Instructions and Guidelines

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CLINICAL DATA UPDATE SYSTEM (CDUS)

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CLINICAL DATA SYSTEM (CDS)***

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***The portal for the submission of data via the CDUS Web application was transitioned to NCICB in 2006. At that time, the name was updated to 'CDS'.

The contents of this document are appropriate for both types (Web or FTP) of data submissions.

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By Capital Technology Information Services, Inc.

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Questions and Comments:

If you have any questions or comments regarding the Clinical Data Update System (CDUS) or submitting your data to CTEP via the CTEP FTP site, please contact the NCI CTEP Help Desk by telephone (301) 840-8202 or toll free 1-888-283-7457, fax (301) 948-2242, or e-mail at ncictephelp@ctep.nci.nih.gov

If you submit your data to CTEP via the CDS web application, please send any queries to: NCICB Application Support Desk by telephone (301) 451-4384 or toll free 1-888-478-4423, or e-mail at ncicb@pop.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 NCI 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 CTEP-sponsored 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 Section1.3, "What Data Should be Submitted," for further details).

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

1.2. WHO SHOULD SUBMIT DATA

Group/Institution Trials:

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

Inter-Group/Multi-Institution Trials:

The Lead Group or the Lead Institution for the protocol is responsible for compiling and submitting the 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, "Administrative," and Section 2.2.1, "Patient Demographic Items") or a Complete CDUS Data Set (containing all appropriate CDUS data elements) will be required. CTEP has grouped data elements into three categories: Mandatory, Requested, and Optional. Please refer to Section 9,

"CDUS Business Rules," for a complete listing of the business rules and 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 CTEP-sponsored investigational agent,
- 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,
- Current Protocol Status Date,
- Person Completing the Report,
  - Name: Last Name^First Name^Middle Initial,
  - Telephone Number,
  - Fax Number (optional),
  - E-mail Address (optional), and
- Change Code.

See Section 2.1.1, "Administrative," for descriptions of the administrative data elements.

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

- Patient ID,
- Patient Zip Code,
- Patient Country Code,
- Patient Birth Date,
- Patient Gender,
- Patient Ethnicity,
- Patient Method of Payment,

- Date of Patient Entry,
- Registering Group Code (all studies with Group participation),
- Registering Institution Code (mandatory as of April 1999),
- Patient Disease Code (mandatory as of July 2005), and
- PATIENT_RACES Table.

See Section 2.2.1, "Patient Demographic Items," for descriptions of the patient demographic data elements.

Note: When available, the submission of correlative study information as well as publication and author information is expected for CDUS-Abbreviated studies.

1.3.2. COMPLETE CDUS DATA SET

The Complete CDUS Data Set contains the information found in the Abbreviated CDUS Data Set in addition to patient administrative information (e.g., treating institution code, patient treatment status), treatment information (e.g., agent administered, total dose per course), adverse event information (e.g., AE type, grade), and response information (e.g., response observed, date response observed). In short, the Complete CDUS Data Set might include all data elements described in Section 2, "DATA ELEMENT DESCRIPTIONS."

Note: Data related to Phase 1 end points are only required to be submitted for Phase 1 trials. The end point should define either the recommended Phase 2 dose or the minimum effective dose, depending on protocol objectives.

The complete report should be submitted quarterly. Response data for all Phase 1 and Phase 2 trials should also be submitted on a quarterly basis.

Note: [1]Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from abbreviated to complete CDUS reporting requirements 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. This discretionary action applies to both CTEP and DCP studies.

1.3.3. TRIAL CATEGORIES

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

1.3.3.1. Treatment Trials that include CTEP-sponsored IND 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 CTEP-SPONSORED IND AGENTS

Early Phase 1 trials often require more intensive monitoring. Early Phase 1 trials will continue to be reported to CTEP using the Clinical Trials Monitoring Service (CTMS). CTEP will abstract the CDUS information subset from the CTMS data on a monthly 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 CTEP-SPONSORED IND 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.

1.3.3.1.3. PHASE 2 TRIALS THAT INCLUDE CTEP-SPONSORED IND 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 trials shall be submitted quarterly.

1.3.3.1.4. PHASE 3 TRIALS THAT INCLUDE CTEP-SPONSORED IND 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 CTEP-sponsored Phase 3 treatment trials.

1.3.3.2. Treatment Trials that do not include CTEP-sponsored IND 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 CTEP-sponsored IND agent (e.g., commercial agents or non-NCI IND agents).

NOTE: 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 and Response data 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 CTEP-sponsored IND agent (commercial agents or non-NCI IND agent).

Note: Consortium Study Guidelines

> Most consortium studies using a CTEP IND agent should submit a CDUS-Complete data set.
>
> If the consortium study does not use a CTEP IND agent, reporting requirements will generally be CDUS-Abbreviated.

NOTE: 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 and response data should be reported as per protocol guidelines.

1.3.3.2.2.2. Non-Group (Cancer Center or other Institution) Trials that do not include a CTEP-sponsored IND agent or 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.

NOTE: The NCI may choose to "upgrade" a Phase 1 or 2 treatment study from Abbreviated to Complete CDUS Data Set reporting requirements 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.

1.3.3.5. Tissue Banking Studies or Archived Studies

All tissue banking studies (archived studies) are required to submit, at a minimum, the current trial status and the current trial status date quarterly.

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

Study Type	DCP	DCTD Non-Treatment[1]	DCTD Treatment NCI Agent[2]	DCTD Treatment Non-NCI Agent[3]
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 CTEP-sponsored IND 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] 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.
[2] CTMS-monitored Phase 1 trials should continue to be reported to CTEP using the CTMS system; these trials will not require additional CDUS reporting.
[3] Please note that the NCI may choose to "upgrade" a Phase 1 or 2 treatment study from abbreviated to complete CDUS reporting requirements 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.

1.3.3.6. Phase '0' Studies

As of 2006, CTEP has approved Phase 0 studies. These are clinical studies, usually taking place before traditional Phase 1 development, that involve limited dosing (less than 7 days and non-recurring) of an investigational agent to determine the pharmacokinetic, pharmacodynamic, imaging, or other non-toxicology properties of the agent. The trial is usually performed under an exploratory IND application. CTEP will define the types of data required at the time of the study approval.

1.4. When Data Should be Submitted

1.4.1. Frequency

CDUS reports must be submitted on a quarterly basis. CDUS reports are due by Jan. 31, Apr. 30, Jul. 31 and Oct. 31. These dates are referred to as the Due Date for the quarter. **Efforts should be made to have files successfully loaded within two weeks of this due date**. 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). These dates are referred to as the Cut-Off Dates for the quarters. **The first CDUS submission is due the quarter after the protocol has been approved by the NCI.**

1.4.2. First CDUS Submission Date

Guideline:

Date of NCI Approval Notice	First CDUS Report	Reporting Schedule (Range)
Dec. 1 to Feb. 28 (29)	Apr. 30	January through March
Mar. 1 to May 31	Jul. 31	April through June
Jun. 1 to Aug. 31	Oct. 31	July through September
Sept. 1 to Nov. 30	Jan. 31	October through December

1.4.3. Submission Duration

CDUS submissions are required for all approved NCI studies until they reach a status of 'complete' or 'administratively complete' (see Section 2.1.1.5, "Current Trial Status," for a complete description of protocol statuses).

CTEP defines the term *complete* as follows: The protocol has been closed to accrual, all patients have completed therapy, and the study has met its primary objectives. A study report/publication 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 and treatment but the primary objectives have not been met, or if a protocol has been approved but has not yet been activated. Once you have submitted all updated

patient data for a protocol (with a current trial status of 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 2.1.1.8, "Additions or Changes Since the Last Report (Change Code)"] should be 'No.' The final CDUS submission for a given protocol should have a status of 'complete' or 'administratively complete.' No further CDUS submissions are required once the protocol has a status of either complete or administratively complete and all updated patient data has been submitted to CTEP.

If for some reason a study has a status of 'complete' 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 had a status of 'complete' 10 years ago and all records have been archived) then you may 'administratively complete' the protocol.

CTEP defines the term *administratively complete* as follows: 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 File Transfer Protocol (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 4 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 person at 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, 1-888-283-7457, fax (301) 948-2242, or e-mail at ncictephelp@ctep.nci.nih.gov.

NOTE: Due to patient privacy rights, the sharing of account information is forbidden by CTEP.

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.

Once the protocol has CTEP approval, the NCI CTEP Help Desk will initially contact the investigator to establish a Web-based user account and set up the system to enable data entry. To request any further change to an existing web account, establish a new web account or request assistance for web-application related concerns, please contact the NCICB Application Support Help Desk by telephone (301) 451-4384 or 1-888-478-4423, or e-mail at ncicb@pop.nci.nih.gov

Internet Explorer 6.0 and above or Netscape 7.1 and above are recommended to access this secured Web application.

Note: The CDUS Web-based application has **NOT** been tested to support MAC or Apple computers.

NOTE: Due to patient privacy rights, the sharing of account information is forbidden by CTEP.

1.6. PROTOCOL CODE INFORMATION

The Protocol Submission Worksheet (PSW) is available to assign codes to specific parameters within a clinical study. Studies that include Subgroups, Treatment Assignments, and/or Correlative Studies 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). Generally CTEP supplies the codes for Subgroups, Treatment Assignments, and/or Correlative Studies; however, the PSW is available for investigators to propose code assignments and descriptions for these code assignments, if preferred. CTEP-assigned codes are submitted to the investigator both at protocol approval (provided in the Coding Letter) and also quarterly with the CDUS *List of Expected Protocols*. It is suggested that the coding letter be reviewed for accuracy prior to activating a study. If there are inaccuracies with the information contained in the coding letter, contact the CTEP PIO at PIO@ctep.nci.nih.gov to correct.

The PSW can be found on the Forms page of the CTEP Home Page.

1.6.1. EMBEDDED 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 CTEP-sponsored IND 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 a Subgroup Identification Code such as 'SubgroupA' or 'Subgroup1'

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 another Classification (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)

Please see the *Treatment Assignment Instructions and Guidelines* available from the CTEP Home Page for a full description of Treatment Assignment Codes (TAC) and Treatment Assignment Descriptions (TAD) (see Section 2.1.2.3) for additional information).

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 some of the data elements identified below**.** CTEP will also abstract some of these items from the original protocol document.

2.1. GENERAL SUMMARY INFORMATION

2.1.1. ADMINISTRATIVE

2.1.1.1. NCI Protocol Number

This is the number assigned to the study (protocol) by the NCI. Inter-Group protocols should use the lead group's assigned number.

Note: Local institution study 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 TO CDUS

Enter today's date (format: YYYYMMDD).

2.1.1.3.2. CUT-OFF DATE FOR CDUS DATA

The most recent date for which any data were used in compiling results (format: YYYYMMDD). This date should reflect the latest date for which information is known. For example, if it is known on March 31 that all data reported are complete for the next quarter, then March 31 would be the Cut-Off Date. However, if this information can only be confirmed as of one week prior to the end of the quarter (March 24), then the date provided would be the March 24.

2.1.1.3.3. CDUS REPORT DUE DATE

The first reporting due date is supplied by CTEP with the Notice of Protocol Approval. Reports are due on the last day of each quarter until the trial has a status of 'Complete' or 'Administratively Complete.' The due dates are January 31, April 30, July 31, and October 31 of each year.

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

2.1.1.3.4. PROTOCOL ACTIVATION DATE

The protocol activation date is the date the trial was opened to accrual.

2.1.1.4. Lead Institution/Group Code (CTEP ID)

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

2.1.1.5. Current Trial Status

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

AP *Approved* - Trial has official CTEP approval.

AC *Active* - Trial is open to accrual.

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 *Complete* - 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 has been submitted to CTEP[4].

AD *Administratively Complete* - 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. Current Trial Status Date

Provide the date that the current trial status became effective. For example, if the current status is active, and the trial became active on January 15, 2006, then 20060115 (format: YYYYMMDD) should be submitted as the current trial status date.

To assist in determining the current trial status and the current trial status date, CTEP includes this information with each site's quarterly CDUS *List of Expected Protocols*. These can be located under the column titles 'Status Code' and 'Status Date.'

2.1.1.7. Person Completing the Report

2.1.1.7.1. NAME

[4] Contact the CTEP Protocol and Information Office (PIO) at (301) 496-1367 or by e-mail at pio@ctep.nci.nih.gov for final study report requirements.

Note: Investigators may potentially be required to provide data elements described in Section 2. A description of the data sets required for submission is found in Section 1.3.

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.

2.1.1.7.2. TELEPHONE NUMBER

Telephone number where the person completing the report may 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.

2.1.1.7.3. FAX NUMBER (OPTIONAL)

Submit a Fax number where the person completing the report may be reached. All Fax numbers should comply with the ASTM/NAN/CCITT format (see Section 2.1.1.7.2, “Telephone Number”).

2.1.1.7.4. E-MAIL ADDRESS (OPTIONAL)

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

Note: Although this is an optional field, every effort should be made to submit this data as it has proven to be the most efficient way for CTEP to communicate with you.

2.1.1.8. 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? Enter '1' (Yes) or '2 ' (No). If 'Yes' is entered, then submit all available data to CTEP. If 'No' is entered, then only General Summary; Administrative data is required. When submitting data on a protocol for the first time, the response should be '1' (Yes).

Note: Please remember that even with the submission of Change Code = 2, the CDUS Business Rules will fire for any data that might be included in your submitted file.

Note: With the implementation of the AdEERS/CDUS Reconciliation Module in April 2006, all AdEERS adverse events will be checked against all CDUS adverse events that are in the CTEP database for discrepancies.

2.1.1.9. Principal Investigator

Provided by CTEP. Abstracted from the protocol document.

2.1.1.9.1. NAME

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

2.1.1.9.2. INVESTIGATOR NUMBER

Principal Investigator's NCI Investigator Number.

2.1.1.10. Funding Information

Provide to CTEP any funding or grant information using the Protocol Submission Worksheet (PSW), if applicable. See Section 1.6 for more information on the PSW.

2.1.1.11. Total Accrual

2.1.1.11.1. Total Planned Accrual

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

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

2.1.1.11.2. 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 from the protocol amendment at the time of amendment approval.

2.1.1.11.3. Actual Accrual

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

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

2.1.1.12. Accrual Rate (patients/month)

2.1.1.12.1. 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 from the protocol document at the time of protocol approval.

2.1.1.12.2. 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 from the protocol amendment at the time of amendment approval.

2.1.1.12.3. Actual Accrual Rate

A system calculation based on the total number of patients accrued to date on the study as reported by the lead Group or lead Institution divided by the total number of months the study has the status of Active in the CTEP database.

The CDUS uses data from the Actual Accrual (see Section 2.1.1.11.3) to make this calculation.

2.1.1.13. Closure Date

2.1.1.13.1. PLANNED CLOSURE DATE

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 from the protocol document at the time of protocol approval.

2.1.1.13.2. 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 from the protocol amendment at the time of amendment approval.

2.1.1.13.3. 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).

2.1.2. SUBGROUPS/TREATMENT ASSIGNMENTS

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

A treatment assignment is a unique treatment characteristic that will be used 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.

Subgroup and Treatment Assignment Codes (TACs) may be submitted using the Protocol Submission Worksheet (PSW). See Section 1.6 for more information on the PSW.

2.1.2.1. Subgroup Code

Each subgroup should have a unique code for identification. The investigator may provide a code (up to 10 characters) for each subgroup with the PSW. CTEP will ab-

stract the subgroup code(s) from the PSW. If a protocol has only one subgroup then CTEP suggests using a Subgroup code such as 'SubgroupA' or 'Subgroup1'.

2.1.2.2. Subgroup Description

2.1.2.2.1. PATIENTS STRATIFIED BY DISEASE

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

2.1.2.2.2. 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 PSW. Based on investigator input, CTEP will abstract the patient characteristics for each subgroup from the PSW.

2.1.2.3. Treatment Assignment (arm/dose level)

Please see the Treatment Assignment Instructions and Guidelines available from the CTEP Home Page for a full description of Treatment Assignment Codes (TAC) and Treatment Assignment Descriptions (TAD).

Because the CDUS Smart Loader will only accept pre-defined TACs, a failure to pro vide CTEP with enough advance notification will result in rejection of the entire CDUS data set. Notification is achieved by sending a Treatment Assignment request to the Protocol and Information Office (PIO) via e-mail at pio@ctep.nci.nih.gov.

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

2.1.3. CORRELATIVE STUDIES

Correlative studies are laboratory, pharmacokinetic or other analyses embedded within the primary protocol. A separate entry should be made for each correlative study. Correlative study titles and codes may be provided by investigators with the Protocol Submission Worksheet (PSW). A separate correlative study should be defined for each analysis.

Note: The reporting requirements for correlative study information include protocols assigned to both CDUS-Abbreviated and to CDUS-Complete reporting. See Section 1.6 for more information on the PSW.

2.1.3.1. Correlative Study Identification (ID)

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

2.1.3.2. Correlative Study Title (laboratory, pharmacokinetic or other correlative studies)

Correlative study(s) titles may be provided by investigators with the PSW. CTEP will abstract the correlative study title from the protocol.

2.1.3.3. Correlative Study Findings

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

2.1.3.3.1. PATIENTS COLLECTED

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

2.1.3.3.2. PATIENTS ANALYZED

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

2.1.3.3.3. SAMPLES COLLECTED

The number of samples gathered across patients. For example, if three samples were collected for six patients on the correlative study, then 18 samples would be reported.

2.1.3.3.4. SAMPLES ANALYZED

The number of samples analyzed across patients.

2.1.3.3.5. CORRELATIVE STUDY FINDINGS OR CONCLUSIONS

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

2.1.4. PHASE 1 END POINTS AND PHASE 1 END POINT DLTS

Depending on protocol objectives, the Phase 1 end points reporting includes either the recommended Phase 2 dose or the minimum effective dose. This information is mandatory for Phase 1 studies assigned to CDUS Complete reporting. This information is not required for other studies.

2.1.4.1. Subgroup Code

Please use the appropriate code (see Section 2.1.2.1, “Subgroup Code”) for designating each subgroup. A separate entry should be made for each subgroup. If a protocol has only one subgroup, CTEP suggests using a Subgroup code such as 'SubgroupA’ or ‘Subgroup1’.

2.1.4.2. Recommended Phase 2 Dose or Minimum Effective Dose

If known, provide the TAC [see Section 2.1.2.3, “Treatment Assignment (arm/dose level)”] for the recommended Phase 2 dose or minimum effective dose for each subgroup as applicable. Determination of the recommended Phase 2 dose or minimum ef-effective dose should be based on protocol criteria.

2.1.4.2.1. DOSE LIMITING TOXICITY (DLT)

2.1.4.2.1.1. Subgroup

Select the appropriate code (see Section 2.1.2.1, “Subgroup Code”) this patient was entered on. CTEP suggests coding patients enrolled on a protocol with a single subgroup with a Subgroup code such as 'SubgroupA’ or Subgroup1’.

2.1.4.2.1.2. Treatment Assignment

Select the appropriate code (see Section 2.1.2.3, “Treatment Assignment (arm/dose level)”) for the patient’s treatment assignment for 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 with a Treatment Assignment Code such as 'TAC1’ or TACA’.

2.1.4.2.1.3. DLT Type

If known, select the appropriate Adverse Event term (NCI Common Terminology Criteria for Adverse Events—CTCAEv3.0) or (NCI Common Toxicity Criteria---CTCv2.0). See the CTEP Home Page for the list of terms for identification of the dose limiting toxicity(s). Determination of dose limiting Adverse Events should be based on protocol criteria. More than one DLT may be entered.

Note: Either CTCv2.0 or CTCAEv3.0 will be used to identify and submit the Adverse Event(s) depending on the assignment made to the protocol by CTEP. Only values available from the CTCv2.0 will be accepted for protocols assigned to CTCv2.0 and only values available from the CTCAEv3.0 will be accepted for protocols assigned to CTCAEv3.0.

2.1.4.2.1.4. DLT (Adverse Event) Other, Specify

Using either the NCI Common Terminology Criteria for Adverse Events (CTCAE v3.0) or the NCI Common Toxicity Criteria (CTC v2.0), provide the specific DLT in the AE_Other_Specify field when 'Other, Specify' is selected from the AE_Type_Code field. See Section 2.2.3.9.2.3 ,” for additional coding details and the two options for submitting AE_Other_Specify).

Note: Other, Specify should only be used if there is not an appropriate CTC or CTCAE term for the event. CTEP must approve uses of the ‘Other, Specify’ free-text field.

2.1.5. General Data Summary by Subgroup and/or Treatment Assignment (Trial Comments)

The General Data Summary by subgroup and/or treatment assignment is optional for trials assigned to CDUS- Complete reporting (e.g., Phase 1 and 2 trials with CTEP-sponsored IND agents), This information is not required for other studies.

2.1.5.1. Subgroup/Treatment Assignment Code

Please use the appropriate code [see Section 2.1.2.1, "Subgroup Code," and Section 2.1.2.3, "Treatment Assignment (arm/dose level)"] 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.

2.1.5.1.1. Adverse Event/Dose Modifications by Subgroup and/or Treatment Assignment

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

2.1.5.1.2. 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).

2.1.6. Publications

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

2.1.6.1. 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.).

2.1.6.1.1. Citation Identification (MedLine UID)

Specify the National Library of Medicine (NLM) Citation Unique Identifier (MedLine UID). The MedLine UID is a unique 8-character, alphanumeric code supplied for every publication included in MedLine. Entry of the MedLine UID eliminates the requested entry of the data elements that follow (Sections 2.1.6.1.2.1 through 2.1.6.1.2.7).

OR

2.1.6.1.2. Full Citation

2.1.6.1.2.1. Author Order and Name

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

2.1.6.1.2.2. Title

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

2.1.6.1.2.3. Journal

Enter the name of the journal where the article appears.

2.1.6.1.2.4. Volume

Enter the volume number of the journal.

2.1.6.1.2.5. Year

Enter the year that the journal was published.

2.1.6.1.2.6. Publisher

Enter the name of the publisher who produced the journal.

2.1.6.1.2.7. Pages

Enter the first and last page numbers of the article.

2.2. PATIENT-SPECIFIC DATA

2.2.1. PATIENT DEMOGRAPHIC ITEMS

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

2.2.1.1. Patient Study ID

Enter the code that uniquely identifies the patient to this protocol. This unique code or ID was assigned when the patient was registered on the study.

Note: All correspondence (e.g., an Expedited Adverse Event Report) 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 Zip Code

For U.S. residents - Enter the patient's home (residence) 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.

2.2.1.3. Patient 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.

Note: Either Zip code (if U.S resident) or country code (if not U.S resident) is mandatory.

2.2.1.4. Patient Birth Date

Enter the year and month of the patient's birth (format: 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 Gender

Enter the appropriate code:

1 = Male

2 = Female

9 = Unknown

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

2.2.1.6. Patient Race and Ethnicity

All NCI-sponsored trials must comply with the race and ethnicity reporting requirement guidelines set forth by the Health and Human Services, Office of Management and Budget. The guidelines are as follows:

- The ability to classify patients under more than one racial category,
- The separation of patient race and patient ethnicity into two data elements

2.2.1.6.1. ETHNICITY FLAG

Provide the patient's ethnicity using the code and descriptions below. The Ethnicity_Flag is used to identify patients with Hispanic or Latino culture or origin, defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. It does not permit a multiple response that would indicate an ethnic heritage that is both Hispanic/Latino and not Hispanic/Latino.

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

2 = Not Hispanic or Latino: A person NOT meeting the definition for Hispanic or Latino.

8 = Not Reported: Patient refused or data not available

9 = Unknown: Patient is unsure of their ethnicity

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

Patient ethnicity data is collected through the PATIENTS table (see 4.3.5 for table information).

2.2.1.6.2. RACE CODE

Provide the patient's race using the code and descriptions below. More than one race code may be used to classify patients who are multiracial. For example, a person of European and Chinese origins will be classified as '01' (White) and '05' (Asian).

01 = White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

03 = Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

04 = Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

05 = Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

06 = American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

98 = Not Reported: Patient refused or data not available

99 = Unknown: Patient is unsure of their race

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

Patient race data is collected through the PATIENT_RACES table (see 4.3.6 for table information).

2.2.1.7. Patient Method of Payment

For U.S. residents, report the patient's primary method of payment using the codes listed below. Do not select a value for Non-U.S. residents.

1 = Private Insurance

2 = Medicare

3 = Medicare and Private Insurance

4 = Medicaid

5 = Medicaid and Medicare

6 = Military or Veterans Sponsored, Not Otherwise Specified (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

Note: If the patient uses two payment methods and cannot determine which one is the primary, report one method through the Method_of_Payment field, report the second method through the TRIAL_COMMENTS table.

2.2.1.8. Date of Patient Entry

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

2.2.1.9. Registering Group Code

Enter the unique CTEP Group code where the patient was originally registered on study. All trials with Group participation are requested to provide the Group Code regardless of whether the study is classified as an Intergroup trial or not. For example, if the lead organization is an institution, but a Cooperative Group is a participant, CTEP requests that the Registering Group information be submitted. If unsure of the CTEP Group code, please check the CTEP Home Page.

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

Assign to 'CTSU' if:

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

Assign to the appropriate Cooperative Group if:

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

Assign to 'Other' if:

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

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

2.2.1.10. Registering Institution Code

Refer to the CTEP Web site for Institution names and codes or for assistance in determining the correct Registering Institution Code for patients registered outside the Lead Group on an Intergroup trial.

2.2.1.10.1. 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 on the CTEP Home Page. If an institution code still cannot be located, please contact the NCI CTEP Help Desk.

2.2.1.10.2. 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 or the CCOP component institution code.

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 Home Page. If an institution code still cannot be located, please contact the NCI CTEP Help Desk.

Note: It is expected that there would be just one registering institution code per patient per trial.

2.2.1.11. Disease Code

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

Note: If the patient's disease includes two primary cancer diagnoses, one should be reported through the Disease_Code field and the other cancer diagnosis should be reported through the TRIAL_COMMENTS table.

Note: As of 2005, Patient Disease Code is Mandatory for studies sponsored by CTEP and approved on or after 10/01/2004 regardless of CDUS-Complete or CDUS-Abbreviated method of monitoring.

2.2.2. PATIENT ADMINISTRATIVE ITEMS

Most patient administrative items are mandatory only for trials assigned to CDUS Complete reporting (e.g., Phase 1 and 2 trials with CTEP-sponsored IND agents) and are not required for other studies.

NOTE: The exception to this is the **PATIENT DISEASE** information. Patient Disease information is MANDATORY for any CTEP study approved on or after 10/01/2004 or for any study requesting to use the CTEP Simplified Disease Classification (SDC) regardless of the method of monitoring assigned.

Items such as Off Treatment Reason, Last Treatment Date, Off Study Reason, and Off Study Date are mandatory when applicable. Example, if the patient is still being treated, these items would not be applicable.

2.2.2.1. Treatment Status (Treatment On Study)

Is the patient currently receiving protocol treatment on-study? Enter '1' (Yes) or '2' (No).

2.2.2.2. 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 = Adverse Event/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 during active treatment].

Note: CTEP defines “active treatment” as any form of therapy identified in the schema of the protocol (e.g., surgery; radiation; commercial chemotherapy agents, investigational agents).

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

06 = Patient withdrawal/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 Adverse Event].

08 = Patient off-treatment for other complicating disease.

10 = Lost to follow-up.

11 = Cytogenetic resistance [the resistance to the treatment by the tissue or tumor due to a genetic trait in the patient].

12 = Disease progression before active treatment. Refer to value '04' (above) for the definition of "active treatment."

13 = No treatment, per protocol criteria.

98 = Other.

Note: If the Off Treatment Reason is 06, 12, or 13 above, CTEP expects no treatment data submitted.

2.2.2.3. Date of Last Treatment

If the patient is off protocol treatment, please provide the date of the patient's last treatment on their last treatment course. This date is mandatory when the patient is reported as being off protocol treatment (in YYYYMMDD format).

2.2.2.4. Off Study Reason

Provide the reason the patient went off-study using the following valid values:

01 = Protocol-defined follow-up completed

02 = Patient lost to follow-up

03 = Patient refused follow-up

04 = Death

05 = Adverse Event/Side Effects/Complications

98 = Other

2.2.2.5. Off Study Date

Provide the date that the patient went off study (in YYYYMMDD format).

2.2.2.6. Subgroups

Select the appropriate code (see Section 2.1.2.1, "Subgroup Code") for the subgroup this patient was entered on. Patients enrolled on a protocol with a single subgroup should be coded using a Subgroup code such as 'SubgroupA' or 'Subgroup1'.

2.2.2.7. Ineligibility Status

Has the patient been declared ineligible? Enter '1' (Yes), or '2' (No). Enter 'Yes' only if the patient has been declared *ineligible*.

Note: All patients registered on the study are considered eligible until determined to be ineligible. Patients who are registered on a study should not be removed from your CDUS reporting due to an ineligibility status.

2.2.2.8. 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.

TABLE C: Performance Status Criteria

ECOG (Zubrod)		Karnofsky		Lansky[5]	
Score	Description	Score[6]	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 self care 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 self care. 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.

2.2.2.9. Prior Therapy

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

Note: Investigators may potentially be required to provide data elements described in Section 2. A description of the data sets required for submission is found in Section 1.3.

2.2.2.9.1. NUMBER OF PRIOR CHEMOTHERAPY REGIMENS

If a patient has previously received a **chemotherapy** regimen, provide the number of 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. The total number should include a chemotherapy regimen that was discontinued for any reason (e.g., completion of therapy, Adverse Event, 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 here and must not be included in this number.

2.2.2.9.2. PRIOR THERAPY TYPE (MEDDRA 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 hormonal therapy). Use CTEP Terms and the codes listed in the Medical Dictional for Regulatory Activities (MedDRA) (see the CTEP Home Page for a list of therapy terms and MedDRA codes).

Anti-Retroviral Therapy: Agents administered to control the replication and/or spread of viruses (e.g., TAT therapy for HIV-1).

Antisense: Treatment with an agent that prevents or impairs the translation of the genetic message for production of a specific protein.

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).

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.

Chemotherapy Multiple 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 Non-Cytotoxic: Prior therapy with agents that are not known to cause damage to cycling cells (e.g., endostatin, mmpi, bevacizumad).

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.

Gene Transfer: Treatment of human disease by gene transfer.

Hematopoietic stem cell transplantation: The intravenous infusion of autologous or allogeneic stem cells collected from the bone marrow, peripheral blood, or um-

bilical cord blood to re establish hematopoietic function in patients with damaged or defective bone marrow or immune systems.

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

Image Directed Local Therapy: A technique whereby an imaging method is used to diagnose, localize and/or treat a carcinogenic lesion, for example, a breast lump. A non-palpable carcinoma may be diagnosed by image-directed biopsy or needle localization. Breast- conserving surgery can be conducted with pre surgical localization with a guide wire using a diagnostic imaging method.

Drug and/orImmunotherapy: 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).

No Prior Therapy: No previous exposure to drug (NOS).

Oncolytic Virotherapy: Anticancer treatment with a live, replication-competent virus.

Radiation Therapy: Targeted ionizing radiation therapy utilizing radioactive implants or seeds.

> Note: Per the MedDRAv9.0 codes, the *Radiation Therapy* term combines the following therapies:
>
> *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.

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

Therapy Not Otherwise Specified (NOS): A therapy used prior to this treatment for which none of these selections is appropriate. Cryotherapy, phototherapy

Vaccine: A substance or group of substances administered to induce the immune system to recognize and destroy tumors or microorganisms, which can be used for prevention, amelioration, or treatment of diseases.

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

TABLE D: MedDRA Codes for Prior Therapies

CTEP Term	MedDRA Preferred Term	MedDRA v9.0 Code**	MedDRA v10.0 Code*
Anti-Retroviral Therapy	Not Available	90003000	90003000
Antisense	Not Available	90003002	90003002
Bone Marrow Transplant	Bone Marrow Transplant NOS	10061730	10061730
Chemotherapy (NOS)	Chemotherapy (NOS)	10050693	10050693
Chemotherapy multiple agents systemic	Chemotherapy multiple agents systemic	10008452	10008452
Chemotherapy non-cytotoxic	Not Available	90003014	90003014
Chemotherapy single agent systemic	Chemotherapy single agent systemic	10008456	10008456
Drug and/or immunotherapy	Not Available	90003006	90003006
Gene Transfer	Gene Transfer	90003004	90003004
Hematopoietic stem cell transplantation		10063581	10063581
Hormonal Therapy	Steroid Therapy NOS	10065646	10065646
Image Directed local therapy		90003016	90003016
No prior therapy	No previous exposure to drug NOS	10052052	10052052
Oncolytic Virotherapy	Not Available	90003008	90003008
Prior Therapy (NOS)	Not Available	90003010	90003010
Radiation Therapy	Radiotherapy	10037770	10037770
Surgery	Operation NOS	10042609	10042609
Therapy (NOS)	Not Available	90003012	90003012
Vaccine	Prophylaxis NOS	10021430	10021430

In order to stay current with updated standards, CTEP intends to update the MedDRA codes annually for the July CDUS submission.

* MedDRA v10.0 codes became mandatory on 7/1/2007.

2.2.2.10. Patient Disease Code

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

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

Note: As of 2005, Patient Disease Code is Mandatory for studies sponsored by CTEP and approved on or after 10/01/2004 regardless of CDUS-Complete or CDUS-Abbreviated method of monitoring. Patient Disease Code is also mandatory for any CTEP study requesting to submit CTEP Simplified Disease Classification Codes regardless of approval date.

2.2.2.11. Response Evaluation Status

Based on the criteria specified within the protocol, determine if the patient is evaluable for a response (see Section 2.2.4, "Response of Patient's Malignancy," for additional information).

2.2.2.12. Baseline Abnormalities Flag

Indicate whether abnormalities were found during the patient's initial history and physical examination. Baseline abnormality information will provide CTEP with a baseline to use when analyzing treatment-related adverse events. The valid values for this field are '1' (Yes), '2' (No), and '9' (Unknown). Set the flag to '1' (Yes) if abnormalities were found during the patient's initial examination.

The following information must be submitted through the BASELINE_ABNORMALITIES table (see Section 4.3.10, "BASELINE_ABNORMALITIES Table") when this flag is set to '1' (Yes).

2.2.2.12.1. Baseline Abnormality Type, Grade, and Other, Specify

Report the Baseline Abnormality Type and Grade using either the NCI Common Terminology Criteria for Adverse Events (CTCAEv3.0) or the NCI Common Toxicity Criteria (CTCv2.0). Provide the specific adverse event in the AE_Other_Specify field when 'Other, Specify' is selected from the AE_Type_Code field. See Section 2.2.3.9.2.3, "Adverse Event. Other, Specify" for additional coding details and the two options for submitting AE_Other_Specify).

Notes to review:

- Baseline Abnormality is defined by CTEP as any abnormal assessment (e.g., physical finding, subjective complaint, or diagnostic test abnormality) identified as part of the routine pre-study work-up **for which a CTC/CTCAE term exists. Document an adverse event at baseline in the same manner as you would document an adverse event during a treatment cycle.**

- Either CTCv2.0 or CTCAEv3.0 will be used to identify and submit the adverse event(s) depending on the assignment made to the protocol by CTEP. Only values available from the CTCv2.0 will be accepted for protocols assigned to CTCv2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAEv3.0.

- Do not submit a patient's diagnosis and/or pre-existing condition as these are normally not CTC/CTCAE terms. These terms are currently being submitted inappropriately by using the Other, Specify mechanism. The Other, Specify option should only be used if there is not an appropriate adverse event term available. If there are any questions, please query the NCI CTEP Help Desk.

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. 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 CDUS-Complete reporting (e.g., Phase 1 and 2 trials with CTEP-sponsored IND agents), and is not required for other studies.

2.2.3.1. Course Identification

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. Use only numeric values to define the course; non-numeric values are not accepted. The course identification is to be numbered sequentially; the CDUS Smart Loader will validate that the course information is provided in chronological order. For example, the start date for course 2 should be later than the start date for course 1.

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

Course ID sequence for initial courses: 1, 2, 3, etc.
Course ID sequence for crossover courses: 101, 102, 103, etc.

2.2.3.2. Course Start Date

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

2.2.3.3. Treatment Assignment

Select the appropriate code [see Section 2.1.2, “SubGroups/Treatment Assignments” and Section 2.1.2.3, “Treatment Assignment (arm/dose level)”] 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 given a Treatment Assignment code such as 'TAC1’ or ‘TACA’.

2.2.3.3.1. PHASE 1 STUDIES

Provide a TAC 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 Protocol and Information Office (PIO) via e-mail at pio@ctep.nci.nih.gov. See Section 2.1.2.3, “Treatment Assignment (arm/dose level),” 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 on the CTEP Home Page. If an institution code cannot be located, please contact 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 of treatment. This includes CCOPs and CCOP components.

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 the CTEP Home Page. If an institution code cannot be located, please contact the NCI CTEP Help Desk.

2.2.3.5. Patient Height

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

2.2.3.6. Patient Weight

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

2.2.3.7. Patient Body Surface Area

Calculated by CTEP based on the patient's height (cm) and weight (kg).

2.2.3.8. Dose of the Investigational Agent Received by Patient

2.2.3.8.1. INVESTIGATIONAL AGENT ADMINISTERED

Use the NSC number of the CTEP-sponsored IND 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 CTEP-sponsored IND 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 dose was changed according to protocol guidelines)

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

3 = No

9 = Unknown

Note: 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 (using numbers) 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 (using the NSC number). This information may contain up to 20 digits of which three may be used for decimal places.

2.2.3.8.1.3. Dose Units

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

2.2.3.9. Patient-Specific Adverse Event Reporting Requirements

An Adverse Event is any unfavorable or 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 investigational agent(s)/intervention.

Routine adverse event reporting is mandatory for all studies assigned to CDUS-Complete reporting (e.g., Phase 1 and 2 trials that utilize a CTEP-sponsored investigational agent).

Note: Routine adverse event reporting via CDUS is not a substitute for the submission of an Expedited Adverse Event Expedited Report (AdEERS). All appropriate adverse events should also be reported via NCI's Adverse Event Expedited Reporting System (AdEERS) To assist in determining the appropriateness of reporting an adverse event, see CTEP, NCI Guidelines: Adverse Event Reporting Requirements Attachment A, available at http://ctep.cancerinfo.nih.gov/reporting/newadverse_2006.pdf..

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

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

To accommodate all reporting situations, the definition of 'No' is used to indicate that the patient did not experience any adverse events that are required to be reported via CDUS. For example, if during a course of treatment a patient only experienced a Grade 1 adverse event with an attribution of 'Unlikely,' then the AE_Experienced flag may be reported as 'No.' The site is not required to report the event.

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

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 NCI Common Terminology Criteria for Adverse Events (CTCAEv3.0) or the NCI Common Toxicity (CTCv2.0) select the appropriate term (see the CTEP Home Page for a list of CTC or CTCAE terms) for the adverse event the patient experienced during this treatment course. More than one adverse event may be entered.

Note: Either CTC v2.0 or CTCAEv3.0 will be used to identify and submit the adverse event(s) depending on the assignment made to the protocol by CTEP. Only values available from the CTCv2.0 will be accepted for protocols assigned to CTCv2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

2.2.3.9.2.2. Grade

Grade represents the severity of the adverse event.

Using the NCI Common Terminology Criteria for Adverse Events (CTCAEv3.0) or the NCI Common Toxicity (CTCv2.0), provide the highest grade for each adverse event experienced. Only the highest-grade of each adverse event type should be reported during a given course. For example, if a patient experiences a grade 1, grade 2, and grade 3 adverse event of Adverse Event Type 'X' during the same course, you would report just the grade 3 adverse event. If this same patient experiences a grade 4 adverse event of Adverse Event Type 'X' during a later course of treatment, you would submit both the grade 3 and the grade 4 as they occurred in different courses.

General definitions of the grading scale include:

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. Adverse Event. Other, Specify

Each category of the NCI Common Terminology Criteria for Adverse Events (CTCAEv3.0) and the Common Toxicity Criteria (CTC)v2.0) provides an 'Other, Specify' option for adverse events that are not listed in the available adverse event criteria (e.g., Gastrointestinal: Other, Specify; Blood/Bone Marrow: Other, Specify; etc.). You must provide the specific adverse event in the AE_Other_Specify field when 'Other, Specify' is selected from the AE_Type_Code field. For example, 'Hyperkeratosis' is not a CTC term but is a very specific dermatologic manifestation associated with the use of a specific class of new agents. In this case, 'DERMATOLOGY/SKIN, Other, Specify' is selected and 'Hyperkeratosis' is entered as the actual adverse event term. All categories of the CTCAE allow for such specificity when the appropriate term is not included in the CTCAE.

Note: For the same Protocol_ID, Patient_ID, Course_ID, AE_Type_Code, and AE_Grade_Code, if more than one adverse event was previously being designated using AE_Other_Specify, the events needed to be designated together using the free text field. Submitting the events separately would have generated a Duplicate Primary Key (R0017) error

For example:

Option 1

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

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

Option 2

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

Note: To adjust for this limitation (effective October 1, 2003), AE_Other_Specify became part of the Primary Key. This provides the option to either combining terms for the submission (Option 2) or submitting the items in separate records (Option 1) without generating a duplicate Primary Key error.

Note: "Other, Specify" should only be used if the appropriate term is NOT included in the CTCAE. All resources should be used in an attempt to avoid the selection of

'Other, Specify'. Use the CTC Index, Safety Profiler, or Other, Specify Guide to verify that there is no appropriate term available before selecting 'Other, Specify'.

2.2.3.9.2.4. Attribution

For routine, CDUS adverse event reporting purposes, "Attribution" defines the relationship between the adverse event and the investigational agent(s)/intervention.

> Note: When a commercial agent(s) is(are) used on the same treatment arm as an investigational agent/intervention (also, investigational drug, biologic, cellular product or other investigational experimental therapy under an IND), the entire combination (arm) is then considered an investigational intervention for reporting purposes in CDUS.

Assess the relationship between the adverse event and the investigational agent(s)/intervention. Then, from the list below, assign the appropriate category code of attribution. An attribution must be assigned to all reported adverse events.

TABLE E: Attribution of Adverse Events for CDUS Reporting

Code	Descriptor	Definition
1	Unrelated	The Adverse Event is clearly not related to the investigational agent(s)/intervention.
2	Unlikely	The Adverse Event is doubtfully related to the investigational agent(s)/intervention
3	Possible	The Adverse Event may be related to the investigational agent(s)/intervention
4	Probable	The Adverse Event is likely related to the investigational agent(s)/intervention
5	Definite	The Adverse Event is clearly related to the investigational agent(s)/intervention

2.2.3.9.2.5. Expedited Adverse Event Report (AER Filed)

Using the codes below, indicate whether an Expedited Adverse Event (AdEERS) report was submitted to CTEP (via the AdEERS application) for this specific adverse event.

1 = Yes

2 = No

9 = Unknown

2.2.3.9.2.6. CDUS Grade/Attribution Requirements

All Grade 1 and 2 adverse events with an attribution of possible, probable, definite must be reported to CDUS. All Grade 3, 4, and 5 adverse events, regardless of attribution, must be reported (see Table F).

TABLE F: Routine Adverse Event Reporting Guidelines for CDUS

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

Adverse event reporting is mandatory for all studies assigned to CDUS-Complete reporting (e.g., Phase 1 and 2 trials that have utilized a CTEP-sponsored IND agent). A complete description of the adverse reporting requirements for investigational agents is outlined in the *NCI Guidelines: Adverse Event Reporting Requirements for NCI Investigational Agents*, available from the CTEP Home Page.

2.2.3.10. Baseline Adverse Events

(See Section 2.2.2.12 for reporting Baseline Abnormalities.) An adverse event should NOT be reported if a patient is entered on a study with a preexisting condition (e.g., elevated laboratory value) as preexisting conditions are not considered adverse events. 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 experienced Grade 2 diarrhea, the adverse event should be re-assessed and reported if it fulfills adverse event reporting guidelines.

2.2.3.11. 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 recurs during a different course (cycle), must be reported each course (cycle) it recurs.

- 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

2.2.3.12. Late (Follow-Up) Adverse Event

Provide the following information when an adverse event is observed after a patient has completed treatment regardless of whether the event has been identified as part of a scheduled or an unscheduled follow-up.

Note: Because these adverse events are not associated with a particular treatment course, they cannot be collected through the ADVERSE_EVENTS table, which is linked to the TREATMENT_COURSES table. Under these circumstances, the adverse event is reported using the LATE_ADVERSE_EVENTS table (see Section 4.3.12, "LATE_ADVERSE_EVENTS Table," for table information).

2.2.3.12.1. Late (Follow-Up) Adverse Event Type, Grade, and Other, Specify

Report the Late (Follow-Up) Adverse Event Type and Grade by using the NCI Common Terminology Criteria for Adverse Events (CTCAEv3.0) or the Common Toxicity Criteria (CTCv2.0). Provide the specific adverse event in the AE_Other_Specify field when 'Other, Specify' is selected from the AE_Type_Code field (see Section 2.2.3.9.2.3 for additional coding details and two options for submitting AE_Other_Specify).

Note: Either CTCv2.0 or CTCAEv3.0 will be used to identify and submit the adverse event(s) depending on the assignment made to the protocol by CTEP. Only values available from the CTCv2.0 will be accepted for protocols assigned to CTCv2.0 and only values available from the CTCAE v3.0 will be accepted for protocols assigned to CTCAE v3.0.

Note: As with adverse events during the treatment phase, 'Other, Specify' should be used only if a valid adverse event term does not exist.

2.2.3.12.2. Attribution

Provide the determination of whether the Late (Follow-Up) adverse event is related to the investigational agent(s)/intervention. (See Section 2.2.3.9.2.4, "Attribution," for details).

2.2.3.12.3. Late (Follow-Up) Adverse Event Start Date

The Adverse Event Start Date is the date when a laboratory value, imaging, or other diagnostic measurement identifies the onset of an adverse event.

2.2.3.13. AdEERS/CDUS Reconciliation Process

2.2.3.13.1. PURPOSE

In an effort to ensure that the events reported to the Expedited Adverse Event Reporting System (AdEERS) and those reported to the Routine Reporting System (CDUS) were a match, CTEP implemented the AdEERS/CDUS Reconciliation Process on April 1, 2006. All matching of event data is based both on the investigator's submitted adverse events and on the reporting guidelines for both AdEERS and for CDUS.

2.2.3.13.2. REASONS FOR A DISCREPANCY

There are many items that might cause a discrepancy:

- Different Patient IDs in the two systems
- Different events/grades or attributions in the two systems
- The complete lack of a reported event in one of the systems

2.2.3.13.3. RESOLUTION

- CTEP defines the criteria for high priority discrepancy events. Discrepancies in these defined events will create a Rejection error and **MUST** be resolved before the end of the quarter.
- All other discrepancies are considered lower priority and result in a Caution error. CTEP expects that these will be reviewed by the submitting site and corrected.

2.2.4. RESPONSE OF PATIENT'S MALIGNANCY INCLUDE FREQUECY

Requested for trials assigned to Complete CDUS reporting, e.g., Phase 1 and 2 trials with CTEP-sponsored IND agents. It is not required for other studies.

2.2.4.1. Evaluable for Response

Based on the protocol criteria, indicate 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).

2.2.4.1.1. RESPONSE (CATEGORY)

If the patient is evaluable for a response, indicate the patient's response. All responses must be confirmed by protocol criteria before being reported. Use the following codes to identify each Response Category:

01 = Complete response

02 = Partial response

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

04 = Stable

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

05 = Progression

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

06 = Not assessed adequately

98 = Other

Notes:

Progression should be reported even if it is experienced after a response (e.g., Less than Partial Response, Partial response, Complete Response).

Protocols that do not use the traditional response criteria provided in the list of values (e.g., where the response is based on serum level changes of a particular factor) should submit the value of 'Other' to indicate a patient's response. If 'Other' is submitted, it is mandatory that information about the patient's response be submitted through the General Response Comments (see Section 2.1.5.1.2 and Section 4.3.14, "TRIAL_COMMENTS Table," for further information).

It is expected that the protocol guidelines will be followed in providing response data. Each time that the protocol defines that a response should be evaluated, then a response should be sent to CTEP via the CDUS submission. There has been some confusion over the fact that this table is called 'Best Response' possibly indicating that only one response per patient is required. CTEP evaluates all the responses that you provide for each patient. The submission of the response data at defined points in the treatment provides the complete data set that CTEP requires for analysis.

2.2.4.1.2. RESPONSE (OBSERVED DATE)

The Observed Date is mandatory for all responses submitted via CDUS-Complete, including Stable Disease or Progression. The Observed Date for each level of response is the initial date that the patient's disease was shown to have responded to

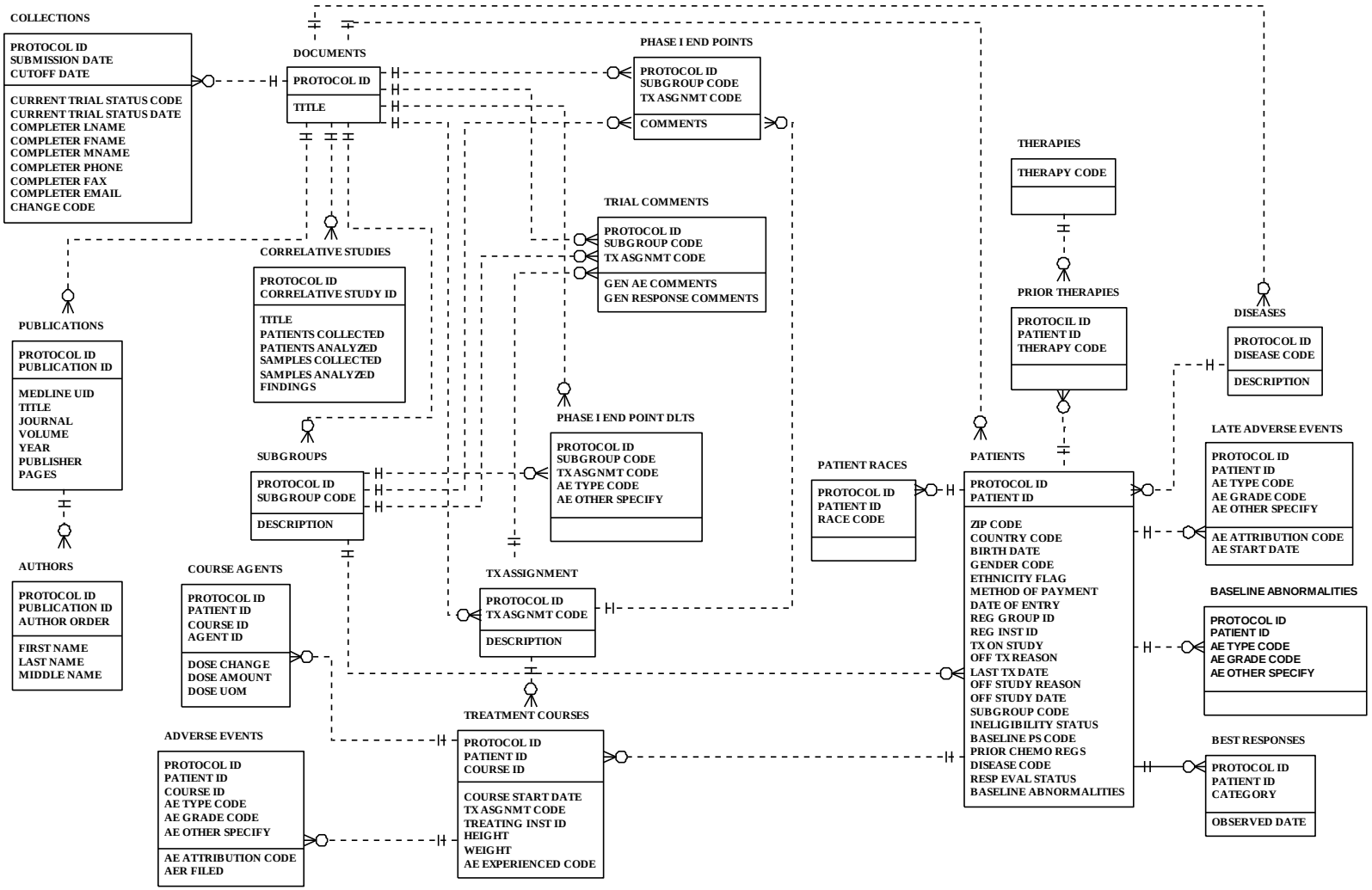
therapy sufficient to meet the protocol-specified criteria for that level of response. Note that the response should be confirmed as per protocol guidelines prior to reporting via CDUS [see Section 2.2.4.1.1, “Response (Category)”].

The Observed Date format is 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 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 Protocol Number_date (format: YYYYMMDD). For example, T95-0036_19980430.

The total number of characters in the file name including the file path must be ≤ 260.

Each text file will contain information for one Protocol only.

Each record associated with a Table in the 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[7] must be in YYYYMMDD format. Partial dates should not be submitted.

If a field is left null in a 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 none, one or many Correlative Studies associated with it.

One Protocol can have none, one or many Publications associated with it.

Every Publication can have one or many Authors.

One Protocol can have none, one or many Patients associated with it.

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

Every Patient can have one or more races.

Every Patient can have under gone multiple Prior Therapies.

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

Every Patient can undergo none, 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 for every Treatment Course for a Patient.

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

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

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

There can be multiple DLTs for every Subgroup.

4.3. FILE FORMAT

Data should be submitted for each of the following tables:

COLLECTIONS

CORRELATIVE_STUDIES

PUBLICATIONS

AUTHORS

PATIENTS

PATIENT_RACES

PRIOR_THERAPIES

TREATMENT_COURSES

COURSE_AGENTS

BASELINE_ABNORMALITIES

ADVERSE_EVENTS

LATE_ADVERSE_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 FILES.”

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)
Current_Trial_Status_Date	Date (YYYYMMDD)
Completer_Name[8]	Varchar2(87)
Completer_Phone	Varchar2(20)
Completer_FAX	Varchar2(20)
Completer_Email	Varchar2(50)
Change_Code	Varchar2(1)

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

"COLLECTIONS","<Protocol_ID>",<Subm_Date>,<CutOff_Date>,"<Current_Trial_Status_Code>",<Current_Trial_Status_Date>,"<Completer_Name>","<Completer_Phone>","<Completer_FAX>","<Completer_Email>","<Change_Code>"

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)
Samples_Collected	Number(6)
Samples_Analyzed	Number(6)
Findings	Varchar2(2000)

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

"CORRELATIVE_STUDIES","<Protocol_ID>","<Correlative_Study_ID>",<Patients_Collected>,<Patients_Analyzed>,<Samples_Collected>,<Samples_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)

[8] 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.

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[9]	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)
Ethnicity_Flag	Varchar2(1)
Method_Of_Payment	Varchar2(2)
Date_Of_Entry	Date (YYYYMMDD)
Reg_Group_ID	Varchar2(25)

[9] 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.

Reg_Inst_ID	Varchar2(25)
TX_On_Study	Varchar2(1)
Off_TX_Reason	Varchar2(2)
Last_TX_Date	Date (YYYYMMDD)
Off_Study_Reason	Varchar2(2)
Off_Study_Date	Date (YYYYMMDD
Subgroup_Code	Varchar2(10)
Ineligibility_Status	Varchar2(1)
Baseline_PS_Code	Varchar2(1)
Prior_Chemo_Regs	Number(2)
Disease_Code	Number(10)
Resp_Eval_Status	Varchar2(1)
Baseline_Abnormalities_Flag	Varchar2(1)

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

"PATIENTS","<Protocol_ID>","<Patient_ID>","<Zip_Code>","<Country_Code>",<Birth_Date>,"<Gender_Code>","<Ethnicity_Flag>","<Method_Of_Payment>",<Date_Of_Entry>,"<Reg_Group_ID>","<Reg_Inst_ID>","<TX_On_Study>","<Off_TX_Rea-
son>",<Last_TX_Date>,"<Off_Study_Reason",<Off_Study_Date>,"<Subgroup_Code>","<Ineligibility_Status>","<Baseline_PS_Code>",<Prior_Chemo_Regs>,<Disease_Code>,"<Resp_Eval_Status>","<Baseline_Abnormalities_Flag>"

4.3.6. PATIENT_RACES TABLE

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

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

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

"PATIENT_RACES","<Protocol_ID>","<Patient_ID>","<Race_Code>"

4.3.7. 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>

4.3.8. 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	*Number(6)*
Course_Start_Date	Date (YYYYMMDD)
TX_Asgnmt_Code	Varchar2(10)
Treating_Inst_ID	Varchar2(25)
Height	Number(6,1)
Weight	Number(6,1)
AE_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>,"<AE_Experienced>"

4.3.9. 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	*Number(6)*
Agent_ID	*Varchar2(8)*
Dose_Change	Varchar2(1)
Dose_Amount	Number(20,3)
Unit_Code	Varchar2(12)

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>"

4.3.10. BASELINE_ABNORMALITIES TABLE

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

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

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

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

4.3.11. ADVERSE_EVENTS TABLE

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

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

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

"ADVERSE_EVENTS","<Protocol_ID>","<Patient_ID>",<Course_ID>,<AE_Type_Code>,<AE_Grade_Code>,"<AE_Other_Specify>",<AE_Attribution_Code>,"<AER_Filed>"

4.3.12. LATE_ADVERSE_EVENTS TABLE

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

Protocol_ID	*Varchar2(35)*
Patient_ID	*Varchar2(20)*
AE_Type_Code	*Number(10)*

AE_Grade_Code	*Number(1)*
AE_Other_Specify	*Varchar2(100)*
AE_Attribution_Code	Number(1)
AE_Start_Date	Date (YYYYMMDD)

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

"LATE_ADVERSE_EVENTS","<Protocol_ID>","<Patient_ID>",<AE_Type_Code>,<AE_Grade_Code>,"<AE_Other_Specify>",<AE_Attribution_Code>,<AE_Start_Date>

4.3.13. 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>

4.3.14. 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_AE_Comments	Varchar2(2000)
Gen_Response_Comments	Varchar2(2000)

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

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

4.3.15. 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>"

4.3.16. 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_Code	*Varchar2(10)*
AE_Type_Code	*Number(10)*
AE_Other_Specify	*Varchar2(100)*

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>",<AE_Type_Code>,"<AE_Other_Specify>"

5. CDUS SMART LOADER SAMPLE FILES

5.1. CDUS SMART LOADER SAMPLE FILE---CDUS-ABBREVIATED

"COLLECTIONS","T95-0036",20070110,20061231,"AC",19961015,"Public^John^Q","(301)111-1212","(301)111-2323","public@med.com","1"
"CORRELATIVE_STUDIES","T95-0036","950036PK",40,40,80,70,"Study Findings"
"CORRELATIVE_STUDIES","T95-0036","950036QOL",40,35,70,60,"Study Findings"
"PUBLICATIONS","T95-0036",1,"","Effectiveness of Taxol plus Cisplatin","Journal of the American Medical Association","50",1997,"McGraw Hill","10-20"
"PUBLICATIONS","T95-0036",2, "99061487","","","",,"","",""
"AUTHORS","T95-0036",1,1,"CAREY^ROBERT^D"
"AUTHORS","T95-0036",1,2,"SMITH^JAMIE^M"
"PATIENTS","T95-0036","A5001","20595","",194206,"1","9","1",19961015,"NSABP","MD005","","",,"","",,"","",,12345678,"","",""
"PATIENTS","T95-0036","A5002","20595","",193608,"2","1","2",19961018,"NSABP","MD005","","",,"","",,"","",,12345678,"","",""
"PATIENTS","T95-0036","A5003","20595","",194010,"1","2","3",19961018,"NSABP","MD005","","",,"","",,"","",,12345678,"","",""
"PATIENT_RACES","T95-0036","A5001","01"
"PATIENT_RACES","T95-0036","A5002","01"
"PATIENT_RACES","T95-0036","A5002","03"
"PATIENT_RACES","T95-0036","A5003","03"

5.2. CDUS SMART LOADER SAMPLE FILE---CDUS-COMPLETE


```
"COLLECTIONS","T95-0036",19970110,19961231,"AC",19961015,"Public^John^Q","(301)111-1212","(301)111-2323","public@med.com","1"
"CORRELATIVE_STUDIES","T95-0036","950036PK",40,40,80,70,"Study Findings"
"CORRELATIVE_STUDIES","T95-0036","950036QOL",40,35,70,60,"Study Findings"
"PUBLICATIONS","T95-0036",1,"","Effectiveness of Taxol plus Cisplatin","Journal of the American Medical Association","50",1997,"McGraw Hill","10-20"
"PUBLICATIONS","T95-0036",2, "99061487","","","","","",""
"AUTHORS","T95-0036",1,1,"CAREY^ROBERT^D"
"AUTHORS","T95-0036",1,2,"SMITH^JAMIE^M"
"PATIENTS","T95-0036","A5001","20595","",194206,"1","9","1",19961015,"NSABP","MD005","1","",,"",,"SUBGROUP1","2","1",2,12345,"1","9"
"PATIENTS","T95-0036","A5002","20595","",193608,"2","1","2",19961018,"NSABP","MD005","2","02",19961105,"04",19980819,"SUBGROUP1","2","2",2,12345,"1","1"
"PATIENTS","T95-0036","A5003","20595","",194010,"1","2","3",19961018,"NSABP","MD005","1","",,"",,"SUBGROUP2","1","1",0,23456,"2","2"
"PATIENT_RACES","T95-0036","A5001","01"
"PATIENT_RACES","T95-0036","A5002","01"
"PATIENT_RACES","T95-0036","A5003","03"
"PATIENT_RACES","T95-0036","A5003","01"
"PRIOR_THERAPIES","T95-0036","A5001",44544
"PRIOR_THERAPIES","T95-0036","A5001",77677
"TREATMENT_COURSES","T95-0036","A5001",1,19961015,"A1","MD005",170.5,61.3,"2"
"TREATMENT_COURSES","T95-0036","A5001",2,19961021,"A1","MD005",170.5,61.3,"1"
"TREATMENT_COURSES","T95-0036","A5002",1,19961018,"A1","MD005",152.4,73.6,"2"
"TREATMENT_COURSES","T95-0036","A5003",1,19961018,"A1","MD005",180.3,95.4,"2"
"COURSE_AGENTS","T95-0036","A5001",1,"673089","2",258,"mg"
"COURSE_AGENTS","T95-0036","A5001",1,"119875","2",375,"mg"
"COURSE_AGENTS","T95-0036","A5001",2,"673089","2",258,"mg"
"COURSE_AGENTS","T95-0036","A5001",2,"119875","2",375,"mg"
"COURSE_AGENTS","T95-0036","A5002",1,"673089","2",245,"mg"
"COURSE_AGENTS","T95-0036","A5002",1,"119875","2",350,"mg"
"COURSE_AGENTS","T95-0036","A5003",1,"673089","2",278,"mg"
"COURSE_AGENTS","T95-0036","A5003",1,"119875","2",380,"mg"
"BASELINE_ABNORMALITIES","T95-0036","A5002",455095,3,""
"ADVERSE_EVENTS","T95-0036","A5001",2,455095,4,"",4,"1"
"LATE_ADVERSE_EVENTS","T95-0036","A5002",455095,4,"",,19980710
"BEST_RESPONSES","T95-0036","A5001","02",19961120
"BEST_RESPONSES","T95-0036","A5002","05",19960530
"BEST_RESPONSES","T95-0036","A5003","06",19961130
"TRIAL_COMMENTS","T95-0036","SUBGROUP1","A1","","Response seen in one of two patients"
"TRIAL_COMMENTS","T95-0036","SUBGROUP2","A1","No Toxicity",""
"PHASE1_END_POINTS"," T95-0036","SUBGROUP1","A1"
"PHASE1_END_POINT_DLTS","T95-0036","SUBGROUP1","A1",455095,""
```

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 to Accrual, Patients still on Treatment
		CB	Closed to Accrual, All Patients have Completed Treatment
		CP	Complete
		AD	Administratively Complete
	Change_Code	1	Yes
		2	No
PATIENTS	Country_Code	See CTEP Home Page	
	Gender_Code	1	Male
		2	Female
		9	Unknown
	Ethnicity_Code	1	Hispanic or Latino
		2	Not Hispanic or Latino
		8	Not Reported
		9	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	
	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	Adverse Event/Side Effects/Complications
		04	Death on Study

Table Name	Column Name	List of Values	Description
PATIENTS (cont.)	Off_TX_Reason (cont.)	05	Patient withdrawal/refusal after beginning protocol therapy
		06	Patient withdrawal/refusal before beginning protocol therapy
		07	Alternative therapy
		08	Patient off-treatment for other complicating disease
		10	Lost to follow-up
		11	Cytogenetic Resistance
		12	Disease Progression before Active Treatment
		13	No treatment, per protocol criteria
		98	Other
	Off_Study_Reason	01	Protocol-defined follow-up completed
		02	Patient lost to follow-up
		03	Patient refused follow-up
		04	Death
		05	Adverse Event/Side Effects/Complications
		98	Other
	Ineligibility_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 MedDRA codes)
	Resp_Eval_Status	1	Yes
		2	No
		3	Too Early
		7	Not Applicable
	Baseline_Abnormalities_Flag	1	Yes
		2	No
		9	Unknown
PATIENT_RACES	Race_Code	01	White
		03	Black or African American
		04	Native Hawaiian or other Pacific Islander
		05	Asian
		06	American Indian or Alaska native
		98	Not Reported
		99	Unknown
PRIOR_THERAPIES	Therapy_Code	See CTEP Home Page	(Use MedDRA Codes)
TREATMENT_COURSES	Treating_Inst_ID	See CTEP Home Page	
	AE_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

Table Name	Column Name	List of Values	Description
COURSE_AGENTS (cont.)	Dose_Change (cont.)	3	No
		9	Unknown
	Unit_Code	billion pfu	Billion pfu
		BVP	Billion Viral Particles
		cells	Cells
		cm	Centimeter
		Ci	Curie
		dL	Deciliter
		dm	Decimeter
		g	Gram
		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
		mcmol	Micromole
		mCi	Millicurie
		mEq	Milliequivalent
		mg	Milligram
		million IU	Million International Units
		million pfu	Million pfu
		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
		MVP	Million Viral Particles
		nCi	Nanocurie
		ng	Nanogram
		nm	Nanometer
		nm light	Nanometers of Light
		Osmol	Osmole

Table Name	Column Name	List of Values	Description
COURSE_AGENTS (cont)	Unit_Code (cont)	Pa	Pascal
		percent	Percent
		pfu	Plague Forming Unit
		psi	Pounds per square inch
		TCID	Tissue Culture Infectious Dose
		TCID50	Tissue Culture Infectious Dose 50
		VP	Viral particles
		N/A	Not Applicable
BASELINE_ABNORMALITIES	AE_Type_Code	See CTEP Home Page	(Use MedDRA Code, see CTCAE for definition)
	AE_Grade_Code	1, 2, 3, 4, 5	(See the CTEP Home Page and CTCAE or the Interactive Web Application for definition and grade)
ADVERSE_EVENTS	AE_Type_Code	See CTEP Home Page	(Use MedDRA Code, see CTCAE for definition)
	AE_Grade_Code	1, 2, 3, 4, 5	(See the CTEP Home Page and CTCAE or the Interactive Web Application for definition and grade)
	AE_Attribution_Code	1	Unrelated
		2	Unlikely
		3	Possible
		4	Probable
		5	Definite
	AER_Filed	1	Yes
		2	No
		9	Unknown
LATE_ADVERSE_EVENTS	AE_Type_Code	See CTEP Home Page	(Use MedDRA Code, see CTCAE for definition)
	AE_Grade_Code	1, 2, 3, 4, 5	(See the CTEP Home Page and CTCAE or the Interactive Web Application for definition and grade)
	AE_Attribution_Code	1	Unrelated
		2	Unlikely
		3	Possible
		4	Probable
		5	Definite
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	AE_Type_Code	See CTEP Home Page	(use MedDRA Code, see CTCAE for definition)

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 both accuracy and completeness. The review process and acceptance or rejection of the data will depend both on the type of error and also 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, "CDUS Business Rules."

7.2. DEFINITIONS FOR MANDATORY, REQUESTED, AND OPTIONAL

The data elements have been grouped into the following categories.

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. DEFINITIONS FOR INCOMPLETE, INCORRECT, INAPPROPRIATE, AND INCONSISTENT

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.

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 for specific file format requirements. To determine valid values/codes, please refer to Section 6.

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 > 136kg) 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.

7.4. CUMULATIVE DATA

Investigators are required to send cumulative data each quarter. Cumulative data is defined as follows: all data submitted from the last successfully processed quarter must be submitted this quarter. 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 latest successful 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 2.1.1.8] 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. Even when submitting a Change Code of '2' (No, the data has not changed since the last report) **AND** no data for any of the other tables (except the Collections table) are submitted:

The CDUS Business Rules will fire for any data that is included in this record.

With the implementation of the AdEERS/CDUS Reconciliation Module in April 2006, all AdEERS adverse events will be checked against all CDUS adverse events that are in the CDUS submitted data file for discrepancies.

Note: To ensure data integrity, all identified cumulative errors must be reviewed by the submitter. Written validation from the site is required before CDUS can proceed. Please send your reviewed comments to the NCI CTEP Help Desk and identify your review results:

I have reviewed this identified removed data and intended to do so. Please remove the identified records from the CTEP database.

I have reviewed this identified removed data and did not intend to do so. I am re-submitting a new data submission with the removed records included.

I have reviewed this identified removed data. I am re-submitting a new data submission with the following records included (please identify these records). You may remove the following records (please identify these records) as my intension was to not include them.

NOTE: Further explanation will be required if the following is identified as removed:

- A large number of adverse events with either a grade 3 or a grade 4 and positive attribution
- Removal of patient(s)
- Removal of multiple treatment course records
- Trends in identified removed data that might indicate an export issue or a web file creation issue
- Any record(s) that CTEP feels needs further explanation after review of the identified removed data.

Table H: Data Submission Problem Description and Required Response[10]

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 5 business days	• All data rejected • List of errors generated with *Rejection Notice* • Resubmission required within 5 business days	• All data rejected • List of errors generated with *Rejection Notice* • Resubmission required within 5 business days	• All data accepted • List of errors generated with *Caution Notice* • Verification or submission of corrected data due for next quarter's submission
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 5 business 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

7.5. SUBMISSION RESULTS

7.5.1. SMART LOADER APPROVAL (SUCCESSFUL/ACCEPTED)

When a protocol data set is accepted (successfully loaded to the CTEP database) by the Smart Loader, the investigator will receive an automatic acceptance notification by e-mail in the form of a CDUS Submission Results Notification notice. The CDUS-Successful Log Report will state "The CDUS Data set for this protocol has been ACCEPTED."

7.5.2. SMART LOADER DISAPPROVAL (REJECTION)

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. These errors will be identified on the CDUS – Error Log Report which is a section of the CDUS Submission Results Notification notice that is e-mailed after the file has

[10] 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 refer to the CDUS Business Rules section for further details.

been processed. 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 both the types of problems that may be identified through the Smart Loader process and also the response required from the investigator for each rejection, cumulative, or caution notice. **A suspension notice will be sent to investigators who fail to respond to these notices within the specified time frame. During this suspension process, the Principal Investigator's investigator privileges are suspended as well as all their other studies are closed to accrual. These restrictions are lifted once the data file is successfully processed**. A description of each notice is provided on the pages that follow.

7.6. TYPES OF 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 (Rejection, Caution, Cumulative).

7.6.1. CDUS REJECTION NOTICE

If a protocol data set contains incomplete, incorrect, or inappropriate mandatory data elements or incorrect requested data elements, the Smart Loader will reject the entire protocol data set, and the investigator will automatically receive a rejection notice. The rejection notice will outline both the specific problems and also how and when these problems should be corrected. Investigators will be required to resubmit their corrected data set within 5 business days. Failure to comply 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 accepted.

7.6.2. CDUS CAUTION NOTICE

If a protocol data set contains inconsistent mandatory or 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. The investigator will automatically receive a caution notice. The caution notice will outline both the specific problems and also how and when they should be corrected or verified. Investigators will be requested to send CTEP either notice of amended data, clarification of data, or correction of data with the next quarterly submission of data.

7.6.2.1. Correction Process for Caution Errors

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 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 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 response to CTEP must indicate that these elements will be corrected and resubmitted to CTEP.

7.6.2.2. Responding to a Caution Notice

All correspondence to CTEP in response to a caution notice must be sent via e-mail to the NCI CTEP Help Desk (ncictephelp@ctep.nci.nih.gov 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), and
- A list of the exact fields that need to be corrected and will be resubmitted with the complete data set.

7.7. CDUS CUMULATIVE NOTICE

The minimal cumulative data submission requirement is data identical to that successfully processed in the previous submission (see Section 7.4, "Cumulative Data," 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.

7.7.1.1. Correction and Response Process for Cumulative Errors

If the Smart Loader has identified data that you have intentionally omitted from the present quarter's submission, please identify this data via an e-mail to CTEP. CTEP will then adjust their records and re-process your file. Please review the guidelines identified in section 7.4 (Cumulative Data). CTEP realizes that the updating of data is part of the normal submission process; however, the removal of many grade 3 or 4 adverse events with positive attributions or the removal of a patient are examples of data deletions that will warrant more precise clarification.

If the Smart Loader has identified data that was inadvertently omitted, please re-submit your file with that previously omitted data included.

7.8. CDUS WARNING AND SUSPENSION PROCESS

A CDUS Warning Notification Letter will be sent to investigators who fail to respond to a CDUS Rejection notice within the time allotted. This Warning Letter will be followed by a CDUS Suspension Letter which will be sent to investigators who fail to respond to a CDUS Warning Letter within the allotted time. This letter 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 both the specific problems and also 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 REPORTS

The CDUS Smart Loader has been developed to evaluate all data submitted to the Clinical Data Update System (CDUS) for both accuracy and completeness. The review process and the acceptance or the 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 Table H 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.

Note: In an effort to ensure that the events reported to the Expedited Adverse Event Reporting System (AdEERS) and those reported to the Routine Reporting System (CDUS) were a match, CTEP implemented the AdEERS/CDUS Reconciliation Process on April 1, 2006. The Error Log Report was enhanced to accommodate this new process. An example of the new report is provided on page 72.

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.

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. All routine CDUS errors are identified at the beginning of the report. These errors are then followed by the errors generated from the AdEERS/CDUS Reconciliation Module. Cumulative identified errors will be displayed between the 2 sets of errors.

The header of the report indicates the Date of Generation, Lead Organization, Primary Contact, Protocol ID, Load Number, and Load Date.

The report groups the errors encountered by category:

- Rejection,
- Caution, and
- Cumulative

For each Rejection 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
- Column Value.

The end of the report lists the 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.

8.1.1. CDUS Error Log Report Column Headings

8.1.1.1. Date of Generation

The date the Smart Loader Error Log Report was produced.

8.1.1.2. Protocol ID

The protocol number for which data was processed via the Smart Loader. This is the identifier supplied by CTEP at protocol approval.

8.1.1.3. Load Number

The load reference number—the number of loads both submitted and processed.

8.1.1.4. Load Date

The date the data were loaded into the system.

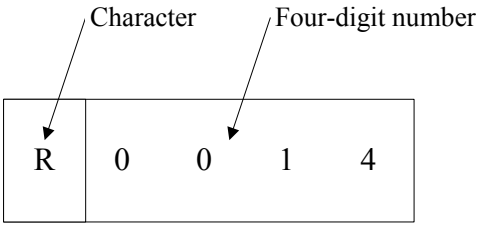
8.1.2. Report Detail

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

8.1.2.1. Error ID

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

Figure 1: CDUS Error Identification Format



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

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

8.1.2.2. Line Number

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

8.1.2.3. Table Name

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), this field will list "DEFAULT" as the table name.

8.1.2.4. Column Name

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.

8.1.2.5. Column Value

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

8.1.2.6. Error Location

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.

8.1.2.7. Unique Identifiers

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

8.1.2.8. Error Category

There are three error categories associated with the Smart Loader. They are Rejection, Caution, and Cumulative. (R,C,D)

8.1.2.9. Error Encountered

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

8.2. Error Description Report

Descriptions of each error message displayed in the CDUS Error Log Report are listed by Error ID in the CDUS – Error Description Report (see Figure 4). As with the CDUS Error Log Report, the error descriptions in the CDUS – Error Description Report are grouped by category:

- Rejection,
- Caution, and
- Cumulative

8.3. SAMPLE REPORTS

The following pages show a sample of:

Error Log Report with no reference to the AdEERS/CDUS Reconciliation Process (Figure 2).This report is received by all CDUS-Abbreviated studies.

Error Log Report with reference to the AdEERS/CDUS Reconciliation Process (Figure 3)

Error Description Report (Figure 4)

All have call out text describing each part of the reports.

FIGURE 2: CDUS Error Log Report

Report

Date the Smart Loader Error Log Report was produced

Identification number of specific protocol

Identification number of specific error

Physical line number

Table name

Load Reference Number

Date the data were loaded in the system

Identifies the specific error category type

Column name

Actual value of the data item

Primary key for specific record

```
CDUS - Error Log Report

Date of Generation:  05-MAR-02
Lead Organization: ABC
Primary Contact: John Doe
Protocol ID:  C87-0007                          Load Number:  14

                                   Load Date : 03-MAR-02

                              Error Category : Rejection
```

Error ID	Line Number	Table Name	Column Name	Column Value	Error Location
R0006	1	PATIENTS	PATIENT_ID	123456789022345	[1234567890223]
R0006	2	PATIENTS	ZIP_CODE	22258-9999-58	[2]
R0006	3	PATIENTS	COUNTRY_CODE	United States	[18]
R0004	3	PATIENTS	COUNTRY_CODE	United States	[18]
R0013	4	PATIENTS	BIRTH_DATE	194201012	[3]
R0006	5	PATIENTS	GENDER_CODE	02	[4]
R0004	5	PATIENTS	GENDER_CODE	02	[4]
R0006	7	PATIENTS	METHOD_OF_PAYMENT	06a	[6]
R0004	7	PATIENTS	METHOD_OF_PAYMENT	06a	[6]
R0013	8	PATIENTS	DATE_OF_ENTRY	199700201	[7]
R0006	9	PATIENTS	REG_GROUP_ID	1234567	[8]
R0004	9	PATIENTS	REG_GROUP_ID	1234567	[8]
R0006	10	PATIENTS	REG_INST_ID	1234567	[9]
R0004	10	PATIENTS	REG_INST_ID	1234567	[9]
R0006	11	PATIENTS	TX_ON_STUDY	02	[10]
R0004	11	PATIENTS	TX_ON_STUDY	02	[10]
R0006	12	PATIENTS	OFF_TX_REASON	003	[11]
R0004	12	PATIENTS	OFF_TX_REASON	003	[11]
R0006	13	PATIENTS	SUBGROUP_CODE	SUBGROUP123	[12]
R0004	13	PATIENTS	SUBGROUP_CODE	SUBGROUP123	[12]
R0006	14	PATIENTS	INELIGIBILITY_STATUS	02	[13]
R0004	14	PATIENTS	INELIGIBILITY_STATUS	02	[13]

Note: Figures 2, 3 and 4 are provided for explanatory purposes only. They are not an exhaustive sets of error messages. Error Log Reports (Figure 2 and Figure 3 (when appropriate) are specific to each data load. The Error Description Report will be mailed with each of the data load results.

FIGURE 2: CDUS Error Log Report (cont.)

```
                                  Error Category : CAUTION
                                  No Caution Errors Encountered


                                  Error Category : CUMULATIVE
                                  No Cumulative Errors Encountered


UNIQUE IDENTIFIERS FOR EACH TABLE LISTED IN THE ERROR REPORT
-------------------------------------------------------------

Table Name          Unique Identifiers
----------          ------------------
DEFAULT
PATIENTS             [ PATIENT_ID ]


CDUS - Smart Loader Summary Report
----------------------------------

Error Category       Errors Encountered
--------------       ------------------
REJECTION             29
CAUTION               0
CUMULATIVE            0

                     Records Without Errors        Records With Errors
--------------       ----------------------        -------------------
COLLECTION             1                           0
PATIENTS               0                           29
PUBLICATIONS           0                           0
```

Caution error category

Cumulative error category

Table name

Unique identifier being listed

Error category type

Total for each error type

Table name

Summarized totals

FIGURE 3: CDUS Error Log Report including AdEERS/CDUS Reconciliation

CDUS - ERROR LOG Report

Date of Generation: 05/18/2006 Page: 1 of 2

Lead Organization: ABCDE Load Date: 05/18/2006

Primary Contact: Harriett Wood

Protocol ID: 12345 Load Number: 1

The CDU Data set for this protocol has been REJECTED

Error Category: REJECTION

Error ID	Line Number	Table Name	Column Name	Column Value	Error Location
R0097	122	TREATMENT_COURSES	COURSE_START_DATE	20050802	[12012, 2]

Error Category: CAUTION

Error ID	Line Number	Table Name	Column Name	Column Value	Error Location
C0003	12	TREATMENT_COURSES	WEIGHT		[1,1]

Error Category: Cumulative
No Cumulative Check Done due to Rejection Errors

	Unique Identifiers
TREATMENT_COURSES	[PATIENT_ID, COURSE_ID]

AdEERS/CDUS Reconciliation

Error Category: REJECTION

Error ID	Patient ID	CATEGORY/AE (CODE)	Grade	Attribution	Ticket Number (s)
R0112	12345A	PULMONARY/Hypoxia (10021143)	5	Unrelated	1376217-A-3

Error ID	Patient ID	CATEGORY/AE (CODE)	Grade	Attribution	Line Number(s)
R0113	12345A	PULMONARY/Dyspnea (shortness of breath) (10013968)	5	Unrelated	145

Error Category: CAUTION

Error ID	Patient ID	CATEGORY/AE (CODE)	Grade	Attribution	Ticket Number (s)
C0012	12345B	NEUROLOGY/Mood alteration-anxiety, agitation (10002855)	4	Unrelated	1988877-0-0

Error ID	Patient ID	CATEGORY/AE (CODE)	Grade	Attribution	Line Number (s)
C0013	12345B	NEUROLOGY/Mood alteration-anxiety, agitation (10002855)	3	Unlikely	189

Error Category	Errors Encountered
REJECTION	3
CAUTION	3
CUMULATIVE	0

No records will be loaded into the active database due to errors

Table Name	Records with No Errors	Records with Errors
COLLECTIONS	1	0
CORRELATIVE_STUDIES	0	0
PUBLICATIONS	0	0
AUTHORS	0	0
PATIENTS	5	0
PRIOR_THERAPIES	5	0
TREATMENT_COURSES	6	2
COURSE_AGENTS	6	0
ADVERSE_EVENTS	16	2
BEST_RESPONSES	4	0
TRIAL_COMMENTS	0	0
PHASE1_END_POINTS	0	0
PHASE1_END_POINT_DLTS	0	0
PATIENT_RACES	5	0
BASELINE_ABNORMALITIES	6	0
LATE_ADVERSE_EVENTS	0	0
* AdEERS/CDUS Reconciliation	-	2

* CDUS data counts will be reflected in the appropriate table(s) under "Records with No Errors" or "Records with Errors"
* AdEERS data counts will be reflected under "Records with Errors" in the AdEERS/CDUS Reconciliation row

FIGURE 4: CDUS Error Description Report

```
                                CDUS - Error Description Report

Date of Generation : 02-MAR-02                    User Name : CTEPIMS


                                Error Category : REJECTION
Error ID                        Description
R0002                           Wrong number of columns
R0003                           Table name not recognized
R0004                           Parent record does not exist
R0005                           Primary key is null
R0006                           Invalid field length
R0007                           Number field enclosed in quotes
R0008                           Date field enclosed in quotes
R0009                           Characters submitted for numeric field
R0010                           Missing quotes
R0011                           Mismatched double quotes
R0012                           Invalid date format
R0013                           Invalid Birth Date format
R0014                           Invalid value
R0015                           Mandatory column is null
R0016                           Error in Protocol ID. This record might be ignored in further processing
R0017                           Duplicate Primary Key record


                                Error Category : CAUTION
Error ID                        Description
C0001                           Requested column is null
C0008                           Requested data not consistent with previous value


                                Error Category : CUMULATIVE
Error ID                        Description
D0001                           Cumulative Data Error
```

Report Title

User Name

Date report was produced

Error Category Type (REJECTION)

Identification number of specific error

Table name

Error Description

Error Description

Error Category Type (CAUTION)

Error Description

Error Category Type (CUMULATIVE)

Note: Figures 2, 3 and 4 are provided for explanatory purposes only. They are not an exhaustive sets of error messages. Error Log Reports (Figure 2 and Figure 3 (when appropriate) are specific to each data load. The Error Description Report will be mailed with each of the data load results.

9. CDUS BUSINESS RULES

The following table provides the business rules effective as of December 1, 2006. Caution rules that generate across multiple tables have been excluded.

Table I: CDUS Business Rules

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
COLLECTIONS	SUBMISSION_DATE	Inappropriate Mandatory	REJECTION	CutOff_Date/Subm_Date/Current_Trial_Status_Date must not be > the system date
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	CutOff_Date/Subm_Date/Current_Trial_Status_Date must not be > the system date
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be greater than or equal to the previous submission's CutOff_DATE
	CUTOFF_DATE	Inappropriate Mandatory	REJECTION	Must be <= Subm_Date
	CURRENT_TRIAL_STATUS_CODE	Inappropriate Mandatory	REJECTION	Submitted status/status date must progress towards completion or must be consistent with either the current CTEP database or with the CTEP database values as of your selected CutOff _Date
	CURRENT_TRIAL_STATUS_CODE	Inappropriate Mandatory	REJECTION	Protocol Status must not be 'Approved' if patients are being accrued
	CURRENT_TRIAL_STATUS_CODE	Inappropriate Mandatory	REJECTION	Status of 'Temporarily Closed to Accrual' or 'Temporarily Closed to Accrual and Treatment' may not be updated to the status of 'Active'. Contact the NCI CTEP Help Desk
	CURRENT_TRIAL_STATUS_CODE	Inappropriate Mandatory	CAUTION	Submitted status/status date is valid as of your Selected CutOff_Date but is not the current trial status/status date. Contact the NCI CTEP Help Desk.
	CURRENT_TRIAL_STATUS_DATE	Inappropriate Mandatory	REJECTION	CutOff_Date/Subm_Date/Current_Trial_Status_Date must not be > the system date
	CURRENT_TRIAL_STATUS_DATE	Inappropriate Mandatory	REJECTION	Submitted status/status date must progress towards completion or must be consistent with either the current CTEP database or with the CTEP database values as of your selected CutOff _Date
	CURRENT_TRIAL_STATUS_CODE	Inappropriate Mandatory	CAUTION	Submitted status/status date is valid as of your Selected CutOff_Date but is not the current trial status/status date. Contact the NCI CTEP Help Desk.
CORRELATIVE_STUDIES	PATIENTS_COLLECTED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	PATIENTS_COLLECTED	Inappropriate Mandatory	REJECTION	Must be >= PATIENTS_ANALYZED
	PATIENTS_COLLECTED	Inappropriate Mandatory	REJECTION	Must be <= SAMPLES_COLLECTED
	PATIENTS_ANALYZED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	PATIENTS_ANALYZED	Inappropriate Mandatory	REJECTION	Must be <= SAMPLES_ANALYZED
	SAMPLES_COLLECTED	Inappropriate Mandatory	CAUTION	Value must not decrease over time

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	SAMPLES_COLLECTED	Inappropriate Mandatory	REJECTION	Must >= SAMPLES_ANALYZED
	SAMPLES_ANALYZED	Inappropriate Mandatory	CAUTION	Value must not decrease over time
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Correlative Study information Mandatory if Correlative ID abstracted and study activated on or after 01/01/2002
PUBLICATIONS	MEDLINE_UID	Incomplete Requested	CAUTION	Requested if itemized publications data is not provided.
	TITLE	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
	JOURNAL	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
	VOLUME	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
	YEAR	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
	PUBLISHER	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
	PAGES	Incomplete Requested	CAUTION	Requested when MEDLINE_UID is NULL
AUTHORS	FNAME	Incomplete Requested	CAUTION	Requested field is NULL
	LNAME	Incomplete Requested	CAUTION	Requested field is NULL
PATIENTS	ZIP_CODE	Incomplete Mandatory	REJECTION	Either Zip Code or Country Code is Mandatory
	COUNTRY CODE	Incomplete Mandatory	REJECTION	Either Zip Code or Country Code is Mandatory
	BIRTH_DATE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	BIRTH_DATE	Inappropriate Mandatory	REJECTION	Must be <= CutOff_DATE
	BIRTH_DATE	Inappropriate Mandatory	REJECTION	Patient age must be <=100 at Date of Entry
	BIRTH_DATE	Inappropriate Mandatory	REJECTION	Must be <= DATE_OF_ENTRY
	GENDER_CODE	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	ETHNICITY_FLAG	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	METHOD_OF_PAYMENT	Incomplete Requested	CAUTION	Requested field in NULL
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= CutOff_DATE
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Date_Of_Entry must be within the date range when the protocol has a status of 'Active'
	DATE_OF_ENTRY	Inappropriate Mandatory	REJECTION	Must be <= Subm_Date
	REG_GROUP_ID	Incomplete Mandatory	REJECTION	Mandatory for intergroup trials
	REG_GROUP_ID	Inappropriate Mandatory	REJECTION	Must be a participant on the study
	REG_INST_ID	Incomplete Mandatory	REJECTION	Mandatory field is NULL
	TX_ON_STUDY	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Response for Progression is mandatory when OFF_TX_REASON = '02'
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Mandatory when TX_ON_STUDY = '2'
	OFF_TX_REASON	Inappropriate Mandatory	REJECTION	Patients.Off_TX_REASON must be NULL if Patients.TX_ON_STUDY = '1'
	OFF_TX_REASON	Incomplete Mandatory	REJECTION	Patients.Off_TX_Reason is mandatory if at least one Adverse Events.AE_Grade_Code = '5'
	LAST_TX_DATE	Incomplete Mandatory	REJECTION	Mandatory when TX_ON_STUDY = '2'; CDUS-Complete or CTMS (CDUS-Complete); study activated on or after 01/01/2002; and Off_TX_Reason is not Code '06', '12', or '13'
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Patient's.Last_TX_Date must be NULL if Patients.TX_ON_STUDY = '1'; CDUS-Complete or CTMS (CDUS-Complete); and study activated on or after 01/01/2002
	LAST_TX_DATE	Inappropriate Mandatory	REJECTION	Must be >= DATE_OF_ENTRY
	OFF_STUDY_REASON	Inappropriate Mandatory	REJECTION	Patients.Off_Study_Reason must be NULL if Patients.TX_On_Study = '1' (Yes) and study activated on or after 01/01/2002
	OFF_STUDY_REASON	Inappropriate Mandatory	REJECTION	Patients.Off_Study_Reason MUST be '04' (Death) if Patients.Off_Treatment_Reason = '04' (Death) and study activated on or after 01/01/2002
	OFF_STUDY_REASON	Incomplete Mandatory	REJECTION	Patients.Off_Study_Reason is mandatory if at least one Adverse Events.AE_Grade_Code = '5' and study activated on or after 01/01/2002
	OFF_STUDY_REASON	Incomplete Mandatory	REJECTION	Mandatory if OFF_STUDY_DATE is NOT NULL
	OFF_STUDY_DATE	Incomplete Mandatory	REJECTION	Mandatory if OFF_STUDY_REASON is NOT NULL
	SUBGROUP_CODE	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	INELIGIBILITY_STATUS	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	BASELINE_PS_CODE	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	PRIOR_CHEMO_REGS	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	DISEASE_CODE	Incomplete Mandatory	REJECTION	Mandatory when study has been assigned to CDUS-Abbreviated; CDUS-Complete or CTMS (CDUS-Complete) monitoring and study approved on or after 10/01/2004 or for studies requesting to submit from the SDC values. Studies with NIH Admin Code other than 'CTEP' are excluded
	DISEASE_CODE	Inappropriate Mandatory	REJECTION	Patients.Disease_Code must be selected from the Simplified Disease Classification values for studies approved on or after 10/01/2004 or for studies requesting to submit from the SDC values.
	DISEASE_CODE	Inappropriate Mandatory	REJECTION	Patients.Disease_Code submitted must be abstracted for the protocol if study assigned to Simplified Disease Classification, study not a phase '1' or a phase '0' study, NIH Admin Code = 'CTEP', and study approved on or after 10/01/2004.
	RESP_EVAL_STATUS	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	RESP_EVAL_STATUS	Incomplete Mandatory	REJECTION	Response record mandatory when RESP_EVAL_STATUS = '1'

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	BASELINE_ABNORMALITIES_FLAG	Incomplete Mandatory	REJECTION	Mandatory when CDUS-Complete or CTMS (CDUS-Complete) monitoring and Activated on or after 01/01/2002
	BASELINE_ABNORMALITIES_FLAG	Incomplete Mandatory	REJECTION	Baseline Abnormalities record mandatory when Patients. BASELINE_ABNORMALITIES_FLAG = '1' = 'Yes'
PATIENT_RACES	RACE_CODE	Incomplete Mandatory	REJECTION	Primary Key is NULL
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	PATIENT_RACES record Mandatory if patient record exists
PRIOR_THERAPIES	THERAPY_CODE	Incomplete Mandatory	REJECTION	Primary Key is NULL
TREATMENT_COURSES	COURSE_START_DATE	Incomplete Mandatory	REJECTION	Mandatory data not submitted
	COURSE_START_DATE	Inappropriate Mandatory	REJECTION	Must be >= DATE_OF_ENTRY
	COURSE_START_DATE	Inappropriate Mandatory	REJECTION	Course_Start_Date MUST be <= Last_TX_Date
	TX_ASGMNT_CODE	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	TREATING_INST_ID	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	HEIGHT	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	HEIGHT	Inappropriate requested	CAUTION	Must be >= 25cm and <= 200cm
	WEIGHT	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	WEIGHT	Inappropriate requested	CAUTION	Must be >= 3kg and <= 136kg
	AE_EXPERIENCED	Incomplete Mandatory	REJECTION	Adverse Event records mandatory when Treatment Courses.AE_ EXPERIENCED = '1'
	AE_EXPERIENCED	Incomplete Mandatory	REJECTION	Mandatory when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
COURSE_AGENTS	DOSE_CHANGE	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	DOSE_AMOUNT	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
	UNIT_CODE	Incomplete Requested	CAUTION	Requested when the study has been assigned to CDUS-Complete or CTMS (CDUS-Complete) monitoring
BASELINE_ABNORMALITIES	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'Other'
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	AE_Other, Specify can only be submitted when AE_Type_Code = ‘Other”. Please

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
				delete the AE_Other_Specify Column Value data
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Mandatory when BASELINE_ABNORMALITIES_FLAG = 'Yes'
	ALL COLUMN NAMES	Inappropriate Mandatory	REJECTION	Baseline Abnormality Records may only be submitted if BASELINE_ABNORMALITIES_FLAG = 'Yes'
ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'Other'; CDUS-Complete or CTMS (CDUS-Complete) and Activated on or after 01/01/2002
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	AE_Other, Specify can only be submitted when AE_Type_Code = 'Other". Please delete the AE_Other_Specify Column Value data
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	The total number of Other, Specify Adverse Events is greater than CTEP permits. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.
	AE_OTHER_SPECIFY	Inappropriate Requested	CAUTION	The total number of Other, Specify Adverse Events is greater than CTEP anticipates. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	Only the highest Adverse Events.AE_Grade_Code value should be reported for each Adverse Events.Course_ID and Adverse Events. AE_Type_Code
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	If Treatment_Courses.AE_Start_Date or Late_Adverse_Events.AE Start_Date is on or after 07/01/2005, only one Grade '5' Adverse Event or Late Adverse Event may be submitted for the patient.
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	At least one Adverse Event.AE_Grade_Code must be = '5' if Patients.Off_TX_Reason = '04'.
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	An Adverse Events/Late Adverse Events.AE_Grade_Code must be = '5' if Patients Off_Study_Reason = '04' (Death); for studies activated on or after 01/01/2002
	AE_ATTRIBUTION_CODE	Incomplete Mandatory	REJECTION	Mandatory when Treatment_Courses.AE_Experienced = '1'
	AER FILED	Incomplete Mandatory	REJECTION	Mandatory when Treatment Courses.AE_Experienced = '1'
	ALL COLUMN NAMES	Incomplete Mandatory	REJECTION	Adverse Event record mandatory when Treatment Courses.AE_Experienced = '1'.
	ALL COLUMN NAMES	Inappropriate Mandatory	REJECTION	Adverse Event record can only be submitted when Treatment Courses. AE_EXPERIENCED = '1'
LATE_ADVERSE_EVENTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'Other'
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	AE_Other, Specify can only be submitted when AE_Type_Code = 'Other". Please delete the AE_Other_Specify Column Value data
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	The total number of Other, Specify Adverse Events is greater than CTEP permits. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.
	AE_OTHER_SPECIFY	Inappropriate Requested	CAUTION	The total number of Other, Specify Adverse Events is greater than CTEP anticipates. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
	AE_START_DATE	Inappropriate Mandatory	REJECTION	AE_Start_Date MUST be greater than the Last_TX_Date
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	An Adverse Events/Late Adverse Events.AE_Grade_Code must be = '5' if Patients Off_Study_Reason = '04' (Death); for studies activated on or after 01/01/2002
	AE_GRADE_CODE	Inappropriate Mandatory	REJECTION	If Treatment_Courses.AE_Start_Date or Late_Adverse_Events.AE Start_Date is on or after 07/01/2005, only one Grade '5' Adverse Event or Late Adverse Event may be submitted for the patient.
BEST_RESPONSES	CATEGORY	Incomplete Mandatory	REJECTION	Response for Progression is mandatory when OFF_TX_Reason = '02'
	CATEGORY	Inappropriate Mandatory	REJECTION	Treatment Course record is mandatory when Best_Responses record exists
	CATEGORY	Inappropriate Mandatory	REJECTION	Value may not decrease except to Progression
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	Must be >= first COURSE_START_DATE
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	OBSERVED_DATE <= CutOff_DATE
	OBSERVED_DATE	Inappropriate Mandatory	REJECTION	There may not be multiple identical Best Responses.Observed_Date for the same patient
TRIAL_COMMENTS	GEN_RESPONSE_COMMENTS	Incomplete Mandatory	REJECTION	Mandatory when BEST_RESPONSES.CATEGORY = '98' (Other); CDUS-Complete or CTMS (CDUS-Complete); Activated on or after 01/01/2002
PHASE1_END_POINTS				
PHASE1_END_POINT_DLTS	AE_OTHER_SPECIFY	Incomplete Mandatory	REJECTION	Mandatory when AE_TYPE_CODE = 'Other'
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	AE_Other, Specify can only be submitted when AE_Type_Code = 'Other". Please delete the AE_Other_Specify Column Value data
	AE_OTHER_SPECIFY	Inappropriate Mandatory	REJECTION	The total number of Other, Specify Adverse Events is greater than CTEP permits. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.
	AE_OTHER_SPECIFY	Inappropriate Requested	CAUTION	The total number of Other, Specify Adverse Events is greater than CTEP anticipates. For assistance, search the CTC Interactive Application Index or contact the NCI CTEP Help Desk.

AdEERS/CDUS Reconciliation Business Rules

Adverse Event record was submitted via the AdEERS system but is not present in the CDUS data. This adverse event meets both routine (CDUS) and expedited (AdEERS) reporting requirements. Failure to resolve this data discrepancy could result in suspension of investigator privileges or study closure.

Adverse Event record was submitted in your CDUS data but is not present in the AdEERS system. This adverse event meets both routine (CDUS) and expedited (AdEERS) reporting requirements. Failure to resolve this data discrepancy could result in suspension of investigator privileges or study closure.

Table Name	Column Name	Problem Type/Error Type	Error Type	Error Description
Adverse Event record was submitted via the AdEERS system but is not present in the CDUS data. This adverse event meets both routine (CDUS) and expedited (AdEERS) reporting requirements. Resolution of this data is expected. Adverse Event record was submitted in your CDUS data but is not present in the AdEERS system. This adverse event meets both routine (CDUS) and expedited (AdEERS) reporting requirements. Resolution of this data is expected.				

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