIENT_RACES table was created to collect multiracial patient classification. • 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). • Revised Race Codes and descriptions and new Ethnicity Codes and descriptions are available. • Race and ethnicity information are now addressed as separate data elements. Ethnicity information is collected in the PATIENTS table.	Mandatory	Mandatory	Required for all protocols. For protocols approved on or after January 1, 2002, race and ethnicity information must be both collected and reported according to the new guidelines.	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. 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.

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
BASELINE_ABNORMALITIES Table (*CDUS Notice of Modifications, Section 2.2)*				
The BASELINE_ABNORMALITIES table was created to collect baseline abnormalities found during a patient's initial history and physical examination.	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	Baseline abnormality information is submitted using the NCI CTC. Baseline abnormality information is mandatory when the Baseline_Abnormalities_Flag in the PATIENTS table is 'Yes.'
LATE_ADVERSE_EVENTS Table (*CDUS Notice of Modifications, Section 2.3)*				
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.	
Value Revisions (*CDUS Notice of Modifications, Section 4)*				
1. Off_TX_Reason from the PATIENTS Table – The value 'Toxicity/Side Effect/Complications' was revised to 'Adverse Event/Side Effect/Complications' to be consistent with CTEP terminology. '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. Therapy_Code from the PRIOR_THERAPIES Table – 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 Therapy_Code list of values.	Not Applicable	Not Applicable	Not Applicable.	See Section 4.2 for the added Therapy_Codes.
3. Unit_Code from the COURSE_AGENTS Table – 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. Race_Code from the PATIENT_RACES Table – The patient Race_Code listing was revised.	Not Applicable	Not Applicable	Not Applicable.	See Section 1.3.6 for Race_Codes.
5. Ethnicity_Flag from the PATIENTS Table – New codes were added for use with the Ethnicity_Flag.	Not Applicable	Not Applicable	Not Applicable.	See Section 2.1.4 for Ethnicity_Flag values.
6. 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.	See Section 4.5 for a complete list of affected fields.

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
Changes to Field Attributes (*CDUS Notice of Modifications, Section 5)*				
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 in the TREATMENT_COURSES, COURSE_AGENTS, and ADVERSE_EVENTS tables was changed from Varchar2(10) to Number(6). Non-numeric values will no longer be accepted for this field.	Not Applicable	Not Applicable	Not Applicable.	
3. The Unit_Code field in the COURSE_AGENTS table was changed from Varchar2(5) to Varchar2(12).	Not Applicable	Not Applicable	Not Applicable.	
New and/or Revised Business Rules (*CDUS Notice of Modifications, Section 6)*				
Please refer to Section 6 of the CDUS Notice of Modification dated May 3, 2002 for a complete list of all new and/or revised business rules. All previous versions are obsolete.				
Clarifications/New Instructions for Data Submissions (*CDUS Notice of Modifications, Section 7)*				
Response Information (*CDUS Notice of Modifications, Section 7.1)*				
1. Patient response information is now mandatory 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).	Mandatory	Not Required	Required only for protocols activated on or after January 1, 2002.	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.	
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.
Treatment Courses AE Experienced Flag (*CDUS Notice of Modifications, Section 7.2)*				
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 *that are required to be reported via CDU.*	Clarification Only		Not Applicable.	

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
Subgroup, Treatment Assignment Codes, and Correlative Study IDs and Descriptions ***(CDUS Notice of Modifications, Section 7.3)***				
Subgroup Codes, Treatment Assignment Codes, and Correlative Study IDs and their descriptions are now assigned by CTEP staff during protocol abstraction and review.	Clarification Only		Not Applicable.	After protocol approval, CTEP-assigned Subgroup Codes, Treatment Assignment Codes and Correlative Study IDs and their descriptions are submitted to the investigator and CDU contact for notification. Subgroup and Treatment Assignment Codes are sent with each site's quarterly *List of Expected Protocols*.
Smart Loader Reminder, Warning, and Suspension Process ***(CDUS Notice of Modifications, Section 7.4)***				
The CDU data resubmission timeline was modified to require verification and/or resubmission of files with rejection errors. If no verification and/or resubmission is received by CTEP, the following correspondences will occur: • A reminder notice will be sent 5 working days after the rejection notice is sent. • A warning notice will be sent 10 working days after the rejection notice is sent. • A suspension notice will be sent 15 working days after the rejection notice is sent. 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: • A late notice will be sent 1 working day after the due date. • A warning notice will be sent 10 working days after the due date. • A suspension notice will be sent 15 working days after the due date.	Clarification Only		Not Applicable.	
Reference Removed ***(CDUS Notice of Modifications, Section 7.5)***				
An invalid footnote was removed from page 11 of the *CDUS Instructions and Guidelines*.	Clarification Only		Not Applicable.	
Registering Group ID ***(CDUS Notice of Modifications, Section 7.6)***				
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.	

Description of Change	Reporting Requirements		Legacy Data Requirements	Comments
	CDUS-Complete	CDUS-Abbreviated		
Registering Institution ID (***CDUS Notice of Modifications, Section 7.7***)				
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.	
Phase I End Points (***CDUS Notice of Modifications, Section 7.8***)				
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.	