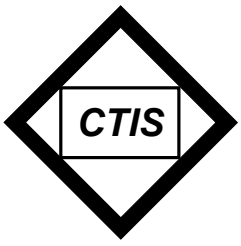
Clinical Data Update System (CDUS) v3.0 Release 2

Notice of Modifications

June 10, 2003

NCI CTEP Help Desk -
Telephone: (301) 840-8202
Fax: (301) 948-2242
E-mail: ncictephelp@ctep.nci.nih.gov



BUILDING THE FUTURE
TOGETHER™

By Capital Technology Information Services, Inc.

TABLE OF CONTENTS

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

1.1 ADVERSE_EVENTS TABLE

The AE_Other_Specify data element was made part of the Primary Key for this table.

1.2 BASELINE_ABNORMALITIES TABLE

The AE_Other_Specify data element was made part of the Primary Key for this table.

1.3 LATE_ADVERSE_EVENTS TABLE

The AE_Other_Specify data element was made part of the Primary Key for this table.

The AE_Attribution_Code, Number(1), data element was added as part of the LATE_ADVERSE_EVENTS Table.

Added <AE_Attribution_Code> to sample record associated with the LATE_ADVERSE_EVENTS Table.

1.4 PHASE1_END_POINT_DLTS TABLE

The AE_Other_Specify data element was added as part of the Primary Key for this table.

AE_Other_Specify Varchar2(100)

Added <AE_Other_Specify> to the sample record associated with the PHASE1_END_POINT_DLTS Table.

1.5 RELATION BETWEEN ENTITIES

Added: There can be one or many Adverse Events specified for every 'AE_Other_Specify.'

SECTION 2: Value Revisions

Updated the description under COLLECTIONS/Current_Trial_Status_Code: 'CL' to "Closed to accrual, Patients still on Treatment" (to be consistent with the description listed in the Current Trial Status section)

Updated the description under COLLECTIONS/Current_Trial_Status_Code: 'CB' to "Closed to accrual, All Patients have Completed Treatment" (to be consistent with the description listed in the Current Trial Status section)

Added under PATIENTS/Ethnicity_Code: "8-Not Reported"

The word 'or' was replaced with '/' in the definition of the PATIENTS/Off_TX_Reason/05 so that it now reads: "Patient withdrawal/refusal after beginning…"

The word 'or' was replaced with '/' in the definition of the PATIENTS/Off_TX_Reason/06 so that it now reads: "Patient withdrawal/refusal before beginning…"

Added under PATIENTS/Off_TX_Reason: "13-No treatment, per protocol criteria"

Added under PATIENTS/Race_Code: "98-Not Reported"

Added under COURSE_AGENTS/Unit_Code: "Percent"

Added under LATE_ADVERSE_EVENTS: AE_Attribution_Code: 1 – Unrelated; 2 – Unlikely; 3 – Possible; 4 – Probable; 5 – Definite

Revised the following to include the CTCAE in the Description column (Effective October 1, 2003):

- BASELINE_ABNORMALITIES/AE_Type_Code
- BASELINE_ABNORMALITIES/AE_Grade_Code
- ADVERSE_EVENTS/AE_Type_Code
- ADVERSE_EVENTS/AE_Grade_Code
- LATE_ ADVERSE_EVENTS/AE_Type_Code
- LATE_ ADVERSE_EVENTS/ AE_Grade_Code

SECTION 3: CDUS Smart Loader Sample File

Added author names to the AUTHORS table to correctly illustrate the data entry:

"CAREY^ROBERT^D"

"SMITH^JAMIE^M"

Revised the LATE_ADVERSE_EVENTS table to reflect the addition of the AE_Attribution_Code field.

From: "LATE_ADVERSE_EVENTS","T95-0036","A5002",455095,4,"",19980710

To: "LATE_ADVERSE_EVENTS","T95-0036","A5002",455095,4,"",,19980710

Revised the PHASE1_END_POINT_DLTS table to reflect the addition of the AE_Other_Specify field.

From: "PHASE1_END_POINT_DLTS","T95-0036","SUBGROUP1","A1",455095

To: "PHASE1_END_POINT_DLTS","T95-0036","SUBGROUP1","A1",455095," "

SECTION 4:New Business Rules

The following tables provide the business rules effective as of the CDUS submission of October 2003. All previous versions are now obsolete.

4.1 NEW 'MAKE SENSE' BUSINESS RULES

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
PATIENTS Table	TX_ON_STUDY	Inappropriate Mandatory	REJECTION	If TX_On_Study = '1' (Yes), Off_Study_Reason MUST be NULL
	OFF_STUDY_REASON	Inappropriate Mandatory	REJECTION	Off_Study_Reason MUST be NULL if TX_On_Study = '1' (Yes)
TREATMENT_COURSES Table	COURSE_START_DATE	Inappropriate Mandatory	REJECTION	Course_Start_Date MUST be <= Last_TX_Date
LATE_ADVERSE_EVENTS Table	AE_START_DATE	Inappropriate Mandatory	REJECTION	AE_Start_Date MUST be greater than the Last_TX_Date

4.2 BUSINESS RULES IN PREPARATION FOR THE CTCAE V3.0

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
PATIENTS Table	OFF_TX_REASON	Inappropriate Mandatory	REJECTION	If Off_Treatment_Reason = '04' (Death); then at least 1 AE MUST be grade 5 (Death)
	OFF_STUDY_REASON	Inappropriate Mandatory	REJECTION	If Off_Study_Reason = '04' (Death); then at least 1 AE MUST be grade 5 (Death)
	OFF_STUDY_REASON	Inappropriate Mandatory	REJECTION	Off_Study_Reason MUST be '04' (Death) if Off_Treatment_Reason = '04' (Death)
ADVERSE_EVENTS Table	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	If AE_Grade_Code = '5' (Death); then either Off_TX_Reason or Off_Study_Reason MUST be '04' (Death)

4.3 REVISED BUSINESS RULES

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
COLLECTIONS	**CURRENT_TRIAL_STATUS_CODE**	**Inappropriate Mandatory**	**REJECTION**	~~**Date must be <= date where protocol status became 'CL' [closed to Accrual]**~~ Status and Status_Date must Progress towards Completion or must be consistent with the CTEP database
PATIENTS	DATE_OF_ENTRY	**Inappropriate Mandatory**	**REJECTION**	~~**Date must be <= date where protocol status became 'CL' [closed to Accrual]"**~~ **Date of Entry must be within the date range when the protocol was Active**
	LAST_TX_DATE	**Incomplete Mandatory**	**REJECTION**	**Mandatory when TX_ON_STUDY = '2'; CDUS-Complete; study activated on or after 01/01/2002; and Off_TX_Reason is not Code 06, 12, or 13**

SECTION 5: Editorial Clarifications and Modifications

The revisions sited in this section were made to the *CDUS Instructions and Guidelines V3R2* in an effort to add clarification or provide additional information in regards to the previously described modifications. In particular, the following affected several sections of the *CDUS Instructions and Guidelines V3R2:*

Common Terminology Criteria for Adverse Events v3.0 (CTCAE): Effective October 1, 2003. All new protocols received by CTEP for review by April 2, 2003 will be assigned to CTCAE v3.0.

Clarified use of the 'CTSU' Registering Group Code: Three conditions are provided to clarify the appropriate use of 'CTSU' as the Registering Group Code.

Treatment Assignment Code (TAC): A more comprehensive description regarding how to use the TACs is now provided in the *Treatment Assignment Instructions and Guidelines* document available from the CTEP Home Page. This clarification may require an evaluation and correction of how you have assigned patients to a TAC. The information previously provided in the *CDUS Instructions and Guidelines* has been minimized.

Clarified Response (Observed Date): The clarifications made to the Response (Observed Date) description may require an evaluation and correction of your protocol's Response (Observed Date) entries.

Please note that the information regarding CTSU and TAC were previously sent under separate cover and therefore is not an additional change.

The revisions are listed in the same order as they appear in the *CDUS Instructions and Guidelines V3R2*.

1.4.1 FREQUENCY

Added: "Efforts should be made to have files successfully loaded within two weeks of the due date."

Note: This sentence was added based on CTEP's suggested successfully loaded due date provided in the e-mail sent to all CDUS participants on January 24, 2003.

1.5.2 CDUS WEB SITE

Added: "Note: The CDUS Web-based application has not been tested to support MAC or Apple computers."

1.6 Section name changed to: **"PROTOCOL CODE INFORMATION"**

1.6.3 TREATMENT ASSIGNMENT (ARM/DOSE LEVELS)

All text removed and replaced with a reference to the *Treatment Assignment Instructions and Guidelines* available from the CTEP Home Page.

2.1.1.3.3. REPORT DUE DATE

Added: "Efforts should be made to have files successfully loaded within two weeks of the due date."

Note: This sentence was added based on CTEP's suggested successfully loaded due date provided in the e-mail sent to all CDUS participants on January 24, 2003.

2.1.1.3.4. PROTOCOL ACTIVATION DATE

Revised section to read: "The protocol activation date is the date the trial was opened to accrual" to be consistent with new definition of the 'Active' status.

2.1.1.5 CURRENT TRIAL STATUS

Revised AP definition to read: "Trial has official CTEP approval."

Revised AC definition to read: "Active - Trial is open to accrual."

2.1.1.6 CURRENT TRIAL STATUS DATE

Revised paragraph two to read: "CTEP includes this information…"

Added to paragraph two: "These can be located under the column titles 'Status Code' and 'Status Date.'"

2.1.1.11.1 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.1.11.2 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.1.12.1 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.1.12.2 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.1.12.3 TOTAL PLANNED ACCRUAL

Revised paragraph one to read: "…Active in the CTEP database."

2.1.1.13.1 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.1.13.2 TOTAL PLANNED ACCRUAL

Deleted from paragraph two: "in the CDUS"

2.1.2 SUBGROUPS/TREATMENT ASSIGNMENTS

Replaced in paragraphs one and two: “utilized” with “used”

2.1.2.3. TREATMENT ASSIGNMENT CODES (ARM/DOSE LEVEL)

A cross reference was added to this section to refer readers to the Treatment Assignment Instructions and Guidelines document available from the CTEP Home Page.

The sentence "Because the CDUS Smart Loader will only accept pre-defined TACs …" was moved from section 2.1.2.3.1 to section 2.1.2.3 to provide additional caution regarding the use of TACs.

Instruction was added regarding how to notify the Protocol and Information Office of TAC information.

Added: “Note: Only those TACs which have been quality checked by CTEP will be considered valid value TACs by CDUS.

2.1.2.3.1. TREATMENT ASSIGNMENT CODES FOR PHASE 1 STUDIES

This section was deleted.

2.1.2.3.2. TREATMENT ASSIGNMENT CODES FOR PHASE 2 STUDIES

This section was deleted.

2.1.2.3.3 AGENT(S)/DOSE REGIMEN/SCHEDULE/ROUTE

This section was deleted.

2.1.4. PHASE 1 END POINTS

Section name changed to: “**PHASE 1 END POINTS AND PHASE 1 END POINT DLTS**”

2.1.4.2.1 DOSE LIMITING TOXICITY (DLT) TYPE

Section name changed to: **DOSE LIMITING TOXICITY (DLT)**

The information originally placed in this section was moved to section 2.1.4.2.1.3.

2.1.4.2.1.3. DLT TYPE

New section. All information originally placed in Section 2.1.4.2.1 was moved to this section.

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (formerly known as CTC) v2.0 and v3.0. Effective October 1, 2003

Added “Note: Either CTCAE v2.0 or v3.0 will be used to identify and submit the Adverse Event(s) depending on the assignment made to the protocol by CTEP.” Only values available from the CTCAE v2.0 will be accepted for protocols assigned to CTCAE v2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

2.1.4.2.1.3 ADVERSE EVENT TYPE

Revised the heading to read: **DLT (ADVERSE EVENT) OTHER, SPECIFY**

Effective October 1, 2003All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE).

Removed information regarding entry of the DLT (Adverse Event) type as it is duplicative with the information presented in section 2.1.4.2.1.

Added information regarding the entry of the DLT using the Other, Specify option from the CTCAE.

Added to the section 2.2.3.9.2.3 cross-reference the two options for submitting AE_Other_Specify.

2.2.1. PATIENT DEMOGRAPHIC ITEMS

Added: "Per CTEP guidelines, patient data are required via CDUS submission for every patient registered on a trial regardless of monitoring method (e.g., CDUS-Complete, CDUS-Abbreviated)."

2.2.1.5. PATIENT'S GENDER

Added: "Note: The use of the value 'Unknown' for a patient's gender should only be used as a final alternative."

2.2.1.6. PATIENT'S RACE AND ETHNICITY

Deleted the last two bullets:

- "The modification of patient race codes and descriptions, and
- The addition of patient ethnicity codes and descriptions."

2.2.1.6.1 ETHNICITY FLAG

New valid value added (effective October 1, 2003): 8 = Not Reported: Patient refused or data not available

The definition of the 'Unknown' valid value (code 9) was revised from 'Ethnicity Unknown' to 'Patient is unsure of their ethnicity'

Added: "Note: The use of the value 'Not Reported' or 'Unknown' for a patient's ethnicity should only be used as a final alternative."

2.2.1.6.2 RACE CODE

New valid value added (effective October 1, 2003): 98 = Not Reported: Patient refused or data not available

The definition of the 'Unknown' valid value (code 99) was revised from 'Race Unknown' to 'Patient is unsure of their race'

Added: "Note: The use of the value 'Not Reported' or 'Unknown' for a patient's race should only be used as a final alternative."

2.2.1.7 PATIENT'S METHOD OF PAYMENT

Added: Note: If the patient uses two primary payment methods, one is reported through the Method_of_Payment field and the second through the TRIAL_COMMENTS table.

2.2.1.9 REGISTERING GROUP CODE

Added the following Note and clarification:

Note: The following is clarification on the use of the Clinical Trials Support Unit (CTSU) value as a Registering Group Code.

Assign to 'CTSU' if:
The patient was registered through the CTSU Data Operations Center
AND the patient was NOT accrued from a Cooperative Group institution or Investigator.

Assign to the appropriate Cooperative Group if:
The patient was accrued from a Cooperative Group institution or Investigator (regardless of whether the patient was registered through the CTSU Data Operations Center).

Assign to 'Other' if:
The patient was NOT registered through the CTSU Data Operations Center
AND the patient was NOT accrued from a Cooperative Group institution or Investigator.

For more information on the CTSU, please go to www.ctsu.org.

2.2.2.2 OFF TREATMENT REASON

The definition for value '04' changed to: "Patient died during active treatment"

Added under value '04': "Note: CTEP defines "active treatment" as any form of therapy identified in the schema of the protocol (e.g., surgery; radiation; commercial chemotherapy agents' investigational agents)."

The word 'or' was replaced with '/' in the definition of value '05' so that it now reads: "Patient withdrawal/refusal after beginning…"

The word 'or' was replaced with '/' in the definition of value '06' so that it now reads: "Patient withdrawal/refusal prior to beginning…"

Added to value '12': A cross reference to value '04' to refer the reader to the definition of "active treatment."

The value "No treatment, per protocol criteria," code 13, was added as a new Off Treatment Reason from the PATIENTS Table. This may require an update if this value is appropriate for your protocol(s).

2.2.2.3 DATE OF LAST TREATMENT

Added to sentence one: "…on their last treatment course"

2.2.2.4 OFF STUDY REASON

Replaced the code: "09" with "98"

2.2.2.9.1. NUMBER OF PRIOR CHEMOTHERAPY REGIMENS

Deleted the word 'different' from the first sentence so that it now reads: If a patient has previously received a chemotherapy regimen, provide the number of single or multi-agent chemotherapy regimens received.

Revised the third sentence so that it now reads: "The total number should include a chemotherapy regimen that was discontinued for any reason…"

2.2.2.9.2. PRIOR THERAPY TYPE (MEDDRA CODE)

Added to paragraph one: "…Medical Dictionary for Medical Affairs (MedDRA)"

Deleted from the list of Prior Therapy Types: "Other Prior Therapy: Cancer treatment not described in the above categories."

Note: The deletion of "Other Prior Therapy" was based on its redundancy with "Prior Therapy (NOS)," code 90003012.

Deleted from the Radiotherapy description: ", or radiotherapy that does not meet the definition for Extensive or Limited Radiation."

Reference (double asterisk) added to the MedDRA v1.99 column in Table D with the following definition: "**MedDRA v1.99 codes are the equivalent to the International Medical Terminology (IMT) codes used in CDUS v2.0."

The MedDRA 5.0 code for Chemotherapy non-cytotoxic changed in Table D of the CDUS Instructions and Guidelines was changed from "90003018" to "90003014." This will require correction if the code "90003018" was originally used on your protocol(s).

2.2.2.10. PATIENT'S DISEASE CODE

Added: Note: If the patient's disease includes two primary cancer diagnoses, one is reported through the Disease_Code field and the second through the TRIAL_COMMENTS table.

2.2.2.12.1. BASELINE ABNORMALITY TYPE, GRADE, AND OTHER, SPECIFY

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE). Effective October 1, 2003

Added: "Note: Baseline Abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up for which a CTCAE term exists."

Added: Note: Either CTCAE v2.0 or v3.0 will be used to identify and submit the Adverse Event(s) depending on the assignment made by CTEP to the protocol. Only values available from the CTCAE v2.0 will be accepted for protocols assigned to CTCAE v2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

Added to the section 2.2.3.9.2.3 cross-reference the two options for submitting AE_Other_Specify.

2.2.3.1. COURSE IDENTIFICATION

Added: Note: When submitting a Course_ID for crossover studies, it is recommended that a second numbering convention be used to differentiate between the two regimens. For example:

Course ID sequence for initial courses: 1, 2, 3, etc.

Course ID sequence for crossover courses: 101, 102, 103, etc.

2.2.3.3.1. PHASE 1 STUDIES

Revised instruction regarding where to send treatment assignment updates from NCI CTEP Help Desk to Protocol and Information Office.

2.2.3.7. PATIENT'S BODY SURFACE AREA

Added: "(cm)" and "(kg)"

2.2.3.9.2.1. ADVERSE EVENT TYPE

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE). Effective October 1, 2003

Added "Note: Either CTCAE v2.0 or v3.0 will be used to identify and submit the Adverse Event(s) depending on the assignment made by CTEP to the protocol." Only values available from the CTCAE v2.0 will be accepted for protocols assigned to CTCAE v2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

2.2.3.9.2.2. GRADE

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE). Effective October 1, 2003

Paragraph two, sentence three, replaced the word "toxicity" so that the sentence now reads: "… just the grade 3 Adverse Event."

2.2.3.9.2.3. ADVERSE EVENT – OTHER, SPECIFY

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE). (Effective October 1, 2003)

Added the following notes and clarification:

> Note: For the same Protocol_ID, Patient_ID, Course_ID, AE_Type_Code, and AE_Grade_Code, if more than one Adverse Event is being designated using AE_Other_Specify, the events must now be designated together using the free text field. Submitting the events separately will generate a Duplicate Primary Key (R0017) error.
>
> For example:
>
> **Option 1**
>
> "ADVERSE_EVENTS","9999","101-88",3,90004068,2,"infection, right oral cavity",1,"9"
> "ADVERSE_EVENTS","9999","101-88",3,90004068,2,"right face/neck
>
> swelling",1,"9"

The AE_Other_Specify data, presented in Option 1 above, should be submitted as one record, as shown in Option 2, below.

Option 2

ADVERSE_EVENTS","9999","101-88",3,90004068,2,"infection, right oral cavity; right face/neck swelling",1,"9"

Note: To adjust for this limitation (effective October 1, 2003), AE_Other_Specify will become part of the Primary Key. This provides the option to either update submissions (Option 2) or to submit the items in separate records (Option 1) without generating a duplicate Primary Key error.

2.2.3.9.3. LATE ADVERSE EVENT

Added to paragraph one: "…regardless of whether the event has been identified as part of a scheduled or unscheduled follow-up."

2.2.3.9.3.1 LATE ADVERSE EVENT TYPE, GRADE, AND OTHER, SPECIFY

All references to the Common Toxicity Criteria (CTC) were changed to the Common Terminology Criteria for Adverse Events (CTCAE). Effective October 1, 2003

Added "Note: Either CTCAE v2.0 or v3.0 will be used to identify and submit the Adverse Event(s) depending on the assignment made by CTEP to the protocol." Only values available from the CTCAE v2.0 will be accepted for protocols assigned to CTCAE v2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

Added to the section 2.2.3.9.2.3 cross-reference the two options for submitting AE_Other_Specify.

2.2.3.9.3.2 ATTRIBUTION

Inserted new section to indicate that attribution is submitted for a Late Adverse Event.

2.2.3.9.3.3 LATE ADVERSE EVENT START DATE

Section number changed.

2.2.4.1.1 Section name changed (deleted the word "Best") to: "RESPONSE (CATEGORY)"

The first sentence of the first paragraph now reads (deleted the word "best"): "If the patient is evaluable for response, indicate the patient's response."

The third sentence of the first paragraph now reads: "Use the following codes to identify each Response Category:"

Added under value 04: "Note: Stable disease is reported using the date the test or procedure was performed indicating that the patient had stable disease."

Added under value 05: "Note: Applicable to disease progression after a response (i.e., PR or CR), after stable disease, or as initial response to protocol therapy."

Added under value 98: “Note: Protocols that do 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) may submit the value of 'Other' to indicate a patient’s response. If 'Other' is submitted, it is mandatory that information about the patient’s response be submitted through the General Response Comments (see Sections 2.1.5.1.2 and 4.3.14 for further information).”

2.2.4.1.2 Section name changed (deleted the word “Best”) to: **“RESPONSE (OBSERVED DATE)”**

Revised paragraph one to read: “The Observed Date is mandatory for all responses submitted via CDUS-Complete, including Stable Disease or Progression. The Observed Date for each level of response is the initial date that the patient’s disease was shown to have responded to therapy sufficient to meet the protocol-specified criteria for that level of response. Note that the response should be confirmed as per protocol guidelines prior to reporting via CDUS (see Section 2.2.4.1.1.).”

Removed second paragraph: “Depending on the best response category, the date would indicate one of the following:”

Added: “The Observed Date format is YYYYMMDD.”

Removed Section: **“2.2.4.1.2.1. PARTIAL RESPONSE (PR) FIRST OBSERVED”**

Removed Section: **“2.2.4.1.2.2. COMPLETE RESPONSE (CR) FIRST OBSERVED”**

Removed Section: **“2.2.4.1.2.3. DISEASE PROGRESSION”**

Removed Section: **“2.2.4.1.2.4. STABLE DISEASE”**

Removed Section: **“2.2.4.1.2.5. OTHER RESPONSE CRITERIA”**

3. CDUS DATA MODEL

The data model was replaced to reflect the changes made to the ADVERSE_EVENTS, LATE_ADVERSE_EVENTS, BASELINE_ABNORMALITIES, and PHASE1_END_POINT_DLTS tables. (Effective October 1, 2003)

4.1. INTRODUCTION

Revised the first sentence in the first paragraph to read: “The CDUS Smart Loader is designed to populate the database…”

Revised the fourth paragraph to read: “Each record associated with a Table in the database will occupy a single line.”