CLINICAL DATA UPDATE SYSTEM (CDUS)

Instructions and Guidelines

Version 2.0

January 18, 1999

NCI CTEP Help Desk -
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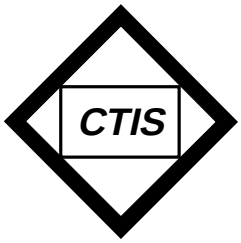

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NOTICE OF MODIFICATIONS

CHANGES FROM VERSION 1.2 TO VERSION 2.0

The following section is included to describe the significant changes made to this document since distribution of the last version (1.2). Publication of this document coincides with the new version of the Clinical Data Update System (CDUS) Smart Loader due for release in April 1999.

To assure a smooth transition, the modifications described below will take effect with the April 1999 CDUS submission. CTEP will screen the data submitted in January 1999 for compliance and provide a "reminder" to submitters whose data contain discrepancies. No immediate action is necessary. The "reminder" serves to alert the submitter that adjustments to the data file are necessary by the April CDUS submission.

You are encouraged to review the entire CDUS document. All future changes and modifications to the CDUS will be listed on the CTEP Home Page. Please check the CTEP Home Page periodically for updates and additional information regarding the CDUS.

A. OVERALL CHANGE

The organization of the *CDUS Instructions and Guidelines* version 2.0 was modified to improve clarity and reduce confusion based on comments from CTEP and the oncology community. The numbering scheme now consists of numbers only, rather than a combination of numbers and letters.

The following sections were added or removed to the *CDUS Instructions and Guidelines* simply to provide clarity. They do not reflect modifications to policies or requirements.

- The *Interpreting the CDUS - Error Log Report* (Section 8), previously published under separate cover, was added to this publication;
- The *CDUS - Business Rules* (Section 9), was added;
- The *CDUS - List Of Data Elements Including Mandatory, Required, Or Optional Conditions* section was removed to eliminate redundancy stemming from the inclusion of the *CDUS - Business Rules* section; and
- The *CDUS - Data Element/Valid Values Mapping* (Attachment A), was added to provide a map of the Valid Values to the data element descriptions found in the CDUS Instructions section (Section 1).

B. CHANGES IN SUBMISSION REQUIREMENTS

1. Registering Institution (Section 2.2.1.9.)

Based on recent negotiations with the Oncology community, the patient's registering institution code is now mandatory for all trials submitted through the CDUS. Collection of the registering institution will facilitate the elimination of several duplicative reports. This requirement becomes

effective with the April 1999 data submission and pertains to all currently accruing trials and trials closed to accrual (e.g., a protocol status of AP, AC, TC, TB, CL, and CB. See Section 2.1.1.5. for further descriptions of protocol statuses). This information is necessary for all patients accrued to trials after January 1, 1995. See Section 2.2.1.9. for further information of the registering institution code.

2. CDUS Business Rules (Section 9)

The *CDUS Business Rules* section was added to provide the business rules that will be implemented in the April 1999 CDUS release. The system previously implied these rules through the error reports generated during data loads. The April 1999 CDUS will validate and enforce these rules, and may require regeneration of corrected files for data loads.

3. Publications (Section 2.1.2.)

The submitter now has the option of providing the Citation Identification (MedLine UID) code number for a publication rather than submitting entire bibliography descriptions.

4. Best Response (Section 2.2.4.1.2.)

The Best Response Observed Date was added as a mandatory data element to the database. When entered, this field will indicate the date of either a Partial Response, Complete Response or Disease Progression.

5. Value Revisions

Two values were revised within the Patients table for increased data accuracy, they are:

- The value **Lost to Follow-up** (code 10) was added as an option to the *Off Treatment Reason* field (see Section 2.2.2.1.2).
- The **Not Reported** (code 0) value option was removed from the *Gender* field (see Section 2.2.1.5.).

6. Requested Data Elements (Section 7.2.2.)

The *CDUS Instructions and Guidelines* version 1.2 used the term “required data elements” to indicate the minimal information necessary for submission. This term was replaced with “requested data elements” to better clarify the difference between mandatory and other data requirements. Revisions were made throughout the document for consistency.

7. Cumulative Data (Sections 7.3.5. and 7.4.2.1.3.)

Submitters are required to provide cumulative data on a quarterly basis. The definition of this term, as well as additional details are provided in these sections.

Questions and Comments:

If you have any questions or comments regarding the Clinical Data Update System (CDUS), please contact the NCI CTEP Help Desk by telephone (301) 840-8202, fax (301) 948-2242, or E-mail at ncictephelp@ctep.nci.nih.gov.

Additional information regarding the CDUS is available on the CTEP Home Page (http://ctep.info.nih.gov).

1. CLINICAL DATA UPDATE SYSTEM (CDUS) INSTRUCTIONS

1.1. OVERVIEW

The Clinical Data Update System (CDUS) is the primary resource of clinical trial data for the Division of Cancer Treatment and Diagnosis (DCTD) and the Division of Cancer Prevention (DCP). CDUS reports should be submitted for all DCTD and DCP sponsored trials (Phase 1, 2 and 3). This includes all DCTD sponsored Cooperative Group and CCOP Research Base treatment trials utilizing DCTD supplied investigational agents and trials utilizing non-NCI agents (commercial or investigational); all DCTD grant funded non-Cooperative Group (Cancer Center or other institution) trials (if CDUS reporting is a grant requirement) utilizing non-NCI agents; all DCTD sponsored Cooperative Group and CCOP Research Base non-treatment trials (accrual > 100 pts.); and all DCP sponsored CCOP Research Base cancer prevention and control trials.

CTEP staff, in conjunction with external participants [e.g., Cooperative Groups, Cancer Centers, Food and Drug Administration (FDA), manufacturers], have made every attempt to define the minimum number of data elements needed to fulfill the regulatory, scientific, and administrative needs of the NCI. The amount of information required for submission to CTEP will vary depending on certain characteristics of the trial (see Section 1.3. for further details).

Specific details about CDUS reporting requirements can be found in the sections that follow.

1.2. WHO SHOULD SUBMIT DATA

For each protocol, the lead Group or Institution is responsible for submitting CDUS data.

Inter-Group/Multi-Institution Trials:

The lead Group or institution for a protocol is responsible for compiling and submitting CDUS data for all participants.

Cooperative Groups participating in pharmaceutical company sponsored studies:

An exception is made in this situation. The participating Cooperative Group will be considered the lead organization and an Abbreviated CDUS Data Set will be submitted quarterly. If multiple Groups are participating on a pharmaceutical sponsored study, then the lead Group will be responsible for compiling and submitting CDUS data for all Group participants.

1.3. WHAT DATA SHOULD BE SUBMITTED

Either an Abbreviated CDUS Data Set (containing the data elements found in Section 2.1.1. and Section 2.2.1.) or a Complete CDUS Data Set (containing all CDUS data elements), will be required. CTEP has grouped data elements into three categories: Mandatory, Requested, and Optional. Please refer to Section 9 of this document for a complete listing of the business rules for more information regarding mandatory and requested data elements. **All data submissions must be cumulative**. The type and amount of data required from an investigator depends upon the following:

- the trial source (Cooperative Group and Community Clinical Oncology Program (CCOP) Research Base vs. non-Cooperative Group);
- whether the trial utilizes a DCTD-supplied Investigational New Drug (IND);
- the phase of the trial; and
- if the trial is sponsored by DCTD or DCP.

1.3.1. ABBREVIATED CDUS DATA SET

The Abbreviated CDUS Data Set is limited to protocol administrative and patient demographic information.

An Abbreviated CDUS Data Set will include the following administrative data elements:

- NCI Protocol Number
- Date Report Submitted
- Cut-Off Date for Data
- Current Protocol Status
- Person Completing the Report
  - Name: Last Name^First Name^Middle Initial
  - Telephone Number
  - Fax Number (optional)
  - E-mail Address (optional)
- Change Code

See Section 2.1.1. for descriptions of the administrative data elements.

An Abbreviated CDUS Data Set will also include the following patient demographic data elements:

- Patient ID
- Patient's Zip Code
- Country Code
- Patient's Birth Date
- Patient's Gender
- Patient's Race/Ethnicity
- Patient's Method of Payment
- Date of Patient Entry
- Registering Group Code (Intergroup studies only)
- Registering Institution Code (mandatory as of April 1999)

See Section for 2.2.1. descriptions of the patient demographic data elements.

1.3.2. COMPLETE CDUS DATA SET

The Complete CDUS Data Set contains the information found in the Abbreviated CDUS Data Set, patient administrative information (e.g., registering institution code, patient treatment status), treatment information (e.g., agent administered, total dose per course), adverse event information (e.g., toxicity type, grade), and response information (e.g., response observed, date response observed). In short, the Complete CDUS Data Set includes all data elements described in Section 2 of this document.

Note: Data related to Phase 1 end points are only required to be submitted for Phase 1 trials.

The complete report should be submitted quarterly (Cooperative Groups may submit Phase 2 response data within 6 weeks of the completion of each stage of the study. Response data for all Phase 1 trials and non-Group Phase 2 trials should be submitted quarterly).

1.3.3. TRIAL CATEGORIES

The following sections describe the various trial "categories" and the amount of information necessary for each[1]. A summary of this information can be found in Table 1 and Table 2. A description of each data element to be collected can be found in Section 2.

1.3.3.1. TREATMENT TRIALS THAT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

Cooperative Group and Research Base trials and non-Cooperative Group (Cancer Center or other institution) trials:

1.3.3.1.1. PHASE 1 – CTMS MONITORED TRIALS THAT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

Early Phase 1 trials often require more intensive monitoring. Early Phase 1 trials will continue to be reported to CTEP using the Clinical Trial Monitoring System (CTMS). CTEP will abstract the CDUS information subset from the CTMS data on a quarterly basis. Investigators will not be obligated to submit any additional data to the CDUS.

1.3.3.1.2. PHASE 1 – NON-CTMS MONITORED TRIALS THAT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

A Complete CDUS Data Set report (all CDUS data elements) is required. Investigators should submit the Complete CDUS Data Set report to CTEP on a quarterly basis.

[1] Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from abbreviated to complete CDUS reporting based on the priority of the trial. Investigators will be notified in writing during the consensus review and protocol approval process regarding the reporting requirements for a given study.

1.3.3.1.3. PHASE 2 TRIALS THAT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

A Complete CDUS Data Set report is required (all CDUS data elements except Phase 1 endpoints). Investigators should submit the Complete CDUS Data Set report to CTEP on a quarterly basis. Response data for all non-Cooperative Group Phase 2 trials should be submitted quarterly. Response data for Cooperative Group Phase 2 trials may be submitted within 6 weeks of the completion of each stage of the study.

1.3.3.1.4. PHASE 3 TRIALS THAT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

An Abbreviated CDUS Data Set report is required. Investigators should submit the Abbreviated CDUS Data Set report to CTEP on a quarterly basis for all DCTD sponsored Phase 3 treatment trials.

1.3.3.2. TREATMENT TRIALS THAT DO NOT INCLUDE DCTD SUPPLIED INVESTIGATIONAL AGENTS

1.3.3.2.1. COOPERATIVE GROUP AND RESEARCH BASE TRIALS

An Abbreviated CDUS Data Set report is required. Phase 1, 2, 3 - Investigators should submit an Abbreviated CDUS Data Set report to CTEP on a quarterly basis for all DCTD sponsored Cooperative Group and CCOP Research Base treatment trials that do not utilize a DCTD supplied investigational agent (e.g., commercial agents or non-NCI IND agents). Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from Abbreviated to Complete CDUS Data Set reporting, based on the priority of a trial. Investigators will be notified in writing during the consensus review and protocol approval process regarding the reporting requirements for a given study.

Note: Adverse events should be reported as per protocol guidelines.

1.3.3.2.2. NON-GROUP (CANCER CENTER OR OTHER INSTITUTION) TRIALS

1.3.3.2.2.1. Approved NCI Grant which requires CDUS Reporting

If CDUS reporting is a Grant requirement, investigators should submit an Abbreviated CDUS Data Set report to CTEP on a quarterly basis for all DCTD funded treatment trials that do not utilize a DCTD supplied investigational agent (commercial agents or non-NCI IND agent). Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from Abbreviated to Complete CDUS Data Set reporting based on the priority of a trial. Investigators will be notified in writing during the consensus review and protocol approval process regarding the reporting requirements for a given study.

Note: Adverse events should be reported as per protocol guidelines.

1.3.3.2.2.2. Non-Group (Cancer Center or other Institution) that do not include a DCTD Supplied Investigational agent or an NCI Grant

CDUS reporting is not required.

1.3.3.3. NON-TREATMENT TRIALS (pharmacokinetic, cytogenetics, etc.)

1.3.3.3.1. COOPERATIVE GROUP AND CCOP RESEARCH BASE NON-TREATMENT TRIALS

For Phase 1, 2, and 3 trials an Abbreviated CDUS Data Set report is required. Investigators should submit an Abbreviated CDUS Data Set report to CTEP on a quarterly basis for all DCTD sponsored Cooperative Group and CCOP Research Base non-treatment trials with a total expected accrual of greater than 100 patients. CDUS reporting is not required if a DCTD sponsored Cooperative Group and CCOP Research Base non-treatment trial has expected accrual of less than 100 patients.

1.3.3.3.2. NON-GROUP (CANCER CENTER OR OTHER INSTITUTION) NON-TREATMENT TRIALS

For Phase 1, 2, and 3 trials, CDUS reporting is not required.

1.3.3.4. DCP SPONSORED CCOP RESEARCH BASE CANCER PREVENTION AND CONTROL TRIALS (chemo-prevention; bio-marker and early detection; symptom management; pain control; rehabilitation and continuing care; and quality of life)

For Phase 1, 2, and 3 trials, an Abbreviated CDUS Data Set report is required. Investigators should submit an Abbreviated CDUS Data Set report to CTEP on a quarterly basis for all DCP sponsored Cooperative Group and CCOP Research Base cancer prevention and control trials.

TABLE A: Summary of CDUS Reporting Requirements for Cooperative Groups and CCOP Research Based trials.

Study Type	DCP	DCTD Non-Treatment[2]	DCTD Treatment NCI Agent[3]	DCTD Treatment Non-NCI Agent[4]
Phase 1	Abbreviated	Abbreviated	Complete	Abbreviated
Phase 2	Abbreviated	Abbreviated	Complete	Abbreviated
Phase 3	Abbreviated	Abbreviated	Abbreviated	Abbreviated

TABLE B: Summary of Reporting Requirements for Non-Cooperative Group (Cancer Centers and other Institutions) Trials Utilizing DCTD Agents or Grant Funding (if CDUS reporting is a grant requirement).

Study Type	DCP	DCTD Non-Treatment[2]	DCTD Treatment NCI Agent[3]	DCTD Treatment Non-NCI Agent[4]
Phase 1	N/A	None	Complete	Abbreviated
Phase 2	N/A	None	Complete	Abbreviated
Phase 3	N/A	None	Abbreviated	Abbreviated

1.4. WHEN DATA SHOULD BE SUBMITTED

1.4.1. FREQUENCY

CDUS reports will be submitted on a quarterly basis. CDUS reports are due by Jan. 31, Apr. 30, Jul. 31 and Oct. 31. Each report should reflect administrative, demographic, accrual and clinical data as of the end of the preceding month (e.g., Dec. 31, Mar. 31, Jun. 30, and Sep. 30). The first CDUS submission is due the quarter after the protocol has been approved by the NCI.

1.4.2. FIRST CDUS SUBMISSION DATE

Example:

Date of NCI Approval Notice	CDUS Due Date
Jan. 1 to Mar. 31	Apr. 30
Apr. 1 to Jun. 30	Jul. 31
Jul. 1 to Sep. 30	Oct. 31
Oct. 1 to Dec. 31	Jan. 31

[2] Abbreviated CDUS is required for DCTD Cooperative Group and Research Base Non-Treatment trials with an expected accrual of 100 or greater patients. DCTD Cooperative Group and Research Base Non-Treatment trials with expected accrual of less than 100 patients will NOT be monitored by the CDUS.

[3] CTMS-monitored Phase 1 trials should continue to be reported to CTEP using the CTMS system; these trials will not require CDU reporting.

[4] Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from abbreviated to complete CDUS reporting based on the priority of the trial. Investigators will be notified in writing during the consensus review and protocol approval process regarding the reporting requirements for a given study.

1.4.3. SUBMISSION DURATION

CDUS submissions are required for all approved NCI studies until they reach a status of 'completed' (see Section 2.1.1.5. for a complete description of protocol statuses).

CTEP defines the term *completed* as the following: The protocol has been closed to accrual, all patients have completed therapy, and the study has met its primary objectives. A study report/publication is attached or has been **submitted** to CTEP. The minimal data requirements for this study report include total accrual, adverse drug experiences and study results to date. A final report/publication will be submitted to CTEP when the data have matured and been analyzed.

A CDUS submission is required if a study has been closed to accrual but the primary objectives have not been met, or if a protocol has been approved but has not been activated. Once you have submitted patient data for a protocol closed to accrual and treatment you may discontinue submitting patient data. In these circumstances, a CDUS submission including the protocol administrative requirements must still be submitted quarterly until protocol completion. The appropriate response to the question "Any additions since the last report" (see Section 2.1.1.7.) should be 'No'. The final CDUS submission for a given protocol should have a status of 'completed' or 'administratively completed'. No further CDUS submissions are required after a protocol has been completed or administratively completed.

If for some reason a study has been 'completed' but the study objectives have not been met (e.g., the study closed prematurely because of **poor** accrual) or the final study report is not available (e.g., the study was 'completed' 10 years ago and all records have been archived) then you may 'administratively complete' the protocol.

CTEP defines the term *administratively completed* as the following: The protocol has been completed prematurely (e.g., due to poor **accrual**, insufficient drug supply, IND closure). The trial is closed to further accrual and all patients have completed protocol treatment. A final study report publication is not anticipated.

1.5. METHODS OF DATA SUBMISSION

All data shall be submitted electronically, using a CTEP FTP site or a CDUS Web site. Paper reports will not be accepted. Each electronic file should contain cumulative data for a single protocol. Electronic files should not contain data for multiple protocols.

Please refer to Section 3, *CDUS-Smart Loader File Format Instructions*, for specific file format requirements.

1.5.1. CTEP FTP SITE

The FTP site ftpctep.nci.nih.gov was established by NCI to accept the submission of data files. To ensure the security and integrity of all data, an account with a username and password will be created for each site that will be submitting CDUS data (e.g., Cooperative Groups, Cancer Centers, etc.).

Additionally, each account will be assigned to a subdirectory within the FTP site. Viewing and submission of data files will be restricted to the assigned subdirectory. Investigators will have access to the files they have submitted, until the files are removed from the site at scheduled periodic intervals.

To request any change to an existing FTP account, or to establish a new FTP account, please contact the NCI CTEP Help Desk by telephone (301) 840-8202, fax (301) 948-2242, or E-mail at ncictephelp@ctep.nci.nih.gov.

1.5.2. CDUS WEB SITE

Investigators who do not have the resources to submit data through the CTEP FTP site mechanism can access a web-based data entry system developed for the submission of data to CTEP. This user-friendly system includes pull-down menus, field instructions, potential selections, and pre-populated fields to minimize data entry.

The NCI CTEP Help Desk will contact the investigator to establish a Web-based user account and set up the system to enable data entry after protocol approval. Internet Explorer 4.0 and higher or Netscape Navigator 4.0 and higher is required to access this secured Web application.

1.6. PROTOCOL CODING

A worksheet is available to assign codes to specific parameters within a clinical study. Studies that include correlative studies, subgroups and/or treatment assignments require the codes described below to facilitate protocol and amendment review and approval. In addition, the codes are utilized for multiple purposes and systems including the CDUS, and the Adverse Event Expedited Reporting (AdEERS). The worksheet can be found on the Forms page of the CTEP Home Page.

1.6.1. CORRELATIVE STUDIES

A Correlative Study Identification Code and a Correlative Study Title must be provided for any laboratory, pharmacokinetic or other correlative study embedded in a clinical trial.

The Correlative Study Identification Code is a unique identification code assigned to each correlative study and is limited to ten alphanumeric characters (e.g., P-123).

The Correlative Study Title is the title given to the study (e.g., O^6-benzylguanine concentrations in plasma).

1.6.2. SUBGROUPS

A Subgroup Identification Code and a Subgroup Description must accompany each clinical trial where a subgroup (stratum) is used to uniformly group patients for separate analysis or treatment. Both are mandatory for studies utilizing a DCTD supplied investigational agent.

The Subgroup Identification Code is a unique identification code assigned to each subgroup and is limited to ten alphanumeric characters (e.g., Subgroup1). Patients on

studies utilizing a single subgroup are entered on the Subgroup Identification Code "SubgroupA."

A Subgroup Description is broken into two classifications. The investigator selects the most appropriate category(s) for describing the stratification or subgroup assignment.

- *Patients Stratified by Disease*: The disease(s) must be indicated for each subgroup. A comprehensive list of CTEP Disease terms is available on the CTEP Home Page.
- *Patients Stratified by Other (e.g., prior therapy, age)*: The patient characteristics (other than disease) used to uniformly group patients for treatment or analysis (e.g., number of prior therapies) must be described.

1.6.3. TREATMENT ASSIGNMENTS (arm/dose levels)

A Treatment Assignment Identification Code and a Treatment Assignment Description must accompany each clinical trial where a unique treatment characteristic is utilized to uniformly group patients for separate analysis or treatment. Each arm or dose level is considered a distinct treatment assignment. The Treatment Assignment Identification Code and Treatment Assignment Description are mandatory for all studies utilizing a DCTD supplied investigational agent.

The Treatment Assignment Identification Code is a unique identification code (e.g., Level 1) assigned to each treatment assignment and is limited to ten alphanumeric characters. Patients on trials utilizing a single treatment assignment are entered on the Treatment Assignment Identification Code "TA1."

The Treatment Assignment Description is a complete description of each treatment assignment (e.g., Cisplatin 100mg/m^2 IV over 1 hr. for one dose on day one, and Taxol 130mg/m^2 IV over 3 hours for one dose on day one, repeat every 21 days). The agent name, dose, route and schedule for every agent within the treatment assignment must be included. A description of any non-pharmacologic treatment modality(s) (e.g., radiation, surgery) is also requested.

2. DATA ELEMENT DESCRIPTIONS

The following sections provide descriptions and valid values for each data element required by CDUS. **Investigators may potentially be required to provide the data elements shown in bold print. Data elements not shown in bold print are included here for reference**. CTEP will abstract these items from the original protocol document.

2.1. GENERAL SUMMARY INFORMATION

2.1.1. **ADMINISTRATIVE** (Mandatory for all trials)

2.1.1.1. **NCI PROTOCOL NUMBER**

This is the protocol number assigned to the study by the NCI. Inter-Group protocols should use the lead Group's protocol number. Local institution or Group protocol numbers must not be used.

2.1.1.2. PROTOCOL TITLE

Supplied by CTEP. Abstracted from the protocol document.

2.1.1.3. REPORT DATES

2.1.1.3.1. **DATE REPORT SUBMITTED**

Enter today's date (YYYYMMDD).

2.1.1.3.2. **CUT-OFF DATE FOR DATA**

The most recent date for which any data were used in compiling results (YYYYMMDD). This date should reflect the latest date for which information is known. For example, if it is known at the end of the first quarter that all data reported are complete for that quarter, then this date would be 19980331. However, if this information can only be confirmed as of one week prior to the end of the quarter, then the date provided should be 19980324.

2.1.1.3.3. REPORT DUE DATE

Supplied by CTEP. Reports are due on the last day of each quarter.

2.1.1.3.4. PROTOCOL ACTIVATION DATE

Supplied by CTEP.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.1.1.4. PRIMARY (lead) INSTITUTION/GROUP SOURCE CODE

Provided by CTEP. The unique CTEP code for the primary, or lead, institution or Cooperative Group.

2.1.1.5. **CURRENT PROTOCOL STATUS**

Enter the protocol's current status using the following codes:

AP *Approved* - Trial is open but no patients have been accrued.

AC *Active* - Trial is open and accruing.

TC *Temporarily Closed to Accrual* - Trial is temporarily not accruing.

TB *Temporarily Closed to Accrual and Treatment* - Trial is temporarily not accruing and patients are not receiving therapy.

CL *Closed to Accrual, Patients still on Treatment* - The protocol has been closed to patient accrual. Patients are still receiving therapy.

CB *Closed to Accrual, All Patients have Completed Treatment* - The protocol has been closed to patient accrual. All patients have completed therapy, but patients are still being followed according to the primary objectives of the study. No additional investigational agents are needed for this study.

CP *Completed* - The protocol has been closed to accrual, all patients have completed therapy, and the study has met its primary objectives. A final study report/publication is attached or has been submitted to CTEP[5].

AD *Administratively Completed* - The protocol has been completed prematurely (e.g., due to poor accrual, insufficient drug supply, IND closure). The trial is closed to further accrual and all patients have completed protocol treatment. A final study report is not anticipated.

Note: The code RE (Reactivated) is no longer a valid option for current protocol status.

2.1.1.6. **PERSON COMPLETING THE REPORT**

2.1.1.6.1. **NAME**

The person submitting the report is required to enter their first and last name in the following format: Last Name^First Name^Middle Initial. The middle initial is an optional entry.

[5] 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.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.1.1.6.2. **TELEPHONE NUMBER**

Telephone number where the person completing the report can be reached. All phone numbers should comply with the ASTM/NAN/CCITT format. For example, (NNN)NNN-NNNN; (NNN)NNN-NNNNXNNNN if using an extension; or NNN(NNN)NNN-NNNN when using an international telephone country code.

2.1.1.6.3. **FAX NUMBER** (optional)

Submit a Fax number where the person completing the report can be reached. All Fax numbers should comply with the ASTM/NAN/CCITT format (see Section 2.1.1.6.2.).

2.1.1.6.4. **E-MAIL ADDRESS** (optional)

Submit an E-mail address where the person completing the report can be reached. Use standard SMTP format.

2.1.1.7. **ADDITIONS OR CHANGES SINCE THE LAST REPORT (CHANGE CODE)**

Does this report contain any new data (General Summary data or patient-specific data) or has any data been changed from the last report? 1 = Yes, 2 = No. If yes, then submit all available data to CTEP. If no, then only General Summary; Administrative (Section 2.1.1.) data is required. When submitting data on a protocol for the first time, the response should be "1" (yes).

2.1.1.8. PRINCIPAL INVESTIGATOR

Provided by CTEP. Abstracted from the protocol document.

2.1.1.8.1. NAME

Principal Investigator's Name (Last Name^First Name^Middle Initial).

2.1.1.8.2. INVESTIGATOR NUMBER

Principal Investigator's NCI Investigator Number.

2.1.1.9. GRANT

Provided by CTEP, if applicable.

2.1.1.10. TOTAL ACCRUAL

2.1.1.10.1. TOTAL PLANNED ACCRUAL

The total number of patients estimated to be accrued to the study based on the information provided in the original protocol.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

CTEP will abstract and enter the Total Planned Accrual in the CDUS from the protocol document at the time of protocol approval.

2.1.1.10.2. AMENDED PLANNED ACCRUAL

The revised total number of patients estimated to be accrued to the study based on the information provided in the most recently received protocol amendment.

CTEP will abstract and enter the Amended Planned Accrual in the CDUS from the protocol amendment at the time of amendment approval.

2.1.1.10.3. ACTUAL ACCRUAL

A system calculation based on the actual number of patients accrued to date on the study as reported by the Group or Institution.

Actual Accrual is based on the total number of eligible patients registered on study.

2.1.1.11. ACCRUAL RATE (patients/month)

2.1.1.11.1. PLANNED ACCRUAL RATE

The total number of patients estimated to be accrued to the study on a monthly basis based on the information provided in the original protocol.

CTEP will abstract and enter the Planned Accrual Rate in the CDUS from the protocol document at the time of protocol approval.

2.1.1.11.2. AMENDED ACCRUAL RATE

The revised total number of patients estimated to be accrued to the study on a monthly basis based on the information provided in the most recently received protocol amendment.

CTEP will abstract and enter the Amended Accrual Rate in the CDUS from the protocol amendment at the time of amendment approval.

2.1.1.11.3. ACTUAL ACCRUAL RATE

A system calculation based on the total number of patients accrued to date on the study as reported by the Group or Institution divided by the total number of months the study has been in active status within the CDUS.

The CDUS uses data from the Actual Accrual (see 2.1.1.10.3.) to make this calculation.

2.1.1.12. CLOSURE DATE

2.1.1.12.1. PLANNED CLOSURE DATE

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

The estimated date the study will meet its accrual goal calculated by the total planned accrual and the planned accrual rate (e.g., Total Planned Accrual/Planned Accrual Rate + Activation Date = Planned Closure Date).

CTEP will abstract and enter the Planned Closure Date in the CDUS from the protocol document at the time of protocol approval.

2.1.1.12.2. AMENDED CLOSURE DATE

The estimated date the study will meet its accrual goal calculated by the Total Planned (or Amended Planned) Accrual and the Planned (or Amended) Accrual Rate. All calculations reflect the most recent amendment.

CTEP will abstract and enter the Amended Closure Date in the CDUS from the protocol amendment at the time of amendment approval.

2.1.1.12.3. PROJECTED CLOSURE DATE

A system calculation based on multiplying the Actual Accrual Rate to determine the number of additional months needed to reach the Total Planned Accrual or Amended Planned Accrual (e.g., Total Planned Accrual/Actual Accrual Rate + Activation Date = Projected Closure Date).

2.1.1.13. **SUBGROUPS**

A subgroup (stratum) is a unique patient characteristic that will be utilized to uniformly group patients for separate analysis or treatment.

2.1.1.13.1. SUBGROUP CODE

Each subgroup should have a unique code for identification. The investigator will provide a code (up to 10 characters) for each subgroup with the Protocol Submission Checklist. CTEP will abstract the subgroup code(s) from the Protocol Submission Checklist. If a protocol has only one subgroup then CTEP suggests using the code "SUBGROUPA".

2.1.1.13.2. SUBGROUP DESCRIPTION

2.1.1.13.2.1. Patients Stratified by Disease

The investigator will provide the disease for each subgroup with the Protocol Submission Checklist. Investigators should use CTEP Terms. Based on investigator input, CTEP will abstract the disease for each subgroup from the Protocol Submission Checklist.

2.1.1.13.2.2. Patients Stratified by Other Classification (e.g., prior therapy, age)

The investigator will provide the patient characteristics (other than disease) for each subgroup with the Protocol Submission Checklist. Based on investi-

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

gator input, CTEP will abstract the patient characteristics for each subgroup from the Protocol Submission Checklist.

2.1.1.14. **TREATMENT ASSIGNMENT (arm/dose level)**

A treatment assignment is a unique treatment characteristic that will be utilized to uniformly group patients for separate analysis or treatment (e.g., Phase 2 or 3 treatment arm and Phase 1 dose levels). Each arm or dose level should be considered a distinct treatment assignment.

2.1.1.14.1. TREATMENT ASSIGNMENT CODES FOR PHASE 1 STUDIES

During protocol submission, a unique treatment Assignment Code and Description should be provided for each dose level that is clearly identified in a Phase 1 study.

When it is determined that a Phase 1 dose level will be added or modified, per protocol defined criteria (e.g., additional dose levels will escalate by X%), the investigator should notify CTEP as soon as possible. Notification is achieved by submitting a treatment assignment update to the NCI CTEP Help Desk (ncictephelp@ctep.nci.nih.gov). The treatment assignment update should include a treatment assignment code and a complete description of the new dose regimen. Upon receipt of the update, CTEP will add the new treatment assignment code and description to the CDUS database. Because the CDUS Smart Loader will only accept pre-defined treatment assignment codes, a failure to provide CTEP with enough advance notification will result in rejection of the entire CDUS data set. If the dose modifications are based on pre-defined protocol criteria, a formal protocol amendment is NOT mandatory (a treatment assignment update is still requested).

2.1.1.14.2. TREATMENT ASSIGNMENT CODES FOR PHASE 2 STUDIES

Each arm or dose level should be assigned a unique code for identification. The investigator provides a code (up to 10 characters) for each treatment assignment with the Protocol Submission Checklist. CTEP will abstract the code for each treatment assignment from the Protocol Submission Checklist. If a protocol has only a single treatment assignment (arm/dose level), then CTEP suggests using treatment assignment code "TA1".

2.1.1.14.3. AGENT(S)/DOSE REGIMEN/SCHEDULE/ROUTE

The investigator provides a complete description of each treatment assignment with the Protocol Submission Checklist. CTEP will abstract the description of each treatment assignment from the Protocol Submission Checklist.

2.1.2. **PUBLICATIONS**

A publication citation must be provided if any data for this study or any associated correlative studies has been published.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.1.2.1. **PUBLICATION IDENTIFICATION (ID)**

The investigator assigns a unique code to identify the publication for CDUS purposes. A sequential number is recommended.

For each publication, provide either the National Library of Medicine citation identification (MedLine UID) or the full citation (e.g., title, author, page number, etc.).

2.1.2.1.1. **CITATION IDENTIFICATION (MEDLINE UID)**

Specify the National Library of Medicine (NLM) Citation Unique Identifier (MedLine UID). The MedLine UID is a unique 8-digit code number supplied for every publication included in MedLine. Entry of the MedLine UID eliminates the requested entry of the data elements that follow (Sections 2.1.2.1.2.1. through 2.1.2.1.2.7.).

OR

2.1.2.1.2. **FULL CITATION**

2.1.2.1.2.1. **Author**

Specify whether each author is the first author, second author, etc. (e.g., 1, 2, 3, etc.) and the author's name in the following format: Last Name^First Name^Middle Initial, e.g., Adams^John^Q.

2.1.2.1.2.2. **Title**

Enter the title of the article as it appears in the publication.

2.1.2.1.2.3. **Journal**

Enter the name of the journal where the article appears.

2.1.2.1.2.4. **Volume**

Enter the volume number of the journal.

2.1.2.1.2.5. **Year**

Enter the year that the journal was published.

2.1.2.1.2.6. **Publisher**

Enter the name of the publisher who produced the journal.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.1.2.1.2.7. **Pages**

Enter the first and last page number that the article appears.

2.1.3. GENERAL DATA SUMMARY BY SUBGROUP AND/OR TREATMENT ASSIGNMENT

The General Data Summary by subgroup and/or treatment assignment is optional for trials assigned to complete CDUS reporting (e.g., Phase 1 and 2 trials with DCTD supplied investigational agents), it is not required for other studies.

2.1.3.1. SUBGROUP/TREATMENT ASSIGNMENT CODE

Please use the appropriate code (see Sections 2.1.1.13. and 2.1.1.14.) for designating each different combination of subgroup and/or treatment assignment. A separate entry should be made for each subgroup and/or treatment assignment combination. Leave field null to report general data summary for all subgroups/treatment assignments.

2.1.3.1.1. TOXICITY/DOSE MODIFICATIONS BY SUBGROUP AND/OR TREATMENT ASSIGNMENT

If known, please provide any observations or conclusions regarding toxicities, adverse events and dose modifications that may not be apparent from other information on this report (free text field).

2.1.3.1.2. RESPONSE BY SUBGROUP AND/OR TREATMENT ASSIGNMENT

If known, please provide any observations or conclusions regarding response that may not be apparent from other information on this report (free text field).

2.1.4. PHASE 1 END POINTS

When Phase 1 end points are known, they are mandatory for Phase 1 studies assigned to complete CDUS reporting. They are not required for other studies.

2.1.4.1. SUBGROUP CODE

Please use the appropriate code (see Section 2.1.1.13.) for designating each subgroup. A separate entry should be made for each subgroup. If a protocol has only one subgroup, CTEP suggests using the code "SUBGROUPA".

2.1.4.2. RECOMMENDED PHASE 2 DOSE

If known, provide the treatment assignment code (see Section. 2.1.1.14.) for the recommended Phase 2 dose for each subgroup as applicable. Determination of the

recommended Phase 2 dose should be based on protocol criteria. If it is known that there will be no recommended Phase 2 dose, the code "NA" should be submitted.

2.1.4.2.1. DOSE LIMITING TOXICITY (DLT)-TYPE

If known, select the appropriate CTEP Code using the Common Toxicity Criteria (CTC) (see CTEP Home Page for the list of CTC Codes) for the dose limiting toxicity(s) for each subgroup as applicable. Determination of dose limiting toxicities should be based on protocol criteria. More than one toxicity may be entered.

2.1.4.2.1.1. **Subgroup**

Select the appropriate code (see Section 2.1.1.13.) for the subgroup this patient was entered on. Patients enrolled on a protocol with a single subgroup should be coded as "SUBGROUPA".

2.1.4.2.1.2. **Adverse Event Type**

Using the Common Toxicity Criteria (CTC), version 2.X, please select the appropriate CTEP Code (see the CTEP Home Page for a list of CTC Codes) for the adverse event the patient experienced during this treatment course. More than one adverse event may be entered.

2.1.4.2.1.3. **Treatment Assignment**

Select the appropriate code (see Section 2.1.1.14.) for the patient's treatment assignment this course (e.g., Phase 2 treatment arm, Phase 1 dose levels). Patients enrolled on a protocol with a single treatment assignment should be coded as "TA1".

2.1.5. CORRELATIVE STUDIES

Correlative studies are laboratory, pharmacokinetic or other correlative studies embedded within the primary protocol. A separate entry should be made for each correlative study. Correlative study titles and codes are provided by investigators with the Protocol Submission Checklist. A separate correlative study should be defined for each analysis that can be drawn. This is requested for trials assigned to complete CDUS reporting, (e.g., Phase 1 and 2 trials with DCTD supplied investigational agents), and not required for other studies.

2.1.5.1. **CORRELATIVE STUDY IDENTIFICATION (ID)**

Each correlative study should have a unique identification code. The investigator will provide a code for each correlative study with the Protocol Submission Checklist. CTEP will abstract the correlative study code from the Protocol Submission Checklist.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.1.5.2. CORRELATIVE STUDY TITLE (laboratory, pharmacokinetic or other correlative studies)

Correlative study(s) titles will be provided by investigators with the Protocol Submission Checklist. CTEP will then abstract the correlative study title from the Protocol Submission Checklist.

2.1.5.3. CORRELATIVE STUDY FINDINGS

Using a separate entry for each correlative study, provide the following information:

2.1.5.3.1. COLLECTED SAMPLES

Number of patients for whom samples (blood, urine, tissue, etc.) have been collected.

2.1.5.3.2. ANALYZED SAMPLES

Number of patients for whom samples (blood, urine, tissue, etc.) have been analyzed.

2.1.5.3.3. CORRELATIVE STUDY FINDINGS OR CONCLUSIONS (free text field)

If known, briefly describe any correlative study findings or conclusions (free text field-optional).

2.2. PATIENT-SPECIFIC DATA

2.2.1. PATIENT DEMOGRAPHIC ITEMS

2.2.1.1. PATIENT ID

Enter the code that uniquely identifies the patient to this protocol.

Note: All correspondence (e.g., an Adverse Drug Experience) to CTEP regarding this patient on this protocol must use this unique identifier. Please contact CTEP regarding any changes to a patient ID on this trial (e.g., patient transfer to a new institution/Group).

2.2.1.2. PATIENT'S ZIP CODE

U.S. residents - Enter the patient's home five-digit Zip code, for example 12345. The Zip code should not be submitted for patients who are not U.S. residents. The last four digits of the complete nine-digit Zip code should not be submitted to assure patient confidentiality. The code "00000" should be submitted if the Zip code is unknown.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.2.1.3. **COUNTRY CODE**

For non-U.S. residents only. This should be used when patient participation from foreign countries is involved. For patients from outside the U.S., enter the foreign country code. Leave blank if the patient is a U.S. resident. CTEP is using the International Standards Organization country codes. If unsure of a foreign country code, please check the CTEP Home Page.

2.2.1.4. **PATIENT'S BIRTH DATE**

Enter the year and month of the patient's birth (YYYYMM). To assure patient confidentiality, only submit the year and month of the patient's birth, do not submit the day of birth.

2.2.1.5. **PATIENT'S GENDER**

Enter the appropriate code:

1 = Male

2 = Female

9 = Unknown

2.2.1.6. **PATIENT'S RACE/ETHNICITY**

Enter the appropriate code:

01 = White, not of Hispanic Origin: A Person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

02 = Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

03 = Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

04 = Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii or the pacific islands including Hawaii, the Philippine Islands and Samoa.

05 = Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent. This area includes, for example, China, India, Japan, and Korea.

06 = American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

98 = Other

99 = Unknown

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.2.1.7. **PATIENT'S METHOD OF PAYMENT**

Report only the patient's primary method of payment using the codes listed below:

1 = Private Insurance

2 = Medicare

3 = Medicare and Private Insurance

4 = Medicaid

5 = Medicaid and Medicare

6 = Military or Veterans Sponsored NOS

6A = Military Sponsored (including CHAMPUS or TRICARE)

6B = Veterans Sponsored

7 = Self pay (no insurance)

8 = No means of payment (no insurance)

98 = Other

99 = Unknown

2.2.1.8. **DATE OF PATIENT ENTRY**

Provide the date the patient entered the study (YYYYMMDD). CTEP recommends using the date the patient signed the Informed Consent form.

2.2.1.9. **REGISTERING INSTITUTION CODE**

2.2.1.9.1. NON-COOPERATIVE GROUP STUDIES

Enter the unique CTEP institution code where the patient was originally registered on study (e.g., institution where the patient signed the Informed Consent).

If unsure of an institution's CTEP institution code, please refer to the institution codes listed at http://ctep.info.nih.gov. If an institution code cannot be located, please contact the NCI CTEP Help Desk. If the NCI CTEP Help Desk is not able to provide an institution code, then the "unknown" institution code ('00000') can be used as a final alternative. The "unknown" institution code should be used infrequently and only after consulting with the NCI CTEP Help Desk.

2.2.1.9.2. COOPERATIVE GROUP STUDIES

Enter the unique CTEP institution code where the patient was originally registered on study (e.g., institution where the patient signed the Informed Consent). For patients registered at a CCOP institution, provide either the CCOP main member institution code or the CCOP component institution code (preferred).

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

Please refer to the rosters available through the Clinical Trials Monitoring Branch Audit Information System (CTMB-AIS) for institution and CCOP code information. Institution codes not found in a Cooperative Group's roster can be found on CTEP's Home Page at http://ctep.info.nih.gov. If an institution code cannot be located, please contact the NCI CTEP Help Desk. If the NCI CTEP Help Desk is not able to provide an institution code, then the "unknown" institution code ('00000') can be used as a final alternative. The "unknown" institution code should be used infrequently and only after consulting with the NCI CTEP Help Desk.

2.2.1.10. REGISTERING GROUP CODE

The Registering Group code is mandatory for Inter-Group trials only. Enter the unique CTEP Group code where the patient was originally registered on study. If unsure of the CTEP Group code, please check the CTEP Home Page.

2.2.2. PATIENT ADMINISTRATIVE ITEMS

Patient administrative items are mandatory, with the exception of the *Off Treatment Reason* (Section 2.2.2.1.2.), for trials assigned to complete CDUS reporting (e.g., Phase 1 and 2 trials with DCTD supplied investigational agents), they are not required for other studies.

2.2.2.1. PART A

2.2.2.1.1. TREATMENT STATUS

Is the patient currently receiving protocol treatment on-study? Enter 1 = Yes, 2 = No.

2.2.2.1.2. OFF TREATMENT REASON

If the patient is off protocol treatment, please select the most appropriate reason the patient has discontinued the treatment:

01 = Treatment completed per protocol criteria.

02 = Disease progression, relapse during active treatment.

03 = Toxicity/Side Effects/Complications [patient removed from treatment because of treatment side effects (either physician directed or patient choice) or because of treatment complications (e.g., infection from placement of catheter)].

04 = Death on study [patient died before a decision to stop all protocol treatment had been made].

05 = Patient withdrawal or refusal after beginning protocol therapy [patient refused to continue protocol therapy for reasons other than side effects, toxicity, or complications (e.g., cost, travel)].

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

06 = Patient withdrawal or refusal prior to beginning a protocol therapy.

07 = Alternative therapy [patient removed from protocol therapy in order to receive an alternative therapy, in spite of not meeting criteria for progression/relapse or experiencing unacceptable toxicity].

08 = Patient off-treatment for other complicating disease.

09 = Patient declared ineligible.

10 = Lost to follow-up.

98 = Other.

2.2.2.2. **PART B**

2.2.2.2.1. **SUBGROUPS**

Select the appropriate code (see Section 2.1.1.13.) for the subgroup this patient was entered on. Patients enrolled on a protocol with a single subgroup should be coded as "SUBGROUPA".

2.2.2.2.2. **ELIGIBILITY STATUS**

Has the patient been declared ineligible? 1 = Yes, 2 = No.

Note: All patients registered onto the study are considered eligible until determined to be ineligible.

2.2.2.2.3. **BASELINE PERFORMANCE STATUS**

Enter the patient's performance status at protocol entry. Please use the Performance Status Criteria as shown in Table C. A conversion for Karnovsky scores to Zubrod scores is provided. Please convert other performance scales (CALGB, Karnovsky, Lansky) to the most appropriate corresponding Zubrod score.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

TABLE C: Performance Status Criteria

ECOG (Zubrod)		Karnofsky		Lansky[6]	
Score	Description	Score[7]	Description	Score[7]	Description
0	Fully active, able to carry on all pre-disease performance without restriction.	100	Normal, no complaints, no evidence of disease.	100	Fully active, normal.
		90	Able to carry on normal activity; minor signs or symptoms of disease.	90	Minor restrictions in physically strenuous activity.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.	80	Normal activity with effort; some signs or symptoms of disease.	80	Active, but tires more quickly
		70	Cares for self, unable to carry on normal activity or do active work.	70	Both greater restriction of and less time spent in play activity.
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours.	60	Requires occasional assistance, but is able to care for most of his/her needs.	60	Up and around, but minimal active play; keeps busy with quieter activities.
		50	Requires considerable assistance and frequent medical care.	50	Gets dressed, but lies around much of the day; no active play; able to participate in all quiet play and activities.
3	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.	40	Disabled, requires special care and assistance.	40	Mostly in bed; participates in quiet activities.
		30	Severely disabled, hospitalization indicated. Death not imminent.	30	In bed; needs assistance even for quiet play.
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair.	20	Very sick, hospitalization indicated. Death not imminent.	20	Often sleeping; play entirely limited to very passive activities.
		10	Moribund, fatal processes progressing rapidly.	10	No play; does not get out of bed.

2.2.2.2.4. PRIOR THERAPY

2.2.2.2.4.1. Prior Therapy Type (IMT Code)

Please indicate all prior cancer treatment the patient has received. More than one therapy may be included. Multi-modality treatments should be listed separately (e.g., mastectomy followed by tamoxifen – code as surgery and

[6] The conversion of the Lansky to ECOG scales is intended for NCI reporting purposes only.
[7] Karnofsky and Lansky performance scores are intended to be multiples of 10.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

hormonal therapy). Use CTEP Terms and IMT Codes (see the CTEP Home Page for a list of therapy terms and IMT Codes).

No Prior Therapy: No prior cancer treatment.

Chemotherapy Single Agent Systemic: Systemic chemotherapy with a single agent regimen. A regimen is described as a distinctive collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. All routes of administration are acceptable as long as the agent is intended for systemic therapy.

Chemotherapy Multi-Agent Systemic: Systemic chemotherapy with a regimen containing multiple agents. A regimen is described as a distinctive collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. All routes of administration are acceptable as long as the agent is intended for systemic therapy.

Chemotherapy Not Otherwise Specified (NOS): Non-systemic chemotherapy treatment (e.g., intra-peritoneal, intra-cavitary, intra-thecal), or chemotherapy not described by Chemotherapy Single Agent Systemic or Multi-Agent Systemic.

Immunotherapy: Biologic cancer therapy. Manipulation of the body's immune system, either directly or indirectly, with therapeutic intent, e.g., tumor vaccines, monoclonal antibodies, cytokines (interferons, interleukins, tumor necrosis factor). Do not include biologic therapy as supportive care (e.g., G-CSF for immuno-protection).

Hormonal Therapy: Cancer therapy which incorporates hormonal manipulation (e.g., tamoxifen, androgen deprivation).

Surgery: Surgical procedure, or operation, with therapeutic intent. Do not include diagnostic procedures (e.g., biopsy).

Extensive Radiation: Cancer therapy using ionizing radiation to a significant (>50%) portion of the body (e.g., craniospinal, total body irradiation, or pelvic radiation).

Limited Radiation: Cancer therapy using ionizing radiation to a limited (<50%) portion of the body.

Radiotherapy Not Otherwise Specified: Targeted ionizing radiation therapy utilizing radioactive implants or seeds, or radiotherapy that does not meet the definition for Extensive or Limited Radiation.

Bone Marrow Transplant: High dose chemotherapy combined with transplantation of bone marrow cells (e.g., allogeneic, syngeneic, autologous bone marrow or peripheral blood stem cell transplantation).

Gene Therapy: Treatment of human disease by gene transfer.

Other Prior Therapy: Cancer treatment not described in the above categories.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

The table below represents the IMT Codes used for Prior Therapy code assignment.

TABLE D: International Medical Terminology for Prior Therapies

CTEP Term	IMT Preferred Term	IMT Code
No prior therapy	Not Available	900100
Chemotherapy single agent systemic	Chemotherapy single agent systemic	23518
Chemotherapy multiple agents systemic	Chemotherapy multiple agents systemic	23514
Chemotherapy (NOS)	Not Available	900102
Hormonal Therapy	Steroid Therapy NOS	23557
Surgery	Operation NOS	4058
Immunotherapy	Not Available	900104
Extensive Radiation	Not Available	900106
Limited Radiation	Not Available	900108
Radiation (NOS)	Not Available	900110
Bone Marrow Transplant	Bone Marrow Transplant NOS	3487
Prior Therapy NOS	Not Available	900112
Gene Therapy	Not Available	900114

2.2.2.2.4.2. **Number of Prior Chemotherapy Regimens**

If a patient has previously received a chemotherapy regimen, provide the number of different single or multi-agent chemotherapy regimens received. A regimen is described as a distinctive planned collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. A chemotherapy regimen may have been discontinued for any reason (e.g., completion of therapy, adverse event [toxicity], or disease progression). If a prior treatment was ABVD/CHOP, it should be coded as one chemotherapy regimen.

Note: The total number of other prior therapy types (e.g., surgery) is not required.

2.2.2.2.4.3. **Patient's Disease Code**

Please indicate the patient's primary cancer diagnosis. Use CTEP Terms and IMT Codes. If unsure of a disease term and/or code, please check the CTEP Home Page for a list of values and IMT Codes.

2.2.3. **PATIENT TREATMENT BY COURSE**

CTEP defines the term *course* (*cycle*) as the following: A series of medical treatments or procedures (e.g., drug, biologic radiation) administered over a designated period.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

The treatment plan may call for repeated courses (cycles) of the treatment. The start, end points and frequency of a course (cycle) should be defined by protocol criteria. If a course (cycle) is not defined by a protocol (e.g., chronic once daily dosing of an oral medication), the patient follow-up schedule may be utilized to define the course length.

Patient Treatment by Course is mandatory for trials assigned to complete CDUS reporting (e.g., Phase 1 and 2 trials with DCTD supplied investigational agents), and not required for other studies.

2.2.3.1. COURSE IDENTIFICATION (ID)

Indicate the course (cycle) of treatment that is being reported on (e.g., 1,2,3,), using the definition of treatment course given in the protocol.

2.2.3.2. COURSE START DATE

Enter the date the course (cycle) began (YYYYMMDD).

2.2.3.3. TREATMENT ASSIGNMENT

Select the appropriate code (see Section 2.1.1.14.) for the patient's treatment assignment this course (e.g., Phase 2 treatment arm, Phase 1 dose levels). Patients enrolled on a protocol with a single treatment assignment should be coded as "TA1".

2.2.3.3.1. PHASE 1 STUDIES

Provide a Treatment Assignment Code for all patients assigned to a pre-identified dose level. When a Phase 1 dose level will be added or modified per protocol defined criteria, the investigator should submit a treatment assignment update to the NCI CTEP Help Desk (ncictephelp@ctep.nci.nih.gov). See Section 2.1.1.14. for further instructions.

2.2.3.4. TREATING INSTITUTION CODE

2.2.3.4.1. NON-COOPERATIVE GROUP STUDIES

Enter the unique CTEP institution code where the patient was treated during the current course. If unsure of an institution's CTEP institution code, please refer to the institution codes listed at http://ctep.info.nih.gov. If an institution code cannot be located, please contact the NCI CTEP Help Desk. If the NCI CTEP Help Desk is not able to provide an institution code, then the "unknown" institution code ('00000') can be used as a final alternative. The "unknown" institution code should be used infrequently and only after consulting with the NCI CTEP Help Desk.

2.2.3.4.2. COOPERATIVE GROUP STUDIES

Enter the unique CTEP institution code where the patient was treated during the current course. For patients registered at a CCOP institution, provide either the

CCOP main member institution code or the CCOP component institution code (preferred).

Please refer to the rosters available through the Clinical Trials Monitoring Branch Audit Database for institution and CCOP code information. Institution codes not found in a Cooperative Group's roster can be found on CTEP's Home Page at http://ctep.info.nih.gov. If an institution code cannot be located, please contact the NCI CTEP Help Desk. If the NCI CTEP Help Desk is not able to provide an institution code, then the "unknown" institution code ('00000') can be used as a final alternative. The "unknown" institution code should be used infrequently and only after consulting with the NCI CTEP Help Desk.

2.2.3.5. **PATIENT'S HEIGHT**

Indicate the patient's height in centimeters. Use protocol criteria to determine if actual or ideal (post-amputation) should be used for dose calculations.

2.2.3.6. **PATIENT'S WEIGHT**

Indicate the patient's weight in kilograms. Based on protocol criteria (actual or ideal) indicate the patient's weight used for dose calculations.

2.2.3.7. PATIENT'S BODY SURFACE AREA

Calculated by CTEP based on the patient's height and weight.

2.2.3.8. **DOSE OF THE INVESTIGATIONAL AGENT RECEIVED BY PATIENT**

2.2.3.8.1. **INVESTIGATIONAL AGENT ADMINISTERED**

The NSC number of the DCTD supplied investigational agent. For confirmation of the NSC number, please check the CTEP Home Page for a list of agent NSC numbers.

Note: For multi-investigational agent protocols (protocols that utilize more than one DCTD supplied investigational agent), each agent should be listed as a separate entry.

2.2.3.8.1.1. **Dose Modification (Change)**

Has this patient received either a dose escalation or a de-escalation of this investigational agent during this course of therapy? Use the following codes:

1 = Yes, planned (i.e., the does was changed according to protocol guidelines).

2 = Yes, unplanned (i.e., the dose change was not a part of protocol guidelines).

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

3 = No

9 = Unknown.

If the patient has received a previous escalation or de-escalation of this investigational agent and there has been no further change to the dose during this course, answer no.

2.2.3.8.1.2. Total Dose of the Investigational Agent Administered per Course

Indicate the actual total dose (#) the patient received during this course. Do not express the dose based on the patient's size (e.g., if the patient has a BSA of 2m2, answer 500 mg, not 250mg/m2). For a multi-investigational agent protocol, please make a separate entry for each agent (NSC #).

2.2.3.8.1.3. Dose Units

Indicate the dosing units (e.g., mg.) administered to the patient. Please see Section 6, CDUS - Valid Values, for a list of dose unit values.

2.2.3.9. PATIENT-SPECIFIC ADVERSE EVENT REPORTING REQUIREMENTS

An adverse event is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable or definite).

Adverse event reporting is mandatory for all studies assigned to complete CDUS reporting (e.g., Phase 1 and 2 trials that have utilized a DCTD supplied investigational agent). A complete description of the adverse reporting requirements for investigational agents are outlined in the *NCI Guidelines: Adverse Event Reporting Requirements for NCI Investigational Agents* (http://ctep.info.nih.gov/PAMO/ProtocolInfOffice.htm).

Frequency – Report quarterly. All adverse events must be reported by the course (cycle) in which they occurred.

Grade/Attribution Requirements – Grade 1 to 3 adverse events with an attribution of possible, probable, definite. All grade 4 and 5 adverse events, regardless of attribution must be reported (see Table E).

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

TABLE E: Routine Adverse Event Reporting Guidelines for CDUS

Attribution	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Unrelated				CDUS	CDUS
Unlikely				CDUS	CDUS
Possible	CDUS	CDUS	CDUS	CDUS	CDUS
Probable	CDUS	CDUS	CDUS	CDUS	CDUS
Definite	CDUS	CDUS	CDUS	CDUS	CDUS

Note: The CDUS is not a substitute for the submission of an Adverse Event Expedited Report. All appropriate adverse events should also be reported as an Adverse Event Expedited Report as outlined in the *NCI Guidelines: Adverse Event Reporting Requirements for NCI Investigational Agents*.

Persistent Adverse Events – An adverse event that persists from one course (cycle) to another should only be reported once unless the grade becomes more severe in a subsequent course. An adverse event, which resolves and then re-occurs during a different course (cycle) must be reported each course (cycle) it re-occurs.

- A patient experiences Grade 3 thrombocytopenia during cycle one. During cycle two the adverse event persists but the severity remains unchanged. During cycle three the adverse event persists but increases in severity to Grade 4. The following should be reported:

  Cycle One – Grade 3 Thrombocytopenia

  Cycle Two – No Report

  Cycle Three – Grade 4 Thrombocytopenia

Baseline Adverse Events – An adverse event should NOT be reported if a patient is entered on a study with a preexisting condition (e.g., elevated laboratory value). If the adverse event increases in severity, the investigator should re-assess the event to determine if an adverse event should be reported (determine attribution). If the adverse event resolves and then returns, the investigator should re-assess the event to determine if the event should be reported. No modification in grading should be made to account for abnormalities noted at baseline. For example:

- A patient enters a trial with an AST equivalent to Grade 1. If the AST remains unchanged at the end of cycle one, the adverse event should NOT be reported. If the AST increases to a Grade 3 level, the adverse event should be re-assessed and reported if it fulfills the other adverse event reporting criteria. The AST would be reported at Grade 3 with no adjustment for the baseline AST equivalent to Grade 1.
- A patient enters a study with diarrhea equivalent to Grade 2. The diarrhea resolves during the first cycle of therapy. If, during a subsequent cycle the patient experi-

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

enced Grade 2 diarrhea, the adverse event should be re-assessed and reported if it fulfills adverse event reporting guidelines.

2.2.3.9.1. PATIENTS EXPERIENCING AN ADVERSE EVENT DURING THE CURRENT COURSE OF THERAPY

Use the following codes to indicate that the patient experienced an adverse event on the current course of therapy:

1 = Yes

2 = No

3 = Too early to evaluate

2.2.3.9.2. PATIENTS EXPERIENCING AN ADVERSE EVENT

Indicate the following information for patients who experience an adverse event.

2.2.3.9.2.1. **Adverse Event Type**

Using the Common Toxicity Criteria (CTC), version 2.X, please select the appropriate CTEP Code (see the CTEP Home Page for a list of CTC Codes) for the adverse event the patient experienced during this treatment course. More than one adverse event may be entered.

2.2.3.9.2.2. **Grade**

Grade represents the severity of the adverse event.

Using the NCI Common Toxicity Criteria (CTC), version 2.X, enter the highest grade for each adverse event experienced. Only the highest-grade of each adverse event type should be reported during a given course. General definitions of the grading scale:

1 - Mild adverse event

2 - Moderate adverse event

3 - Severe adverse event

4 - Life-threatening or disabling adverse event

5 - Fatal adverse event

2.2.3.9.2.3. **Attribution**

Attribution is the determination of whether an adverse event is related to a medical treatment or procedure.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

Assess the relationship between the adverse event and the investigational agent, then from the list below, assign the appropriate category of attribution. Attribution must be assigned to all reported adverse events.

TABLE F: Attribution of Adverse Events

Code	Descriptor	Definition
5	Definite	The adverse event is *clearly related* to the investigational agent(s)
4	Probable	The adverse event is *likely related* to the investigational agent(s)
3	Possible	The adverse event *may be related* to the investigational agent(s)
2	Unlikely	The adverse event is *doubtfully related* to the investigational agent(s)
1	Unrelated	The adverse event is *clearly not related* to the investigational agent(s)

2.2.3.9.2.4. Adverse Event Expedited Report (formerly Adverse Event Reporting)

Using the codes below, indicate whether an Adverse Drug Experience (AdEER) report was submitted to CTEP for this specific adverse event.

1 = Yes

2 = No

9 = Unknown

2.2.4. RESPONSE OF PATIENT'S MALIGNANCY

Requested for trials assigned to Complete CDUS reporting, e.g., Phase 1 and 2 trials with DCTD supplied investigational agents[8]. It is not required for other studies.

2.2.4.1. EVALUABLE FOR RESPONSE

Based on the protocol criteria, whether the patient is evaluable for response. Use the following codes:

1 = Yes

2 = No

3 = Too Early

7 = Not applicable (e.g., response is not a protocol end point).

[8] Response data for all Phase 1 trials and all non-Cooperative Group Phase 2 trials should be submitted quarterly. Response data for Cooperative Group and CCOP Research Base Phase 2 trials may be submitted within six weeks of the completion of each stage of the study.

Note: Investigators may potentially be required to provide data elements shown in bold print. A description of the data sets required for submission are found in Section 1.3.

2.2.4.1.1. BEST RESPONSE (CATEGORY)

If the patient is evaluable for response, please indicate the patient's best response. All responses must be confirmed by protocol criteria before being reported. Enter the appropriate code:

01 = Complete response

02 = Partial response

03 = Less then partial response (including categories of minor response and mixed response)

04 = Stable

05 = Progression

06 = Not assessed adequately

98 = Other

2.2.4.1.2. BEST RESPONSE (OBSERVED DATE)

Depending on the best response category, the date would indicate one of the following:

2.2.4.1.2.1. Partial Response (PR) First Observed

If applicable, indicate the date a Partial Response (PR) was first observed. The date a PR was first observed is the date of the initial imaging study in which the patient's tumor had diminished in size sufficient to meet the protocol-specific criteria for PR. The PR should be confirmed prior to reporting via the CDUS.

2.2.4.1.2.2. Complete Response (CR) First Observed

If applicable, indicate the date a Complete Response (CR) was first observed. The date a CR was first observed is the date of the initial imaging study in which the patient's tumor had diminished in size sufficient to meet the protocol specific criteria for CR. The CR should be confirmed prior to reporting via the CDUS.

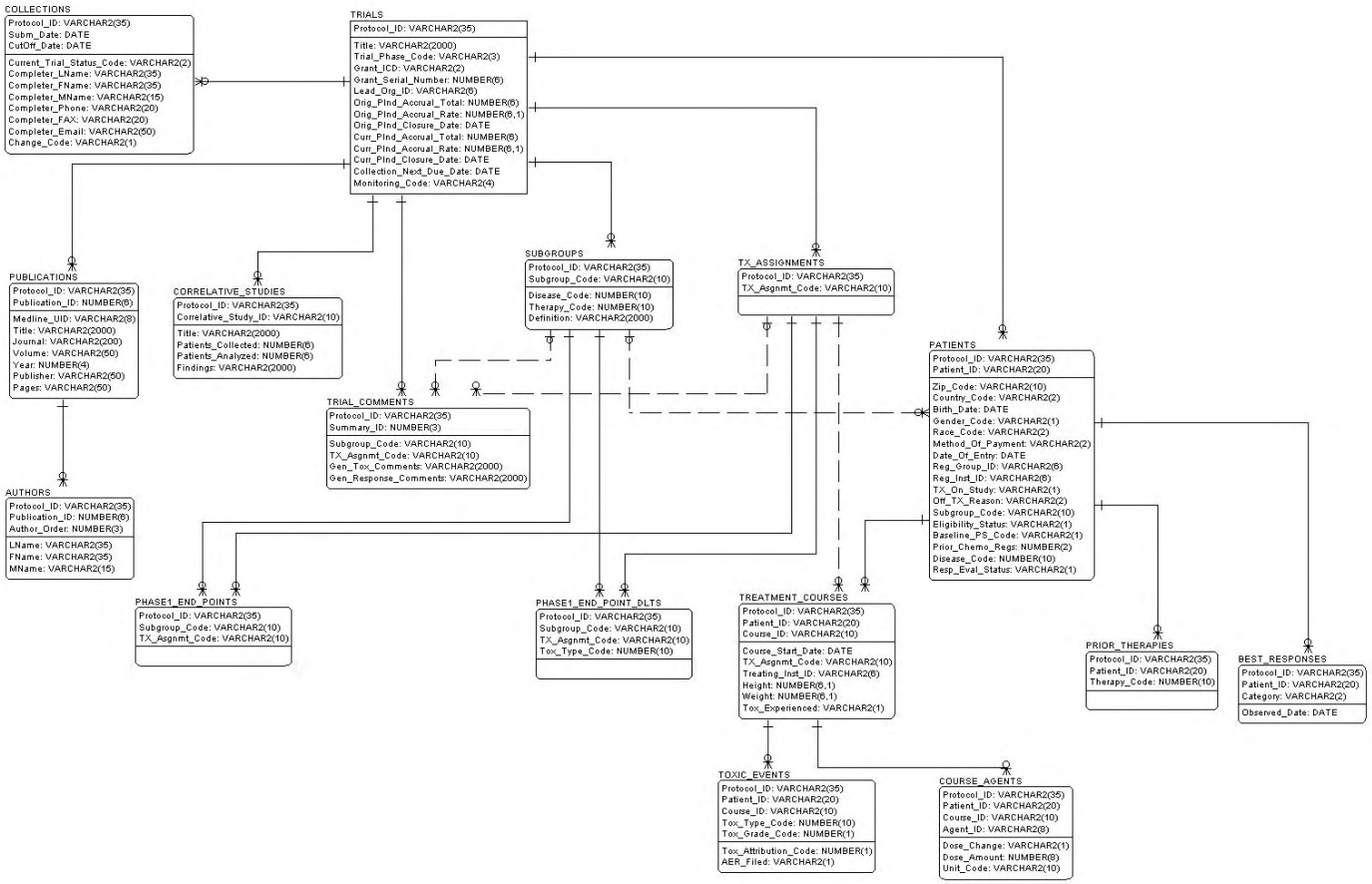
2.2.4.1.2.3. Disease Progression

Applicable to disease progression after a response (i.e., PR or CR), after stable disease, or as initial response to protocol therapy. If applicable, indicate the date that disease progression was first documented (e.g., enter the date that disease progression was first observed (YYYYMMDD).

3. CDUS - DATA MODEL

The CDUS Data Model is depicted in Figure 1. This model is provided to assist in understanding the relationships among the CDUS data elements. The model can also be used as a reference for enhancing existing systems or in the development of new systems if desired.

FIGURE 1: The CDUS Data Model diagram



4. CDUS - SMART LOADER FILE FORMAT INSTRUCTIONS

4.1. INTRODUCTION

The CDUS Smart Loader is designed to populate the CDUS database from a single text file that is electronically submitted to CTEP. The general format of a Smart Loader file is as follows:

CTEP recommends use of the following file naming convention: NCI ProtocolNumber_date (YYYYMMDD). For example, T95-0036_19980430.

Each text file will contain information for one Protocol only.

Each record associated with a Table in the CDUS database will occupy a single line.

Each record will be preceded by the Table Name it belongs to.

Each field in the record will be comma (,) delimited.

All the Varchar2 data types will be enclosed within double quotes (" ").

All dates[9] must be in YYYYMMDD format. Partial dates should not be submitted.

If a field is left null in record, a comma should still be submitted for that field.

4.2. RELATION BETWEEN ENTITIES

One Protocol can have one or many Collections associated with it (one collection per quarter for every Protocol).

One Protocol can have one or many Correlative Studies associated with it.

One Protocol can have one or many Publications associated with it.

Every Publication can have one or many Authors.

One Protocol can have one or many Patients associated with it.

One Protocol can have one or many Summaries (Toxicity/Response) associated with it.

Every Patient can have under gone multiple Prior Therapies.

Every Patient can exhibit multiple Best Responses, one per each Best Response Category entered.

Every Patient can undergo one or many Treatment Courses.

Each Treatment course can be comprised of one or many Course Agents.

There can be one or many Adverse Events (toxicities) for every Treatment Course for a Patient.

There can be multiple Phase 1-End-Points for every Subgroup.

There can be multiple DLTs for every Subgroup.

[9] With the exception of patient's date of birth which must be submitted in YYYYMM format.

4.3. FILE FORMAT

Data should be submitted for each of the following tables:

COLLECTIONS

CORRELATIVE_STUDIES

PUBLICATIONS

AUTHORS

PATIENTS

PRIOR_THERAPIES

TREATMENT_COURSES

COURSE_AGENTS

TOXIC_EVENTS

BEST_RESPONSES

TRIAL_COMMENTS

PHASE1_END_POINTS

PHASE1_END_POINT_DLTS

A list of the data items contained in each table is presented in the following sections. The format for the data items contained in each table is also presented. For an example of how each record should appear when containing actual data, please see Section 5, *CDUS Smart Loader Sample File*.

Note: Italicized items represent primary keys for the respective tables.

4.3.1. COLLECTIONS TABLE

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)
Completer_Name[10]	Varchar2(87)
Completer_Phone	Varchar2(20)
Completer_FAX	Varchar2(20)

[10] 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.

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>","<Completer_Name>","<Completer_Phone>","<Completer_FAX>","<Completer_Email>","<Change_Code>"

4.3.2. CORRELATIVE_STUDIES TABLE

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)
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>,"<Findings>"

4.3.3. PUBLICATIONS TABLE

Each record associated with the PUBLICATIONS Table should consist of the following information:

Protocol_ID	Varchar2(35)
Publication_ID	Number(6)
Medline_UID	Varchar2(8)
Title	Varchar2(2000)
Journal	Varchar2(200)
Volume	Varchar2(50)
Year	Number(4)
Publisher	Varchar2(50)
Pages	Varchar2(50)

A sample record associated with the PUBLICATIONS Table will appear as follows:

"PUBLICATIONS","<Protocol_ID>",<Publication_ID>,"<Medline_UID>","<Title>","<Journal>","<Volume>",<Year>,"<Publisher>","<Pages>"

4.3.4. AUTHORS TABLE

Each record associated with the AUTHORS Table should consist of the following information:

Protocol_ID	Varchar2(35)
Publication_ID	Number(6)
Author_Order	Number(3)
Author_Name[11]	Varchar2(87)

A sample record associated with the AUTHORS Table will appear as follows:

"AUTHORS","<Protocol_ID>",<Publication_ID>,<Author_Order>,"<Author_Name>"

4.3.5. PATIENTS TABLE

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)
Gender_Code	Varchar2(1)
Race_Code	Varchar2(2)
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)
Subgroup_Code	Varchar2(10)
Eligibility_Status	Varchar2(1)
Baseline_PS_Code	Varchar2(1)
Prior_Chemo_Regs	Number(2)
Disease_Code	Number(10)
Resp_Eval_Status	Varchar2(1)

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

[11] Author_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.

"PATIENTS","<Protocol_ID>","<Patient_ID>","<Zip_Code>","<Country_Code>",<Birth_Date>,"<Gender_Code>","<Race_Code>","<Method_Of_Payment>",<Date_Of_Entry>,"<Reg_Group_ID>","<Reg_Inst_ID>","<TX_On_Study>","<Off_TX_Reason>","<Subgroup_Code>","<Eligibility_Status>","<Baseline_PS_Code>",<Prior_Chemo_Regs>,<Disease_Code>,"<Resp_Eval_Status>"

4.3.6. PRIOR_THERAPIES TABLE

Each record associated with the PRIOR_THERAPIES Table should consist of the following information:

Protocol_ID	Varchar2(35)
Patient_ID	Varchar2(20)
Therapy_Code	Number(10)

A sample record associated with the PRIOR_THERAPIES Table will appear as follows:

"PRIOR_THERAPIES","<Protocol_ID>","<Patient_ID>",<Therapy_Code>

4.3.7. TREATMENT_COURSES TABLE

Each record associated with the TREATMENT_COURSES Table should consist of the following information:

Protocol_ID	Varchar2(35)
Patient_ID	Varchar2(20)
Course_ID	Varchar2(10)
Course_Start_Date	Date (YYYYMMDD)
TX_Asgnmt_Code	Varchar2(10)
Treating_Inst_ID	Varchar2(6)
Height	Number(6,1)
Weight	Number(6,1)
Tox_Experienced	Varchar2(1)

A sample record associated with the TREATMENT_COURSES Table will appear as follows:

"TREATMENT_COURSES","<Protocol_ID>","<Patient_ID>","<Course_ID>",<Course_Start_Date>,"<TX_Asgnmt_Code>","<Treating_Inst_ID>",<Height>,<Weight>,"<Tox_Experienced>"

4.3.8. COURSE_AGENTS TABLE

Each record associated with the COURSE_AGENTS Table should consist of the following information:

Protocol_ID	Varchar2(35)
Patient_ID	Varchar2(20)
Course_ID	Varchar2(10)
Agent_ID	Varchar2(8)
Dose_Change	Varchar2(1)
Dose_Amount	Number(8)
Unit_Code	Varchar2(5)

A sample record associated with the COURSE_AGENTS Table will appear as follows:

"COURSE_AGENTS","<Protocol_ID>","<Patient_ID>","<Course_ID>","<Agent_ID>","<Dose_Change>",<Dose_Amount>,"<Unit_Code>"

4.3.9. TOXIC_EVENTS TABLE

Each record associated with the TOXIC_EVENTS Table (Adverse Events) should consist of the following information:

Protocol_ID	Varchar2(35)
Patient_ID	Varchar2(20)
Course_ID	Varchar2(10)
Tox_Type_Code	Number(10)
Tox_Grade_Code	Number(1)
Tox_Attribution_Code	Number(1)
AER_Filed	Varchar2(1)

A sample record associated with the TOXIC_EVENTS Table will appear as follows:

"TOXIC_EVENTS","<Protocol_ID>","<Patient_ID>","<Course_ID>",<Tox_Type_Code>,<Tox_Grade_Code>,<Tox_Attribution_Code>,"<AER_Filed>"

4.3.10. BEST_RESPONSES TABLE

Each record associated with the BEST_RESPONSES Table should consist of the following information:

Protocol_ID	Varchar2(35)
Patient_ID	Varchar2(20)
Category	Varchar2(2)
Observed_Date	Date (YYYYMMDD)

A sample record associated with the BEST_RESPONSES Table will appear as follows:

"BEST_RESPONSES","<Protocol_ID>","<Patient_ID>","<Category>",<Observed_Date>

4.3.11. TRIAL_COMMENTS TABLE

Each record associated with the TRIAL_COMMENTS Table (Summary information by subgroup and/or treatment assignment)should consist of the following information:

Protocol_ID	Varchar2(35)
Subgroup_Code	Varchar2(10)
TX_Asgnmt_Code	Varchar2(10)
Gen_Tox_Comments	Varchar2(2000)
Gen_Response_Comments	Varchar2(2000)

Note: The Summary_ID depicted in the data model is for internal purposes only.

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

"TRIAL_COMMENTS","<Protocol_ID>","<Subgroup_Code>","<TX_Asgnmt_Code>","<Gen_Tox_Comments>","<Gen_Response_Comments>"

4.3.12. PHASE1_END_POINTS TABLE

Each record associated with the PHASE1_END_POINTS Table should consist of the following information:

Protocol_ID	Varchar2(35)
Subgroup_Code	Varchar2(10)
TX_Asgnmt_Code	Varchar2(10)

A sample record associated with the PHASE1_END_POINTS Table will appear as follows:

"PHASE1_END_POINTS","<Protocol_ID>","<Subgroup_Code>","<TX_Asgnmt_Code>"

4.3.13. PHASE1_END_POINT_DLTS TABLE

Information about Phase 1 End Point Dose Limiting Toxicity is presented in this table. Each record associated with the PHASE1_END_POINT_DLTS Table should consist of the following information.

Protocol_ID	Varchar2(35)
Subgroup_Code	Varchar2(10)
*TX_Asgnmt_C*ode	Varchar2(10)
Tox_Type_Code	Number(10)

A sample record associated with the PHASE1_END_POINT_DLTS Table will appear as follows:

"PHASE1_END_POINT_DLTS","<Protocol_ID>","<Subgroup_Code>","<TX_Asgnmt_Code>",<Tox_Type_Code>

5. CDUS SMART LOADER SAMPLE FILE

"COLLECTIONS","T95-0036",19970110,19961231,"AC","Public^John^Q","(301)111-1212","(301)111-2323","public@med.com","1"

"CORRELATIVE_STUDIES","T95-0036","950036PK",40,40,"Study Findings"
"CORRELATIVE_STUDIES","T95-0036","950036QOL",40,50,"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",1, "99061487","","","",,"","",""
"AUTHORS","T95-0036",1,1,"CAREY"
"AUTHORS","T95-0036",1,2,"SMITH"

"PATIENTS","T95-0036","A5001","20595","",194206,"1","06","1",19960707,"NSABP","MD005","1","","SUBGROUP1","1","1",2,12345,"1"
"PATIENTS","T95-0036","A5002","20595","",193608,"2","01","2",19960527,"NSABP","MD005","1","","SUBGROUP1","1","2",2,12345,"1"
"PATIENTS","T95-0036","A5003","20595","",194010,"1","03","3",19960605,"NSABP","MD005","1","","SUBGROUP2","1","1",0,23456,"2"

"PRIOR_THERAPIES","T95-0036","A5001",44544
"PRIOR_THERAPIES","T95-0036","A5001",77677

"TREATMENT_COURSES","T95-0036","A5001","1",19960710,"A1","MD005",170.5,61.3,"2"
"TREATMENT_COURSES","T95-0036","A5001","2",19960715,"A1","MD005",170.5,61.3,"1"
"TREATMENT_COURSES","T95-0036","A5002","1",19960605,"A1","MD005",152.4,73.6,"2"
"TREATMENT_COURSES","T95-0036","A5003","1",19960615,"A1","MD005",180.3,95.4,"2"

"COURSE_AGENTS","T95-0036","A5001","1","673089","2",258,"MG"
"COURSE_AGENTS","T95-0036","A5001","1","119875","2",375,"MG"
"COURSE_AGENTS","T95-0036","A5001","2","673089","2",258,"MG"
"COURSE_AGENTS","T95-0036","A5001","2","119875","2",375,"MG"
"COURSE_AGENTS","T95-0036","A5002","1","673089","2",245,"MG"
"COURSE_AGENTS","T95-0036","A5002","1","119875","2",350,"MG"
"COURSE_AGENTS","T95-0036","A5003","1","673089","2",278,"MG"
"COURSE_AGENTS","T95-0036","A5003","1","119875","2",380,"MG"

"TOXIC_EVENTS","T95-0036","A5001","2",455095,4,4,"1"

"BEST_RESPONSES","T95-0036","A5001","05",19960730
"BEST_RESPONSES","T95-0036","A5002","04",19960530
"BEST_RESPONSES","T95-0036","A5003","06",19960715

"TRIAL_COMMENTS","T95-0036","SUBGROUP1","A1","","Response seen in one of two patients"
"TRIAL_COMMENTS","T95-0036","SUBGROUP2","A1","No Toxicity",""

"PHASE1_END_POINTS"," T95-0036","SUBGROUP1","A1"

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

6. CDUS - VALID VALUES

The following table describes the valid values used for the CDUS data elements.

TABLE G: Valid Values

Table Name	Column Name	List of Values	Description
COLLECTIONS	Current_Trial_Status_Code	AP	Approved
		AC	Active
		TC	Temporarily Closed to Accrual
		TB	Temporarily Closed to Accrual and Treatment
		CL	Closed, Patients Still on Treatment
		CB	Closed, All Patients have Completed Treatment
		CP	Completed
		AD	Administratively Completed
	Change_Code	1	Yes
		2	No
PATIENTS	Country_Code	See CTEP Home Page	
	Gender_Code	1	Male
		2	Female
		9	Unknown
	Race_Code	01	White
		02	Hispanic or Latino
		03	Black or African American
		04	Native Hawaiian or other Pacific Islander
		05	Asian
		06	American Indian or Alaska native
		98	Other
		99	Unknown
	Method_Of_Payment	1	Private Insurance
		2	Medicare
		3	Medicare and Private Insurance
		4	Medicaid
		5	Medicaid and Medicare
		6	Military or Veterans Sponsored NOS
		6A	Military Sponsored (including CHAMPUS &TRICARE)
		6B	Veterans Sponsored
		7	Self Pay (No Insurance)
		8	No means of payment (no insurance)
		98	Other
		99	Unknown
	Reg_Group_ID	See CTEP Home Page	

Table Name	Column Name	List of Values	Description
PATIENTS (cont.)	Reg_Inst_ID	See CTEP Home Page	
	TX_On_Study	1	Yes
		2	No
	Off_TX_Reason	01	Treatment completed per protocol criteria
		02	Disease progression, relapse during active treatment
		03	Toxicity/Side Effects/Complications
		04	Death on Study
		05	Patient withdrawal or refusal after beginning protocol therapy
		06	Patient withdrawal or refusal before beginning protocol therapy
		07	Alternative therapy
		08	Patient off-treatment for other complicating disease
		09	Patient declared ineligible
		10	Lost to follow-up
		98	Other
	Eligibility_Status	1	Yes
		2	No
	Baseline_PS_Code	0	Normal Activity, asymptomatic
		1	Symptomatic, fully ambulatory
		2	Symptomatic; in bed < 50% of time
		3	Symptomatic; in bed > 50% of time
		4	100% bedridden
	Disease_Codes	See CTEP Home Page	(Use IMT Codes)
	Resp_Eval_Status	1	Yes
		2	No
		3	Too Early
		7	Not Applicable
PRIOR_THERAPIES	Therapy_Code	See CTEP Home Page	(Use IMT Codes)
TREATMENT_COURSES	Treating_Inst_ID	See CTEP Home Page	
	Tox_Experienced	1	Yes
		2	No
		3	Too Early to evaluate
COURSE_AGENTS	Agent_ID	See CTEP Home Page	(Use NSC Numbers)
	Dose_Change	1	Yes, planned
		2	Yes, unplanned
		3	No
		9	Unknown
	Unit_Code	cm	Centimeter
		Ci	Curie
		dL	Deciliter
		dm	Decimeter
		g	Gram

Table Name	Column Name	List of Values	Description
COURSE_AGENTS (cont.)	Unit_Code (cont.)	Eq	Gram-equivalent weight
		mol	Gram-molecular weight (mole)
		gravity	Gravity (in centrifugation)
		Hz	Hertz
		IU	International Unit
		JCM2	Joules per centimeter square
		keV	Kilo-electron volt
		kg	Kilogram
		kHz	Kilohertz
		kPa	Kilopascal
		L	Liter
		MHz	Megahertz
		Mrad	Megarad
		m	Meter
		mcCi	Microcurie
		mcg	Microgram
		mcL	Microliter
		mcm	Micrometer
		mCi	Millicurie
		mEq	Milliequivalent
		mg	Milligram
		MMM	Milligrams per milliliter per minute
		mL	Milliliter
		mm	Millimeter
		mmol	Millimole
		MeV	Million electron volts
		mU	Million Unit
		mOsmol	Milliosmole
		milliunit	Milliunit
		mV	Millivolt
		nCi	Nanocurie
		ng	Nanogram
		nm	Nanometer
		nm light	Nanometers of Light
		Osmol	Osmole
		Pa	Pascal
		pg	Picogram
		pfu	Plague Forming Unit
		psi	Pounds per square inch
		unit	Unit
		VP	Viral particles
		N/A	Not Applicable
TOXIC_EVENTS	Tox_Type_Code	See CTEP Home Page	(Use IMT Codes, see CTC for definition)
	Tox_Grade_Code	1, 2, 3, 4, 5	(See the CTEP Home Page and CTC for definition)
	Tox_Attribution_Code	1	Unrelated
		2	Unlikely
		3	Possible

Table Name	Column Name	List of Values	Description
TOXIC_EVENTS (cont.)	Tox_Attribution_Code (cont.)	4	Probable
		5	Definite
	AER_Filed	1	Yes
		2	No
		9	Unknown
BEST_RESPONSES	Category	01	Complete Response
		02	Partial Response
		03	Less than partial Response
		04	Stable
		05	Progression
		06	Not assessed adequately
		98	Other
PHASE1_END_POINT_DLTS	Tox_Type_Code	See CTEP Home Page	(use IMT Code)

7. CDUS - SMART LOADER APPROVAL, DISAPPROVAL, AND CORRECTION PROCESS

7.1. OVERVIEW

The CTEP Smart Loader has been developed to evaluate all data submitted to the Clinical Data Update System (CDUS) for accuracy and completeness. The review process and acceptance or rejection of the data will depend on the type of error and whether a data element is considered mandatory or requested for the protocol for which data are being submitted. A listing of the business rules, including mandatory and requested data information, can be found in Section 9.

7.2. MANDATORY, REQUESTED, AND OPTIONAL DEFINITIONS

The data elements have been grouped into the following categories. These categories are described below.

7.2.1. MANDATORY DATA ELEMENTS

Mandatory data elements are those defined by CTEP as the minimum information required for processing the data submission and to track patient enrollment on a study. Investigators must submit all mandatory data elements.

7.2.2. REQUESTED DATA ELEMENTS

Requested data elements are those defined by CTEP as the minimal information necessary to fulfill the regulatory, scientific and administrative needs of the NCI. Investigators must provide all known requested data elements.

7.2.3. OPTIONAL DATA ELEMENTS

Submission of optional data is at the investigator's discretion. In general the optional fields are free text. These fields (e.g., E-mail address, correlative study findings, general data summaries by subgroup, and/or treatment assignment) should be used by investigators to provide additional data that may not be readily apparent from other information submitted.

7.3. INCOMPLETE, INCORRECT, INAPPROPRIATE, AND INCONSISTENT DEFINITIONS

As described previously, the CDUS Smart Loader has been developed to review each file before it is loaded into the CDUS to help CTEP identify problems or potential problems with data submissions. The anticipated problems have been grouped into the following four categories: incorrect, incomplete, inappropriate, and inconsistent. These categories are described below.

7.3.1. INCOMPLETE DATA

Data files that do not contain all mandatory and requested data elements will be considered incomplete.

7.3.2. INCORRECT DATA

Data that are submitted in the wrong format or with invalid codes will be considered incorrect. Please see Section 4, CDUS-Smart Loader File Format Instructions, for specific file format requirements. To determine valid codes, please refer to Section 1, Clinical Data Update (CDU) Instructions, and Section 6, CDUS-Valid Values.

7.3.3. INAPPROPRIATE DATA

Data that do not meet electronically preset criteria will be considered inappropriate. Examples of inappropriate submissions include values that fall outside of an expected range (e.g., patient weight > 120kg) or an incongruous date sequence (e.g., first day of treatment must be > protocol activation date). The Smart Loader will check the database for elements that have been approved in an earlier submission (e.g., Submission 1: patient weighed 150kg - data subsequently verified and approved. Submission 2: patient weighs 150kg - data accepted after review of the existing approved data in the Active Database) and will not generate an error in this case.

7.3.4. INCONSISTENT DATA

Data elements that are not expected to change from one submission to the next (e.g., patient's gender) will be considered inconsistent.

7.3.5. CUMULATIVE DATA

Investigators are required to send cumulative data each quarter; all data submitted from previous quarters must be submitted in subsequent quarters. Submissions may contain new data as well as updates to previously submitted data. The minimal submission requirement is data identical to that sent in the previous submission. The CDUS Smart Loader confirms the cumulative data, identifies updates within the file, and inserts the new or revised data within the record. This process is performed for every table where data are loaded. If the data are not cumulative, the file is rejected, which terminates the data load process and produces an error report.

The value of the submitted Change Code (see Section 2.1.1.7.) may affect whether the cumulative data are confirmed. Submitting a Change Code of "1" (Yes, the data has changed since the last report) results in an automatic confirmation of cumulative data. The only instance where a cumulative data confirmation is not performed is when a Change Code of "2" (No, the data has not changed since the last report) AND no data for any of the tables are submitted.

Note: Submissions where no data was changed since the previous quarter (Change Code = 2) but include data other than administration items, will result in a cumulative data confirmation.

7.4. SMART LOADER APPROVAL, DISAPPROVAL, AND CORRECTION PROCESS

The Smart Loader approval, disapproval, and correction process is described below.

7.4.1. SMART LOADER APPROVAL

After a protocol data set has been accepted by the Smart Loader, the investigator will receive automatic acceptance notification by E-mail, in the form of a CDUS Approval Notice.

7.4.2. SMART LOADER DISAPPROVAL

Depending on the problems identified during the Smart Loader process, the investigator may be required to resubmit a data set, submit verification of data, or a combination of both. CTEP will not make manual changes to data submitted by investigators; all corrections or changes to elements in a data set must be made through resubmission of the entire data set. Table H summarizes the types of problems that may be identified through the Smart Loader process, and the response required from the investigator for each. Rejection, warning, cumulative, or caution notices will be sent to the investigator depending on the type of problem identified. A suspension notice will be sent to investigators who fail to respond to these notices within the specified time frame. A description of each notice is provided on the pages that follow.

Table H: Data Submission Problem Description and Required Response[12]

Data Type	Problem Type			
	Incomplete	**Incorrect**	**Inappropriate**	**Inconsistent**
Mandatory Data	• All data rejected • List of missing data elements generated with *Rejection Notice* • Resubmission required within 10 working days	• All data rejected • List of errors generated with *Rejection Notice* • Resubmission required within 10 working days	• Data set on hold • List of errors generated with *Warning Notice* • All data must be verified or resubmitted within 10 working days	• Data set on hold • List of errors generated with *Warning Notice* • All data must be verified or resubmitted within 10 working days
Requested Data	• Remaining data set is accepted • List of missing data elements generated with *Caution Notice* • Verification or submission of corrected data due for next quarter's submission	• All data rejected • List of errors generated with *Rejection Notice* • Resubmission required within 10 working days	• All data accepted • List of errors generated with *Caution Notice* • Verification or submission of corrected data due for next quarter's submission	• All data accepted • List of errors generated with *Caution Notice* • Verification or submission of corrected data due for next quarter's submission
Optional Data	N/A	N/A	N/A	• All data accepted • List of errors generated with *Caution Notice* • Verification or submission of corrected data due for next quarter's submission
Note: All Warning or Caution errors that cannot be fixed unless by resubmission will be logged as Rejection errors. The two data elements where this will occur are Patients_Analyzed from the CORRELATIVE_STUDIES table and Birth_Date from the PATIENTS table.				

7.4.2.1. ERROR NOTICES

For each submission an error log report will be generated and mailed to the submitter. The following descriptions provide details for each error category.

7.4.2.1.1. CDUS REJECTION NOTICE

If a protocol data set contains incomplete or incorrect mandatory data elements, incorrect requested, the Smart Loader will reject the entire protocol data set, and the investigator will automatically receive a rejection notice. The rejection notice will outline the specific problems and how and when they should be corrected. Investigators will be required to resubmit their corrected data set within 10 working

[12] This table represents the general policy regarding the type of action required based on problem and data type. The actual action taken for a specific problem type may be different. Please to the CDUS Business Rules section for further details.

days. Failure to comply within 10 working days may result in the suspension of an investigator and/or temporary closure of the study.

The resubmitted data set must resolve all errors listed in the rejection notice before the data set can be approved.

7.4.2.1.2. CDUS WARNING NOTICE

If a protocol data set contains inappropriate or inconsistent mandatory data elements, the data set will be placed on hold. All problem data will be flagged for further CTEP review, and the investigator will automatically receive a warning notice. The warning notice will outline the specific problems and how and when they should be corrected or verified.

All errors listed in a warning notice must be addressed in a CDUS Warning Response, and when required, a corrected data set must also be submitted to CTEP. Failure to comply within 10 working days may result in the suspension of the investigator and/or temporary closure of the study.

7.4.2.1.2.1. Correction Process

Amended Data - Data elements that are in fact correct but that have been identified as inconsistent through the Smart Loader process (e.g., a patient's gender has been corrected from a previous submission) must be noted as amended data in the CDUS Warning Response to CTEP.

Clarified Data - Data elements that are in fact correct but have been identified as inappropriate through the Smart Loader process (e.g., a very large patient falls outside of the expected weight range) must be clarified in the CDUS Warning Response (i.e., CTEP must be informed that the weight as reported is correct).

Corrected Data - If the Smart Loader has identified problems that are in fact mistakes and require correction of the data by the investigator, the CDUS Warning Response to CTEP must indicate that these elements will be corrected and returned to CTEP with a new, complete submission within 10 days.

7.4.2.1.2.2. Responding to a Warning Notice

All correspondence to CTEP in response to a warning notice must be sent via E-mail and must include the following information:

- File Name.
- NCI Protocol Number.
- Name of person completing the report, and his/her phone number
- A list of the exact fields that need to be amended from a previous submission and why (e.g., inform CTEP that a mistake was made on the patient's gender in the previous submission and the current submission is correct).
- A list of the exact fields that need to be clarified and why (e.g., inform CTEP that the weight as reported is correct).

- A list of the exact fields that need to be corrected and will be resubmitted with the complete data set within 10 days.

7.4.2.1.3. CUMULATIVE

The minimal cumulative data submission requirement is data identical to that sent in the previous submission (see Section 7.3.5. for a detailed description). Once the data file is received, the cumulative data are confirmed and updates or new data are inserted within the record. The file is rejected when a discrepancy is found, this terminates the data load process and generates an error report that is sent to the submitter.

7.4.2.1.4. CDUS CAUTION

If a protocol data set contains incomplete, inappropriate or inconsistent requested or optional data elements, the Smart Loader will accept the entire data set; all problem data will be flagged for further CTEP review, and the investigator will automatically receive a caution notice. The caution notice will outline the specific problems and how and when they should be corrected or verified. Investigators will be requested to send a notice of amended data, a clarification of data, or a correction of data (as described above under CDUS Warning Notice) with the next quarterly submission of data.

7.4.2.1.5. CDUS SUSPENSION NOTICE

A CDUS Suspension Notice will be sent to investigators who fail to respond to a CDUS Rejection or Warning notice within the time allotted. The notice will state that the investigator is suspended and will not receive IND agents (on-going patients will be continued on a case by case basis) and/or that the study has been temporary closed. The suspension notice will outline the specific problems and how they should be corrected. CTEP's Clinical Trials Monitoring Branch will be sent a copy of all suspension notices.

8. INTERPRETING THE CDUS ERROR LOG REPORT

The CDUS Smart Loader has been developed to evaluate all data submitted to the Clinical Data Update System (CDUS) for accuracy and completeness. The review process and acceptance or rejection of the data will depend on the type of error and whether a data element is considered mandatory or non-mandatory for the protocol for which data are being submitted. See Appendix A for a complete description of mandatory, requested, and optional definitions. The following section describes the Error Log Report that the system will generate for a data load via the Smart Loader.

If you have any questions or comments regarding the CDUS, please contact the NCI CTEP Help Desk by telephone at (301) 840-8202, by fax (301) 948-2242, or E-mail at ncictephelp@ctep.nci.nih.gov. Additional information regarding the CDUS is available on the CTEP Home Page (http://ctep.info.nih.gov).

8.1. ERROR LOG REPORT

The CDUS Error Log Report is generated whenever a data file is uploaded via the Smart Loader. The report indicates the types of errors encountered to enable the submitting organization to make the necessary corrections and resubmit the data.

The header of the report indicates the Date of Generation, Protocol ID, Load Number, and Load Date.

The report groups the errors encountered by category:

- Rejection,
- Warning,
- Cumulative, and
- Caution.

For each Rejection, Warning or Caution error, the report lists the:

- Error ID,
- Line Number,
- Table Name,
- Column Name,
- Column Value, and
- Error Location [the primary key(s) for the record].

For each Cumulative error, the report lists:

- Error ID,
- Table Name, and
- Coumn Value

The end of the report lists totals for each error category; it also summarizes the total number of records with and without errors (if applicable) by table name. Cumulative errors are not included in the summarized totals.

8.2. DESCRIPTION REPORT

Descriptions of each error message in the CDUS Error Log Report are listed by Error ID in the CDUS Error Messages Manual (see Figure 3). As with the CDUS Error Log Report, the error descriptions in the CDUS Error Messages Manual are grouped by category:

- Rejection,
- Warning,
- Cumulative, and
- Caution.

8.3. CDUS ERROR REPORT COLUMN HEADINGS

8.3.1. DATE OF GENERATION

This date indicates the date the Smart Loader Error Log Report was produced.

8.3.2. PROTOCOL ID

The Protocol ID is the protocol number for which data was loaded via the Smart Loader.

8.3.3. LOAD NUMBER

This is the load reference number.

8.3.4. LOAD DATE

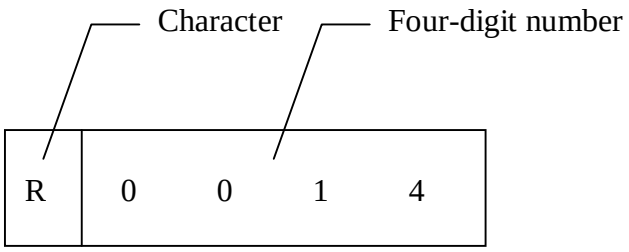
The Load Date indicates the date the data were loaded into the system.

8.4. REPORT DETAIL

This section describes the specific type of data details available in the report.

8.4.1. ERROR ID

This is the identification number of the error. Each error generated by the Smart Loader has a predefined identification number. The format of these numbers is:



The first character indicates the Error Category. It can be Rejection (R), Caution (C), Warning (W), or Cumulative (D).

Please refer to the Smart Loader Error Messages Manual for a detailed error description corresponding to an error ID.

8.4.2. LINE NUMBER

This is the physical line number of the record in the submitted data file. The blank lines present in the file are also counted.

8.4.3. TABLE NAME

This is the name of the table related to the current error. If the Smart Loader is unable to decide the table name (i.e., when table name itself is wrong), then this field will list "DEFAULT" as the table name.

8.4.4. COLUMN NAME

This is the name of the column related to the current error. This field is left blank if the column name is irrelevant or not unique in the current error context. For example, for the error Wrong number of columns, this field is left blank.

8.4.5. COLUMN VALUE

This column contains the actual data values that were summarized in the data file. In case of a cumulative error, the column value corresponds to the record(s) existing in the active database, not those submitted with the current file.

8.4.6. ERROR LOCATION

This field indicates the value of the Unique Record Identifiers (URI), or primary keys, for the current table. The names of the URI fields for the current record are listed in the section UNIQUE IDENTIFIERS FOR EACH TABLE LISTED IN THE ERROR REPORT. There is one-to-one mapping from the Name to the Value. For example, if patient_id is the first name listed, then the first value in the Error Location is the value of the patient_id.

If the Smart Loader is unable to find the URI for the current record, then the Error Location indicates the first four field values of the current record.

8.4.7. UNIQUE IDENTIFIERS

This lists the field names which together uniquely identify a record in the table.

8.4.8. ERROR CATEGORY

There are four error categories associated with the Smart Loader. They are Rejection, Warning, Cumulative and Caution.

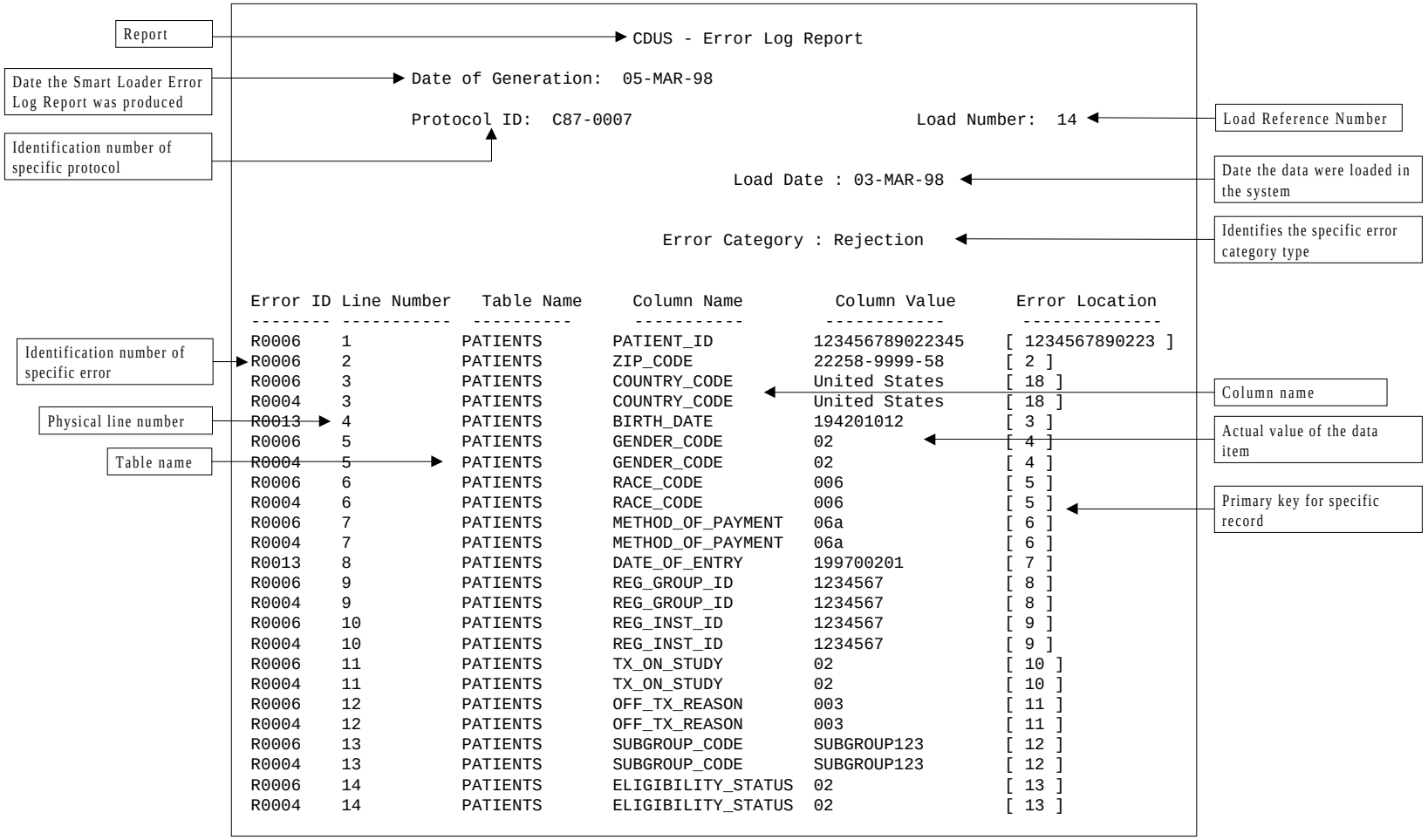
8.4.9. ERROR ENCOUNTERED

This lists the total number of errors encountered for an error category. This number is the count of the errors reported in the corresponding section.

8.5. SAMPLE REPORTS

The following pages show a sample Error Log Report and Error Messages Manual with callout text describing each part of the reports.

FIGURE 2: CDUS Error Log Report



Note: Figures 2 and 3 are provided for explanatory purposes only, they are not exhaustive sets of error messages. Error Log Reports (Figure 2) specific to each data load will be mailed with data load results.

FIGURE 2: CDUS Error Log Report (continued)

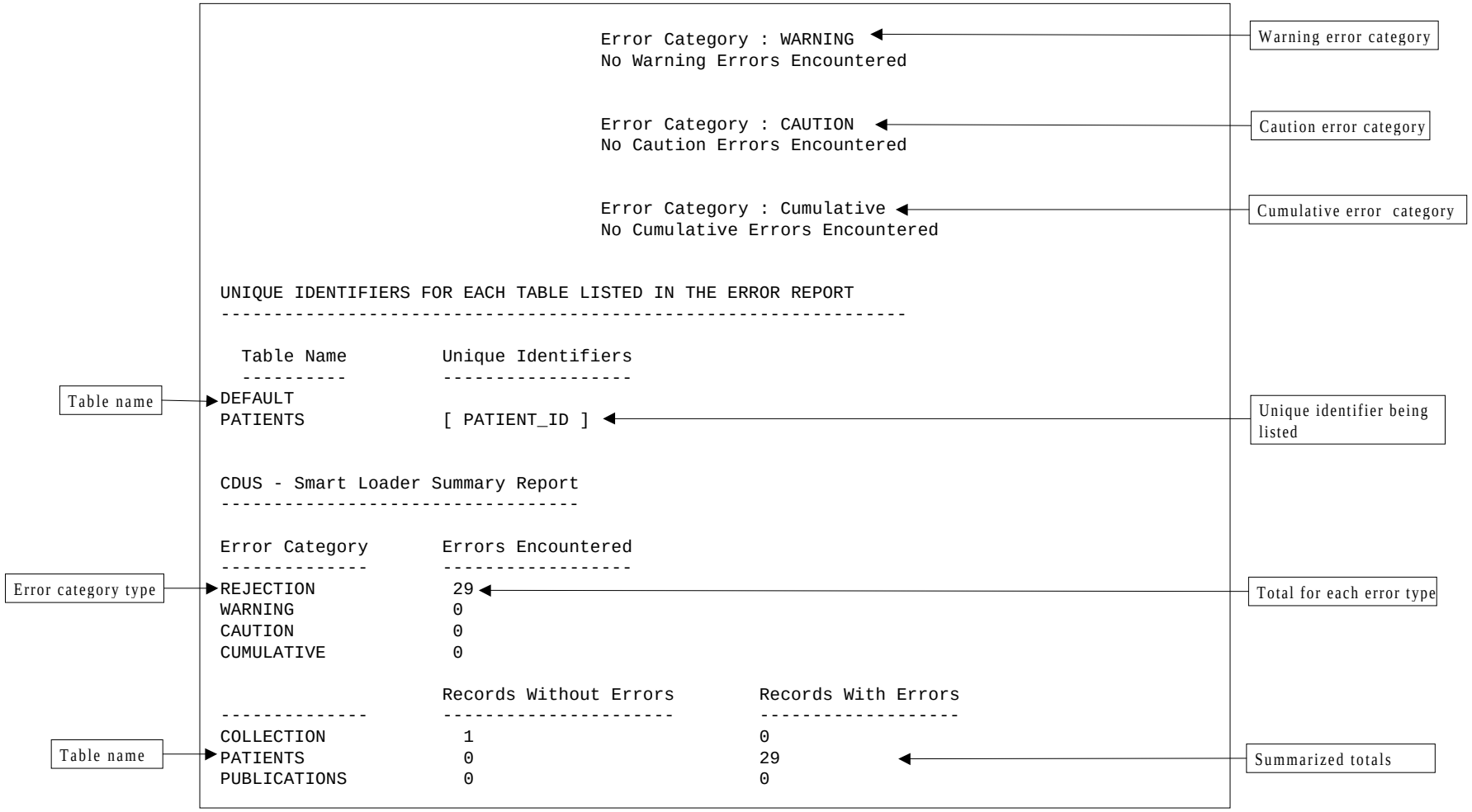
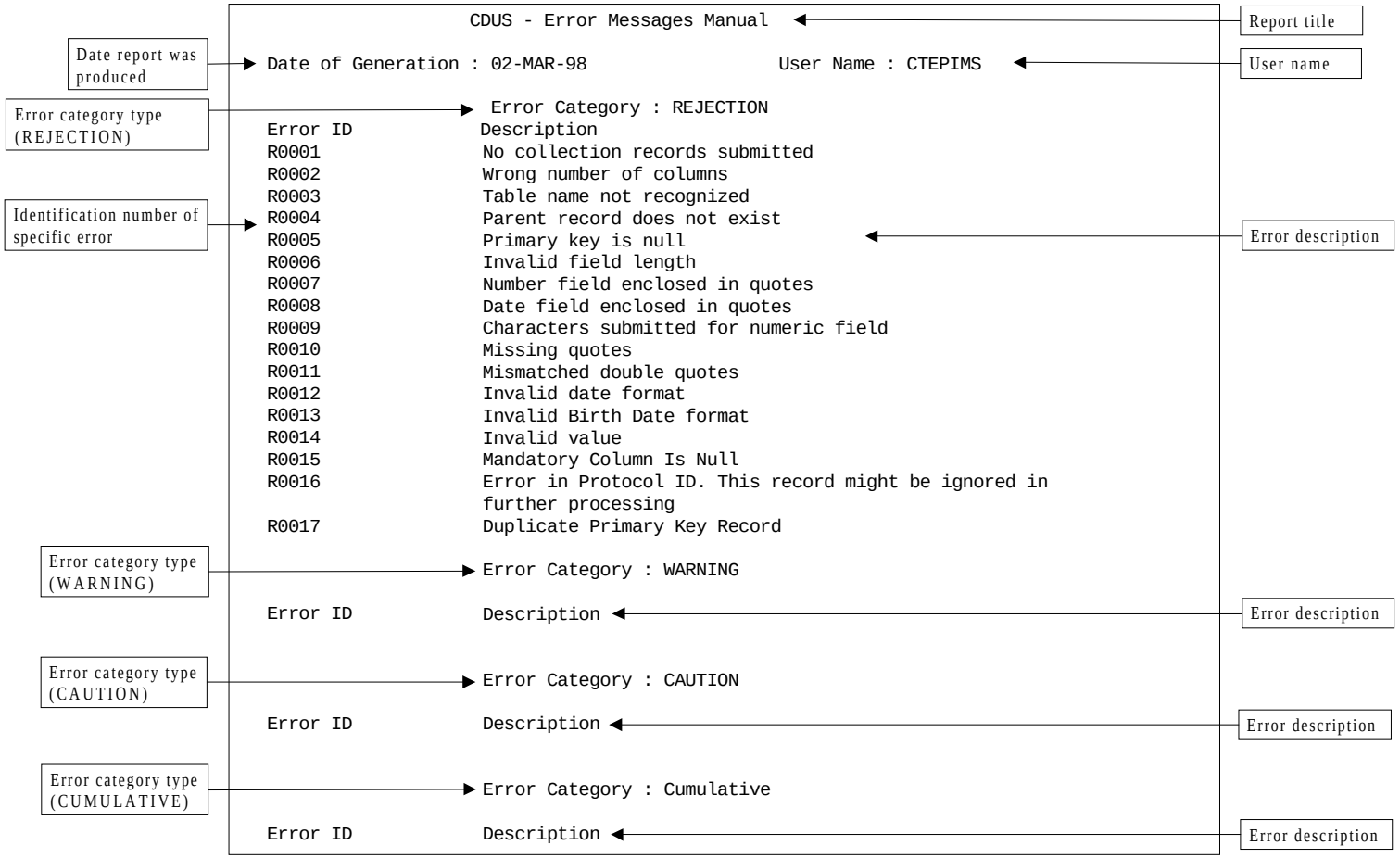


FIGURE 3: CDUS Error Messages Manual



Note: Figures 2 and 3 are provided for explanatory purposes only, they are not exhaustive sets of error messages. Error Log Reports (Figure 2) specific to each data load will be mailed with data load results.

9. CDUS BUSINESS RULES

The following table provides the business rules used by the upcoming CDUS submission due in April 1999.

Table I: CDUS Business Rules

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
COLLECTIONS	CURRENT_TRIAL_STATUS_CODE***	Inappropriate Mandatory	REJECTION	Must progress towards completion
	CURRENT_TRIAL_STATUS_CODE***	Inappropriate Mandatory	REJECTION	Protocol status must be active if patients are being accrued
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be <= Subm_Date
	LEAD_ORG_ID	Inconsistent Mandatory	REJECTION	Mandatory data not consistent with previous value
CORRELATIVE_STUDIES	PATIENTS_ANALYZED	Inappropriate Requested	REJECTION	Must be <= Patients_Collected
	PATIENTS_ANALYZED	Incomplete Requested	CAUTION	Requested field is NULL
	PATIENTS_COLLECTED	Incomplete Requested	CAUTION	Requested field is NULL
PUBLICATIONS	MEDLINE_UID***	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	JOURNAL***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	JOURNAL	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	PAGES***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	PAGES	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	PUBLISHER***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	PUBLISHER	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	TITLE***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	TITLE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	VOLUME***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	VOLUME	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	YEAR***	Incomplete Requested	CAUTION	Requested when Medline_UID is NULL
	YEAR	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
AUTHORS	FNAME	Incomplete Requested	CAUTION	Requested field is NULL
	FNAME	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	LNAME	Incomplete Requested	CAUTION	Requested field is NULL

*** Rule was added or modified since Version 1.2 of the CDUS.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	LNAME	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
PATIENTS	BASELINE_PS_CODE	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	BIRTH_DATE	Inappropriate Requested	CAUTION	Patient age must be <= 100 at Date_of_Entry
	BIRTH_DATE	Inappropriate Requested	REJECTION	Must be <= Date_of_Entry
	BIRTH_DATE	Incomplete Requested	CAUTION	Requested field is NULL
	BIRTH_DATE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= Subm_Date
	DATE_OF_ENTRY	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	DISEASE_CODE***	Incomplete Mandatory	REJECTION	Mandatory when it is a Phase 1 trial with a DCTD supplied investigational agent
	DISEASE_CODE***	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	ELIGIBILITY_STATUS	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	GENDER_CODE***	Incomplete Requested	CAUTION	Requested field is NULL
	GENDER_CODE***	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	METHOD_OF_PAYMENT	Incomplete Requested	CAUTION	Requested field is NULL
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Mandatory when TX_On_Study = 2
	OFF_TX_REASON	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	PRIOR_CHEMO_REGS	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	PRIOR_CHEMO_REGS	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	RACE_CODE***	Incomplete Requested	CAUTION	Requested field is NULL
	RACE_CODE***	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	REG_GROUP_ID	Inappropriate Mandatory	REJECTION	Must be participant on protocol
	REG_GROUP_ID	Incomplete Mandatory	REJECTION	Mandatory for intergroup trials
	REG_GROUP_ID	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	REG_INST_ID	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	REG_INST_ID***	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	RESP_EVAL_STATUS	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	SUBGROUP_CODE	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	SUBGROUP_CODE	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	TX_ON_STUDY	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring

*** Rule was added or modified since Version 1.2 of the CDUS.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	ZIP_CODE	Incomplete Requested	CAUTION	Requested when Country_Code = 'US'
	ZIP_CODE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
PRIOR_THERAPIES	THERAPY_CODE	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
TREATMENT_COURSES	COURSE_START_DATE	Inappropriate Requested	REJECTION	Must be >= Date_of_Entry
	COURSE_START_DATE	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	COURSE_START_DATE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	HEIGHT	Inappropriate Requested	CAUTION	Must be >= 25cm and <= 200cm
	HEIGHT	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	HEIGHT	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	TOX_EXPERIENCED	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	TOX_EXPERIENCED	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	TREATING_INST_ID	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	TREATING_INST_ID	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	TX_ASGNMT_CODE	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to complete CDUS monitoring
	TX_ASGNMT_CODE	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
	WEIGHT	Inappropriate Requested	CAUTION	Must be >= 3kg and <= 120kg
	WEIGHT	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	WEIGHT	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
COURSE_AGENTS	DOSE_AMOUNT	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	DOSE_AMOUNT	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	DOSE_CHANGE	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	DOSE_CHANGE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
	UNIT_CODE	Incomplete Requested	CAUTION	Requested when the study has been assigned to complete CDUS monitoring
	UNIT_CODE	Inconsistent Requested	CAUTION	Requested data not consistent with previous value
TOXIC_EVENTS	AER_FILED	Incomplete Mandatory	REJECTION	Mandatory when Tox_Experienced = 1
	TOX_ATTRIBUTION_CODE	Incomplete Mandatory	REJECTION	Mandatory when Tox_Experienced = 1
	TOX_ATTRIBUTION_CODE	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
BEST_RESPONSES	CATEGORY	Inappropriate Mandatory	REJECTION	Value may not decline, except to Progression
	CATEGORY	Incomplete Mandatory	REJECTION	Mandatory when Patient Resp_Eval_Status = 1

*** Rule was added or modified since Version 1.2 of the CDUS.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	OBSERVED_DATE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	OBSERVED_DATE***	Incomplete Mandatory	REJECTION	Mandatory when Off_TX_Reason = 02
	OBSERVED_DATE	Inconsistent Mandatory	WARNING	Mandatory data not consistent with previous value
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

*** Rule was added or modified since Version 1.2 of the CDUS.

APPENDIX A: CDUS DATA ELEMENT/VALID VALUES MAPPING

The following table maps each Table/Column combination with the data element description provided in Section 2of this document.

Table/Column Name		Section Number from the Data Elements Section (Section 2)
AUTHORS	Author_Name	2.1.2.1.2.1.
	Author_Order	2.1.2.1.2.1.
	Protocol_ID	2.1.1.1.
	Publication_ID	2.1.2.1.
BEST_RESPONSES	Category	2.2.4.1.1.
	Observed_Date	2.2.4.1.2.
	Patient_ID	2.2.1.1.
	Protocol_ID	2.1.1.1.
COLLECTIONS	Change_Code	2.1.1.7.
	Completer_Email	2.1.1.6.4.
	Completer_FAX	2.1.1.6.3.
	Completer_Name	2.1.1.6.1.
	Completer_Phone	2.1.1.6.2.
	Current_Trial_Status_Code	2.1.1.5.
	CutOff_Date	2.1.1.3.2.
	Protocol_ID	2.1.1.1.
	Subm_Date	2.1.1.3.1.
CORRELATIVE_STUDIES	Correlative_Study_ID	2.1.5.1.
	Findings	2.1.5.3.3.
	Patients_Analyzed	2.1.5.3.2.
	Patients_Collected	2.1.5.3.1.
	Protocol_ID	2.1.1.1.
	Title	2.1.5.2.
COURSE_AGENTS	Agent_ID	2.2.3.8.1.
	Course_ID	2.2.3.1.
	Dose_Amount	2.2.3.8.1.2.
	Dose_Change	2.2.3.8.1.1.
	Patient_ID	2.2.1.1.
	Protocol_ID	2.1.1.1.
	Unit_Code	2.2.3.8.1.3.
PATIENTS	Baseline_PS_Code	2.2.2.2.3.
	Birth_Date	2.2.1.4.
	Country_Code	2.2.1.3.
	Date_Of_Entry	2.2.1.8.
	Disease_Code	2.2.2.2.4.3.
	Eligibility_Status	2.2.2.2.2.
	Gender_Code	2.2.1.5.
	Method_Of_Payment	2.2.1.7.

Table/Column Name		Section Number from the Data Elements Section (Section 2)
PATIENTS (cont.)	Off_TX_Reason	2.2.2.1.2.
	Patient_ID	2.2.1.1.
	Prior_Chemo_Regs	2.2.2.2.4.2.
	Protocol_ID	2.1.1.1.
	Race_Code	2.2.1.6.
	Reg_Group_ID	2.2.1.10.
	Reg_Inst_ID	2.2.1.9.
	Resp_Eval_Status	2.2.4.1.
	Subgroup_Code	2.2.2.2.1.
	TX_On_Study	2.2.2.1.1.
	Zip_Code	2.2.1.2.
PHASE1_END_POINTS	Protocol_ID	2.1.1.1.
	Subgroup_Code	2.1.4.1.
	TX_Asgnmt_Code	2.1.4.1.1.
PHASE1_END_POINT_DLTS	Protocol_ID	2.1.1.1.
	Subgroup_Code	2.1.4.1.1.1.1.
	Tox_Type_Code	2.1.4.1.1.1.2.
	TX_Asgnmt_Code	2.1.4.1.1.1.3.
PRIOR_THERAPIES	Patient_ID	2.2.1.1.
	Protocol_ID	2.1.1.1.
	Therapy_Code	2.2.2.2.4.1.
PUBLICATIONS	Journal	2.1.2.1.2.3.
	MedLine UID	2.1.2.1.1.
	Pages	2.1.2.1.2.7.
	Protocol_ID	2.1.1.1.
	Publication_ID	2.1.2.1.
	Publisher	2.1.2.1.2.6.
	Title	2.1.2.1.2.2.
	Volume	2.1.2.1.2.4.
	Year	2.1.2.1.2.5.
TOXIC_EVENTS	AER_Filed	2.2.3.9.2.4.
	Course_ID	2.2.3.1.
	Patient_ID	2.2.1.1.
	Protocol_ID	2.1.1.1.
	Tox_Attribution_Code	2.2.3.9.2.3.
	Tox_Grade_Code	2.2.3.9.2.2.
	Tox_Type_Code	2.2.3.9.2.1.
TREATMENT_COURSES	Course_ID	2.2.3.1.
	Course_Start_Date	2.2.3.2.
	Height	2.2.3.5.
	Patient_ID	2.2.1.1.
	Protocol_ID	2.1.1.1.
	Tox_Experienced	2.2.3.9.1.
	Treating_Inst_ID	2.2.3.4.
	TX_Asgnmt_Code	2.2.3.3.
	Weight	2.2.3.6.

Table/Column Name		Section Number from the Data Elements Section (Section 2)
TRIAL_COMMENTS	Gen_Response_Comments	2.1.3.1.2.
	Gen_Tox_Comments	2.1.3.1.1.
	Protocol_ID	2.1.1.1.
	Subgroup_Code	2.1.1.13.1.
	TX_Asgnmt_Code	2.1.1.14.