# CTMS

## 3.12

**DATA TRANSFER
SPECIFICATIONS MANUAL**

**FOR THE
NCI/DCTD/CTEP
CLINICAL TRIALS MONITORING SERVICE
CASE REPORT FORMS**

**Prepared By:**

**Theradex®
CN 5257
Princeton, New Jersey  08543**

**October 2003**

**Version 3.12**

*Data Transfer Specifications Manual*
*for the NCI/DCTD/CTEP Clinical Trials Monitoring Service*
*Case Report Forms*

main telephone:   609.799.7580
CTMS fax:                609.799.9391

postal address:                CN 5257
                               Princeton, NJ 08543

parcel address:                14 Washington Road
                               Princeton Junction, NJ 08550

# INTRODUCTION

A set of standardized forms for clinical trial data has been developed by NCI/DCTD/CTEP for use by investigators when reporting data to the Clinical Trials Monitoring Service. Use of these Case Report Forms (described in the CTMS Case Report Forms Completion Manual) constitutes the "standard" method of submitting data to CTMS.

However, in an attempt to reduce duplicated effort and to increase data quality, two alternative systems for data transferal have been authorized. The first uses on-site microcomputer-based data capture software known as ACES®, provided by CTMS. This system incorporates data validation on entry, local reporting capabilities, and electronic data transfer to the CTMS database. The other option allows the submission of data in electronic files conforming to CTMS content and formatting conventions.

This option, described in detail below, should be attractive to investigators whose institutions operate their own data collection computer systems already. This requires some computer programming at the individual contributing institutions, but this is an investment which is more than offset by the avoidance of paper forms. The principal effort lies in resolving which items in the local database correspond to each of the CTMS fields.

This manual supercedes Version T310 (11/02) of the *Data Transfer Specifications Manual* but only with minor changes and clarifications.

# CONTENT

## Organization

Electronic data submissions to CTMS are conceptually alternate forms of the standard Case Report Forms.  Consequently the data model for the files to be prepared mimics the content of those forms, augmented with a few administrative items related to the transfer process.

Non-lab data is collected on 25 CRFs which are transposed into 29 electronic files, each identified with a 2-character code.

| | | | |
|---|---|---|---|
| Enrollment | EN | Eligibility Checklist | EC |
| Prior Treatment Summary | TF | Prior Therapy Supplement | PT |
| Prior Radiation Supplement | PR | Prior Surgery Supplement | PS |
| Concomitant Measures | CM | Baseline Medical History | MH |
| Baseline Symptoms | BS | Extent of Disease | LS, XT |
| Physical Exam | PE | Study Drug Administration | DA |
| Course Initiation | CI | Course Assessment | CA |
| Adverse Events | TX | Infection Episode | IE |
| Pharmacokinetics | PK | Urinary Excretion | UX |
| Scintigraphy | SH, SS | Off Study Summary | FO |
| Follow-Up | FP, DS | Comments | PH |
| Late Adverse Events | LA | Correlative Studies | CS |
| Protocol End Point | EP, DT | | |

Lab data is collected on 9 CRFs which are transposed into 17 electronic files, each identified with a 2-character code.

| | | |
|---|---|---|
| Flowsheet A | | |
| | Vital Signs, Transfusion, Cardiac | PL |
| | Hematology | HM |
| Flowsheet B | | |
| | Blood Chemistries | BC |
| | Urinalysis | US |
| Flowsheet C | | |
| | Bone Marrow | BM |
| | Serology | SR |
| | Other Serum Chemistries | SC |
| Flowsheet D | | |
| | Blood Gases, Respiratory Function | RF |
| | Red Cell Indices | RC (part A) |
| | Other Urinalysis | OU |
| Flowsheet E | | |
| | Immune Parameters | IP |
| | Serum Immune Electrophoresis | SE |
| | Urine Immune Electrophoresis | UE |
| | Electrophoresis | RC (part B) |
| Flowsheet F | | |
| | Literal Labs | LL |
| | | |
| Special Numeric Labs | Special Numeric Labs | EX |
| Special Literal Labs | Special Literal Labs | LX |
| Unanticipated Labs | Unanticipated Labs | UL |

**Data Elements**

The authoritative reference for the definitions of the clinical terms on the CRFs is the *Manual for the Completion of the NCI/CTEP Clinical Trials Monitoring Service Case Report Forms*, *Version 3.12*.

Note that CTMS does not expect the submission of every field on every form. To allow consistent reporting and cross-comparison of protocols, CTEP and CTMS have designed the Case Report Forms to contain a superset of the fields which would be of interest across the full range of oncology studies. CTMS requires the submission of all data which is specifically referenced in the study protocol or which would reasonably be needed to evaluate the performance of the study. Some institutions develop programs to submit all data collected, others prefer to tailor the extracted set to the protocol; either is acceptable.

In addition to the clinical data, a set of administrative items is prefixed to every record in each transmission file to identify it and facilitate synchronization between the source database and the CTMS database.

| | |
|---|---|
| File_ID | This file's ID code, 2 or 3 characters, e.g. EN |
| Version | Version ID for the Layout of this file, e.g. T310 |
| Extracted | Date the data in this file was extracted from its source |
| Entered_By | An identifier for the person who last updated any of the data in this record |
| Created | Earliest date that any data in this record was entered (i.e. the earliest 'Changed') |
| Changed | Latest date that any data in this record was revised (or the record deleted) |
| Chg_Time | Time of the latest revision (or deletion) (hhmmss) |
| Filler | (reserved for CTMS use) |
| Del_Flag | "D" if this record (identified by its key fields) was deleted, otherwise blank. The record with these keys will be removed from the central CTMS database. |
| Del_Date | Deletion Date (if record was deleted) |
| Protocol | The NCI/CTMS protocol identifier, e.g. T98-0137 |
| Inst_ID | The CTMS-assigned ID (nickname) for the institution submitting this record |
| Entry_Pass | Optional. "1" or "2" indicates that data was collected with single or double entry |
| Touch_Date | Optional. Any relevant date, e.g. of non-update viewing, or archiving, or audit trailing |
| Touch_Time | Optional. A time related to the Touch_Date |
| Course_Num Pseudo_Crs | Course Number for data in this record; use '0' for pre-study data. Use "0" in files where Course is not applicable (where field label is "Pseudo Course Num") |
| Patient | Patient Identifier, unique within protocol. (alphanumeric) |

The formats (literal/numeric, size) for every item are listed in the file specifications in Appendix C. This information is also available from CTMS in the form of a quoted, comma-delimited text file.

On each file layout the fields marked with asterisks are the key fields. The only key field in which a "missing" value is allowed is the Lab_Time.

Many fields are restricted to particular lists of possible entries. These code lists are contained in Appendix A. The notation "code=description" is used on some of the code list entries to explain the proper selection.

The notation "CTEP CDUS" refers to the Clinical Data Update System by which NCI/CTEP collects summary data on clinical studies. For consistency, CTMS has adopted the CDUS Code Lists for equivalent terms. Information on the CDUS and its lists is available on the CTEP internet web site (CTEP.cancer.gov) under the "Informatics" section.

**Conventions**

CTMS has instituted a set of conventions for coding abnormal data and special situations.

First, as noted above, records which have been previously submitted may be deleted by submitting a new record with the same keys and the Del_Flag set to "D". This allows the complete removal of records submitted in error.

Non-key clinical data fields which are literally blank in a transmitted record will not be updated in the CTMS database regardless of updates applied to other fields in the same record. This allows a site which has difficulty merging data from disparate local sources into the CTMS-specified records to submit multiple "partial" records, each supplying a subset of the fields.

Since blank fields are ignored, individual fields in a record cannot be "deleted" by submitting blanks. However, they *can* be deleted by submitting a "missing" value, for example "*" (a single asterisk) if literal or "-2" (negative 2) if numeric. ("Missing" data is discussed more fully below.)

All numeric fields in a newly created record in the CTMS database are initialized to -2, and all literal fields are initialized with blanks. The fields are then updated with the incoming values. Thus "naturally" blank fields can be created and will remain literally blank; the "*" entry is only necessary to remove data from a field which had been filled.

One file - Unanticipated Labs - is provided to transfer lab data for which no field has been defined in the standard CRFs. Since such data might be either numeric or literal, two fields are provided in the UL record. The one which is appropriate to the data item is to be filled, and the other left literally blank.

All numeric fields are intended to convey non-negative values; negatives are reserved for codes. Only one field in the standard CRFs is known to be affected by this, and the solution has been to map it to a pair of fields in the transfer file. If naturally-negative items must be submitted via the protocol-specific Special Numeric Labs file or the Unanticipated Labs overflow file then the sign must be reversed to positive according to a convention negotiated with CTMS.

All date fields should consist of the century, year, month, and day as 8 digits: "CCYYMMDD". The time-stamp fields are either hour-minute "HHMM" or hour-minute-second "HHMMSS", with the hour given on a 24-hour clock. Midnight is to be represented as "2400" in the preceding day, rather than "0000" (which is reserved to indicate "definitely unknown"). Times between midnight and 1 am should be submitted with leading zeroes – "00MM".

The preferred units of measure for fields without an associated "units" field are indicated in the CTMS CRF manual. The units to be used for reporting study drug administration will be determined in consultation with the data manager when CTMS initiates monitoring of a new protocol. These units must be used consistently to allow automated summarization of doses to be reported.

All the lab files contain a "Significant" field paired with every lab data field. These fields are purely optional and may be left blank. These fields allow an indication that the lab result is clinically significant - (Y)es or (N)o, or (H)igh or (N)ormal or (L)ow - compared to the local normal range.

All the lab files contain "Lab_Group" and "Lab_Code" fields. These are optional, but may be used to tag and track the specific lab that performed the tests reported in the record (e.g. for referencing lab normals). The Lab_Group is an arbitrary eight-character label for a lab or group of labs; the Lab_Code is a four-digit code to distinguish labs or changing lab standards within the Group. Specific values are at the choice of the submitting site. If no information of this type is conveniently available, both fields may be left blank as they are optional to CTMS.

**Missing Data**

The key fields in each record must contain real data values, but it is recognized that some clinical data items may be missing. CTMS has implemented a set of conventional codes to indicate different types and reasons for this. Codes other than the simple "Missing" are not required, but are available for use when the information is known and relevant.

| In Literal Fields | |
|---|---|
| Null-Valued, Not Entered, or otherwise Missing | |
|     In a new record | *  or blank (preferred) |
|     In an update record | * |
| Definitely Unknown | @ |
| Not Applicable | # |
| Required but Not Done | ! |
| Not Legible | % |
| | |
| **In Numeric Fields** | |
| Null-Valued, Not Entered, or otherwise Missing | -2 |
| Definitely Unknown | -4 |
| Not Applicable | -1 |
| Required but Not Done | -5 |
| Not Legible | -3 |
| Value exceeds range available in format | -8 |
| | |
| **In Date Fields**  (note: these are integers) | |
| Null-Valued, Not Entered, or otherwise Missing | -2 |
| Definitely Unknown | -4 |
| Not Applicable | -1 |
| Not Legible | -3 |
| Ongoing (from the past, or into the future) | -6 |
| Unknown Day of Month | 00 as the day |
| Unknown Month of Year | 0000 as the month/day |
| | |
| **In Time Fields**  (note: these are integers) | |
| Null-Valued, Not Entered, or otherwise Missing | -2 |
| Definitely Unknown | 0      (note: midnight is 2400) |
| Not Applicable | -1 |
| Not Legible | -3 |

Generally, the key fields in each file (indicated by an "*" in the layout listings) may not contain "missing" codes. However, there are a few exceptions.

In the lab data files, the Lab_Time field may be entered as "0" if the time is "definitely unknown" or "-2" if it is "missing". Local standards can be used to make this distinction. Usually "missing" implies that the time might be determined upon further investigation, while "unknown" implies that the time will never be entered.

In addition, "fuzzy date" (unknown day or month) coding is allowed in a few files where precise dates might not be available: the Onset_Date in Baseline Symptoms (BS); the Date in Prior Surgery (PS); the Start_Date and Last_Dose_Date in Prior Radiation (PR); the Start_Date and Stop_Date in Prior Therapy Supplement (PT), and the dates in the Prior Treatment Summary. In BS the Onset_Date may be "-4: definitely unknown".

Also in PR, PS, and PT, the Item field may be "-2: missing" if this additional sequencer is not needed to qualify multiple records with the same other keys.

**Format**

The data being submitted electronically should be assembled into "flat" ASCII text files consisting of records with fields in fixed columns without delimiters. Specifications for the layout of each file are contained in Appendix C. This information is also available from CTMS in the form of a quoted, comma-delimited text file.

Each table lists the field names, brief descriptions, and the field formats. The fields are listed in order, and for convenience the table includes the starting column of each field and the total record length.

The following format codes are used in the layout specification tables. All fields are alphanumeric; there are no machine-coded numerics.

| Ann | Literal value | Left justified in a field of width "nn". |
|---|---|---|
| Inn | Integer value | Right justified in a field of width "nn", no decimal point. |
| Fnn.mm | Numeric value | Decimal justified in a field of width "nn". No commas. No more than "nn-mm-1" digits before the decimal point. No more than "mm" digits after the decimal point. |
| D8 | Date | 8-digit date, "ccyymmdd". |
| T4 | Time (minutes) | 4-digit time, "hhmm". (with leading zeroes if before 10am) |
| T6 | Time (seconds) | 6-digit time, "hhmmss". (with leading zeroes if before 10am) |

Literal values may be submitted in either lower-case or upper-case, but generally case is ignored and CTMS treats most literal fields as upper case. The exceptions are: dose units; the Comment-file "Note"; and the long text fields in Medical History and Physical Exam.

Note that the File ID and the Layout Version ID are embedded in the record layout. This allows automated processing of the submitted batches. All records in a file must have the same File ID and be formatted to the same Layout Version. If multiple files of a given type are submitted in one batch, all those files must be formatted to the same Layout Version. However, files of different types may be formatted to different Layouts; this will typically occur as the database evolves and requires that the content and layout of particular files be updated.

If the Changed Date and Time fields are used, the physical order of records in the files will not be important because they will be sorted into "changed" sequence before processing. Otherwise they will be processed in their original order within the batch. If the Changed Date and Time fields are present in both an update transaction and the pre-existing record in the database, the transaction will be rejected if its 'changed' preceeds the existing record.

Records should not be submitted unless they contain data which has not been sent in a previous submission. Since all submissions are reviewed by the CTMS monitors, resources are wasted when redundant data is submitted. However, prior data is acceptable within a particular record when other fields are being updated. (Alternatively, fields not being updated may be formatted as blanks.)

**TRANSMISSION**

CTMS expects data to be submitted in a timely manner to allow "real-time" monitoring of a study in progress. To accommodate a variety of institutional situations, there is some flexibility in the interpretation of this. Generally, CTMS expects that data will be batched and submitted at two-week intervals so that it is not too "stale". Allowance is made for data which is, for example, delayed because specimens are sent to an outside lab. On the other hand, lab data which is directly accessible from in-house lab systems is expected to be submitted promptly. Also, and particularly, CTMS will not approve a practice of holding data for a particular course of treatment until its conclusion. A "Course Initiation" record must be submitted at the start, and subsequent drug administration, lab results, and adverse events should be submitted as they occur.

Each file of data prepared for transmission must be given an individual file name conforming to the following rules. The file name must be in standard DOS "8.3" notation, i.e. a "name" of no more than eight characters plus an "extension" of no more than three. The file extension must be "TAP". The first three characters of the name must be the File_ID right-padded with the underscore ("_"). The remaining five characters are optional. Thus "EN_MAY25.TAP" is a valid name for a file of Enrollment data.

Data from different protocols may be submitted in different files or concatenated (or even mixed) into single files of each type. Multiple files of the same type may be uploaded in the same transmission. Within a batch, all the files of a given File_ID are concatenated in the order of their "last written" dates as obtained from the transmission file directory.

Because of this concatenation, all the files of a given file type in a batch must be formatted to the same version specification. Different versions may be used within a single batch, but only for different file types. Thus, for example, lab data could be submitted using spec T220 and enrollment data using spec T310, but drug administration cannot be submitted using T220 for some protocols and T310 for others within the same batch.

Deletion records may be submitted in separate files, appended to files with update records, or intermixed with the updates. They will be processed in sequence based on the "changed" date and time stamp. A deletion record will be ignored if the database contains a record with a later stamp.

Data files may currently be transmitted to CTMS in two ways, on diskette or by using a CTMS-developed and distributed data transfer system, "ACESlink". Transmission of files on DOS/Windows-compatible diskettes is simple but discouraged because it introduces an additional time lag, is subject to physical damage, and requires manual handling. Consequently ACESlink is the preferred method of data transmission.

The current version of ACESlink (8) is a stand-alone component of the ACES® PC-based data capture system that CTMS provides to investigators who do not have institutional support for electronic data capture. It is based on the use of standard internet e-mail protocols to transfer the data files as an bundle in a single attachment. ACESlink-8 is implemented as a Windows application that will retrieve the data files from a designated extraction directory, encrypt them into the bundle, (optionally) email them directly to CTMS, and track receipts from CTMS. Documentation for ACESlink and assistance with installation and operation is available from CTMS.

The former version of ACESlink (7) is still in operation but will eventually be phased out. It consists of a local client that uses a modem to directly dial a host and then upload the designated files using a robust transfer protocol and a fail-soft handshake protocol. ACESlink-7 is implemented as a set of batch files and scripts which drive "RELAY®", a PC-based communications program. (The submitting institution must provide and install RELAY and maintain a long-distance phone line.)

**NOTES**

Following are notes on specific fields.

| All | Version | The Layout Version ID may become different from file to file. If updates or corrections require changing the layout of a particular file, a new specification will be issued with an incremented Version ID. |
|-----|---------|-----------|
| All | Patient | The Patient ID may be either left justified or right justified. |
| All | Course_Num | This is assigned by reference to each course start date without regard to any 'time', e.g. a lab test taken on the same day but earlier than the time of first drug administration for the second course would be considered course = 2. |
| BS | Onset_Date | The "fuzzy" notation can be used for dates with unknown day or month. Use "-4: definitely unknown" if even a partial date cannot be ascertained. |
| CA | Dose_Diff | This field uses the codelist from the CDUS to indicate whether the actual treatment is the same implied by the Treatment Assignment Code for the course. |
| CA | Prog_Date | The date of progression is mandatory when the Response is coded as Progressive Disease. |
| EC | Quest_*nn* | These fields are answers to a set of Protocol-specific Eligibility Questions which are abstracted by the CTMS monitor and conveyed to the institution's data manager. |
| EN | Race | Federal standards require the flexibility to record multiple races identifiers. To accommodate this, submit the CDUS races code(s) as two-digit literals separated by blanks and concatenated into a single string. |
| EN | Age | When the Age is five years and above it should be specified as a whole number of years. For children less than five, rounding to one decimal place is sufficient but two digits are accepted. |
| EN | Grade | The Disease Grade field is obsolete and optional, but provided in the specification for backward compatibility with earlier versions. |
| EN | Filter | reserved for CTMS use. Submit Blank or 0. |
| EN | Pay_Method | This is a literal field; submit one- or two-character literals, left justified. |
| EX | Test_*nn* | These fields will be assigned, in consultation with the data manager, for the reporting of protocol-specific numeric lab results which are not present in the standard lab files. |
| FO | Off_Treat | The date the last course is discontinued, or completed (including the normal observation period). Not the date of the last drug administration. |
| FO | Date_Prog | The date of progression is mandatory if the Best_Response is coded as Progressive Disease or if the Reason Offstudy is Progressive Disease |
| LX | Field_*nn* | These fields will be assigned, in consultation with the data manager, for the reporting of protocol-specific literal lab results which are not present in the standard lab files. |
| MH | all text fields | These fields may contain mixed case text, which will be preserved. |
| PE | all text fields | These fields may contain mixed case text, which will be preserved. |
| PH | Note | This field allows for the submission of a free text comment, for example a physician note or a clarification of an entry on some other form. |
| PR | Start_Date | The "fuzzy" notation can be used for dates with unknown day or month. |
| PR | Last_Dose_Date | The "fuzzy" notation can be used for dates with unknown day or month. |
| PR | Item | The Item field is an optional additional arbitrary qualifier to allow more than one record to be submitted for the same Start_Date and Radiation keys. If it is not needed then "-2" may be submitted |

| PS | Date | The "fuzzy" notation can be used for dates with unknown day or month. |
|----|------|----------------------------------------------------------------------|
| PS | Item | The Item field is an optional additional arbitrary qualifier to allow more than one record to be submitted for the same Date and Proc_Site keys. If it is not needed then "-2" may be submitted |
| PT | Start_Date | The "fuzzy" notation can be used for dates with unknown day or month. |
| PT | Stop_Date | The "fuzzy" notation can be used for dates with unknown day or month. |
| PT | Item | The Item field is an optional additional arbitrary qualifier to allow more than one record to be submitted for the same Start_Date and Agent keys. If it is not needed then "-2" may be submitted |
| PH | Note_Type | To tie the note to a particular file, use the appropriate File_ID. If there is no relevant CRF, use PH. If the note overflows 1024 characters, create continuation notes by appending 1, 2, etc. to the Note_Type. The note may contain mixed-case text, which will be preserved. |
| RF | Base_Exc | "Base Excess" is the only lab data field in the standard set which might take a negative value. Since the CTMS convention reserves negative values for 'missing' codes, a negative Base Excess must be entered in an artificial companion field, the "Base Deficit" |
| RF | Base_Def | The value entered for "Base Deficit" should be the absolute value (thus a positive value) of a negative Base Excess lab test result. |
| TX | Tox_Code | This field is restricted to codes from the CTEP CDUS Toxic_Events Tox_Type_Code list for the version of the CTC specified by the protocol (the "MedDRA" codes for CTC toxicity terms). Appendix B describes how these codes can be obtained. |
| TX | Grade | The severity grade for each adverse event must be assigned according to the version of the NCI Common Toxicity Criteria which is applicable to the protocol. While these generally range from 1 to 5, the CTC2 disallows some grades for certain types of toxicity. A current listing of the allowable grades for each CTC2 type is included in Appendix B, but the "informatics" pages of the NCI/CTEP internet website (CTEP.cancer.gov) should be checked periodically for updates. These grade restrictions are mandatory because of the CTEP/CDUS. |
| TX | Apex_Nadir | The Apex/Nadir field is obsolete and optional, but provided in the specification for backward compatibility with earlier versions. |
| UL | Body_Site | Since this is a key field, a value is required. If the Body Site is unknown or not applicable, use "UNAVAIL". |
| UL | Value_Type | The Unanticipated Labs file is provided to transfer lab data for which no field has been defined in the standard CRFs. Since such data might be either numeric or literal, two fields are provided in the UL record. This field indicates the nature of the datum. |
| UL | Units | Use this field to indicate the units of measurement when the Value_Type is numeric. |

Blank Page

(spacer for two-sided copying)

# APPENDIX A

## Codelists for Data Fields with Restricted Values

| BS | | |
|---|---|---|
| | Grade | 1 =Mild,<br>2 =Moderate,<br>3 =Severe,<br>4 =Life_Threatening,<br>5 =Fatal |
| | Relation | Y =Yes,<br>N =No,<br>U =Unknown |
| | Tox_Code | Restricted to codes from the<br>CTEP CDUS Toxic_Events.Tox_Type_Code list<br>(see Appendix B) |
| CA | | |
| | Dose_Diff | 1 =Yes_(planned),<br>2 =Yes_(unplanned),<br>3 =No,<br>9 =Unknown |
| | Crs_Disp | COMP =Completed_Course,<br>DIS =Discontinued_Course |
| | Response | NA =Not_Assessed,<br>CR =Complete,<br>PR =Partial,<br>MR =Less_than_Partial,<br>SD =Stable_Disease,<br>PD =Progression,<br>NE =Not_Evaluable,<br>NP =Not_Applicable_per_protocol,<br>TE =Too Early,<br>DU =Disease Unchanged |
| | Toxicity | Y =Yes,<br>N =No |
| CI | | |
| | Ht_Units | cm (only) |
| | Wgt_Units | kg (only) |
| | Treat_Inst | Restricted to codes from the<br>CTEP CDUS standard Institution code list |

| CM | | |
|---|---|---|
| | Schedule | no code list; use these terms or other standard nomenclature<br>QD, QOD,<br>HS, AC, PC,<br>BID, TID, QID,<br>QWK, BIW, TIW,<br>STAT, PRN,<br>Q4H, Q6H, Q8H, Q12H, etc. |
| | Units | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>are preferred. |
| DA | | |
| | Lev_Units | Specified by CTMS<br>but with override allowed.<br>Generally chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list |
| | Tot_Units | Specified by CTMS<br>but with override allowed.<br>Generally chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list |
| | Dur_Units | MN =Minutes,<br>HR =Hours,<br>DY =Days,<br>WK =Weeks |
| | Route | IM =Intramuscular,<br>IV =Intravenous,<br>CIV =Continuous_intravenous<br>IVI =Intravenous_infusion,<br>IVP =Intravenous_push,<br>ID = Intradermal<br>IA =Intra-arterial,<br>SC =Subcutaneous,<br>SQ =Subcutaneous,<br>IT =Intrathecal,<br>IP =Intraperitoneal,<br>IH =Intrahepatic,<br>IHI =Intrahepatic_infusion,<br>RT =Radiation_treatment<br>RA =Rectal_administration,<br>T =Topical,<br>PO =Oral<br><br>or other route as specified in the protocol |

| (DA) | Schedule | no code list; use these terms or other standard nomenclature<br>QD, QOD,<br>HS, AC, PC,<br>BID, TID, QID,<br>QWK, BIW, TIW,<br>STAT, PRN,<br>Q4H, Q6H, Q8H, Q12H, etc. |
|------|----------|-----|
| **DS** | | |
| | Autopsied | Y =Yes,<br>N =No,<br>U =Unknown |
| | Result | M =Death_Caused_by_Malignancy,<br>T =Death_Caused_by_Toxicity,<br>I =Death_Caused_by_Infection,<br>O =Other_Cause |
| | Cause | M =Malignant_Disease,<br>T =Toxicity_from_Treatment,<br>I =Infection,<br>O =Other |
| **DT** | | |
| | Tox_Code | restricted to codes from the<br>CTEP CDUS Toxic_Events.Tox_Type_Code list<br>(see Appendix B) |
| **EC** | | |
| | Quest_nn | Y =Yes,<br>N =No,<br>X =Not_applicable |
| | Eligible | Y =Yes,<br>N =No |

| EN | | |
|---|---|---|
| | Pay_Method | '1' =Private_Insurance,<br>'2' =Medicare,<br>'3' =Medicare_and_Private_Insurance,<br>'4' =Medicaid,<br>'5' =Medicaid_and_Medicare,<br>'6' =Military_or_Veterans_Sponsored_NOS,<br>'6a' =Military_Sponsored_<br>      (Including_CHAMPUS_&_TRICARE),<br>'6b' =Veterans_Sponsored,<br>'7' =Self_Pay_(No_Insurance),<br>'8' =No_means_of_payment_(No_Insurance),<br>'98' =Other,<br>'99' =Unknown |
| | Perf_Stat | ECOG preferred, but Karnofsky allowed if specified by protocol.<br>0 =Asymptomatic_and_fully_active,<br>1 =Symptomatic; fully_ambulatory;<br>      restricted_in_physically_strenuous_activity,<br>2 =Symptomatic;_ambulatory;_capable_of_self-care;<br>      >50%_waking_hours_out_of_bed,<br>3 =Symptomatic;_limited_self-care;<br>      >50%_waking_hours_in_bed,<br>4 =Completely_disabled;_no_self-care;_bedridden |
| | Prim_Site | no code list, but these terms are preferred:<br>CNS/Spinal,<br>Bone,<br>Skin,<br>Lung,<br>Liver,<br>Spleen,<br>Lymph,<br>Oropharynx,<br>Esophagus,<br>Stomach,<br>Breast,<br>Ovary,<br>Testicles,<br>Kidneys/Adrenals,<br>Bone_Marrow,<br>Lymph_Nodes,<br>Small_Intestine,<br>Colon,<br>Rectum |

| (EN) | Race | '01' =White,<br>'03' =Black or African American,<br>'04' =Native_Hawaiian/Pacific_Islander/Filipino,<br>'05' =Asian/Indian_Subcontinent,<br>'06' =American Indian or Alaska Native,<br>'99' =Unknown |
|---|---|---|
| | Ethnicity | '1' = Hispanic or Latino<br>'2' = Non-Hispanic<br>'9' = Unknown |
| | Sex | M =Male,<br>F =Female |
| | Ht_Units | cm (only) |
| | Wgt_Units | kg (only) |
| | Reg_Group | restricted to codes from the<br>CTEP CDUS standard Cooperative Group codelist |
| | Reg_Inst | restricted to codes from the<br>CTEP CDUS standard Institution codelist |
| | Disease | restricted to codes from the<br>CTEP CDUS Patients.Disease_Codes list<br>(the "IMT" codes for diseases) |
| **FO** | | |
| | Best_Resp | CR =Complete_Response,<br>PR =Partial_Response,<br>MR =Less_than_Partial,<br>SD =Stable_Disease,<br>PD =Progression,<br>NE =Not_Evaluable,<br>NA =Not_Assessed,<br>NP =Not_Applicable_per_protocol,<br>TE =Too Early |

| (FO) | Reason | Use the codes indicated on the Off Treatment/Off Study CRF<br>C = Study complete,<br>X = Declined to participate<br>B = Disease progression before treatment<br>Z = No Treatment, per protocol<br>U = Not treated – other reasons<br>P = Disease progression on study<br>T = Adverse events / side effects<br>G = Cytogenetic resistance<br>R = Refused further treatment<br>V = Protocol violation<br>D = Death on study<br>S = Complicating disease / intercurrent illness<br>A = Switched to alternative treatment<br>I = Late determination of ineligibility<br>O = Off treatment – other reasons<br>Y = Treatment complete but patient refused follow-up<br>F = Treatment complete, follow-up ongoing<br>H = Follow-up period completed<br>L = Lost to further follow-up<br>W = Refused further follow-up<br>E = Late adverse events / side effects<br>M = Death during follow-up period<br>K = Off study during follow-up – other reasons |
|---|---|---|
| **FP** | | |
| | Status | 1 =Alive with disease<br>2 =Alive with no evidence of disease<br>3 =Alive with disease status unknown<br>4 =Unknown<br>5 =Died |
| **LA** | **see TX** | |
| **LL** | | |
| | Lab_Test | CEKG =ELECTROCARDIOGRAM,<br>CXR =CHEST_X-RAY,<br>XRAY =X-RAY,<br>BRNCHGRM =BRONCHOGRAM,<br>UPGISER =UPPER_GI_SERIES,<br>LWGISER =LOWER_GI_SERIES,<br>SKELSURV =SKELETAL_SURVEY,<br>CATSCAN,<br>HOLTMON =HOLTER-MONITOR,<br>BONESCAN,<br>EEG,<br>BMCELLTY =BM_CELLULARITY,<br>UCASTS,<br>MRI,<br>MUGASCAN,<br>ULTRASND =ULTRA_SOUND<br>PETSCAN,<br>CULTURE |

| (LL) | | |
|------|------|------|
| | Norm_Abnor | N =Normal, <br> A =Abnormal |
| **LS** | | |
| | Category | M =Measurable, <br> E =Evaluable, <br> N =Not_Evaluable |
| | Followed | Y =Yes, <br> N =No |
| | Organ | no code list, but these terms are preferred: <br> CNS/Spinal, <br> Bone, <br> Skin, <br> Lung, <br> Liver, <br> Spleen, <br> Lymph, <br> Oropharynx, <br> Esophagus, <br> Stomach, <br> Breast, <br> Ovary, <br> Testicles, <br> Kidneys/Adrenals, <br> Bone_Marrow, <br> Lymph_Nodes, <br> Small_Intestine, <br> Colon, <br> Rectum, <br> Pleural_Effusion, <br> Ascites, <br> Abdomen, <br> Pelvis |
| | Prev_Rad | Y =Yes, <br> N =No |
| **PE** | | |
| | Abdomen | X =Not_Examined, <br> N =Normal, <br> A =Abnormal |
| | Breasts | X =Not_Examined, <br> N =Normal, <br> A =Abnormal |
| | Cardio | X =Not_Examined, <br> N =Normal, <br> A =Abnormal |

| (PE) | Dermat | X =Not_Examined, N =Normal, A =Abnormal |
|------|--------|------------------------------------------|
|  | Endo_Met | X =Not_Examined, N =Normal, A =Abnormal |
|  | Gastro | X =Not_Examined, N =Normal, A =Abnormal |
|  | Genital | X =Not_Examined, N =Normal, A =Abnormal |
|  | HEENT | X =Not_Examined, N =Normal, A =Abnormal |
|  | Hem_Lym | X =Not_Examined, N =Normal, A =Abnormal |
|  | MuscSkel | X =Not_Examined, N =Normal, A =Abnormal |
|  | Neck | X =Not_Examined, N =Normal, A =Abnormal |
|  | Neurolog | X =Not_Examined, N =Normal, A =Abnormal |
|  | Other | X =Not_Examined, N =Normal, A =Abnormal |
|  | Pelvis | X =Not_Examined, N =Normal, A =Abnormal |
|  | Psychol | X =Not_Examined, N =Normal, A =Abnormal |
|  | Respirat | X =Not_Examined, N =Normal, A =Abnormal |
|  | Urinary | X =Not_Examined, N =Normal, A =Abnormal |

| PH | | |
|---|---|---|
| | Note_Type | any File_ID, to associate note with that CRF;<br>PH if there is no relevant File_ID;<br>PV =documents a Protocol_Violation.<br>(File_ID's for lab data are in the margins of the Flowsheet CRFs) |
| | Note | Free text up to 1024 characters.<br>Lower case will be preserved. |
| PK | | |
| | Par_Un_As1 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | Par_Un_as2 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | Par_Units | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | Met_Un_As1 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | Met_Un_As2 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | Met_Units | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |

| PR | | |
|---|---|---|
| | Thrpy_Code | Restricted to the following codes for therapies on the Prior Treatment Summary CRF:<br><br>ER = Extensive_Radiation,<br>LR = Limited_Radiation,<br>R  = Radiation_(NOS) |
| | Response | CR =Complete_Response,<br>PR =Partial_Response,<br>MR =Marginal_Response,<br>SD =Stable_Disease,<br>PD =Progressive_Disease,<br>AJ =Adjuvant_Treatment,<br>PA =Palliative_Treatment,<br>NA =Not_Assessed,<br>NE =Not_Evaluable,<br>UK =Unknown |
| | Site | no code list, but these terms are preferred:<br>CNS/Spinal,<br>Bone,<br>Skin,<br>Lung,<br>Liver,<br>Spleen,<br>Lymph,<br>Oropharynx,<br>Esophagus,<br>Stomach,<br>Breast,<br>Ovary,<br>Testicles,<br>Kidney/Adrenals,<br>Bone_Marrow,<br>Lymph_Nodes,<br>Small_Intestine,<br>Colon,<br>Rectum,<br>Serum |
| PS | | |
| | Surg_Code | Y = Yes, Therapeutic,<br>N = Not_Therapeutic |

| PT | | |
|---|---|---|
| | Thrpy_Code | Restricted to the following codes for therapies on the Prior Treatment Summary CRF:<br><br>AR = Anti-Retroviral<br>AS = Antisense<br>BM = Bone Marrow Transplant<br>C = Chemotherapy (NOS)<br>CM = Chemotherapy multiple agents systemic<br>CS = Chemotherapy single agent systemic<br>NC = Non-cytotoxic Chemotherapy<br>G = Gene Transfer<br>H = Hormonal<br>I = Immunotherapy<br>OV = Oncolytic Virotherapy<br>V = Vaccine<br>PT = Prior Therapy (NOS)<br>R = Radiotherapy (NOS)<br>LR = Limited Radiotherapy<br>ER = Extensive Radiotherapy<br>S = Surgery |
| | Response | CR =Complete_Response,<br>PR =Partial_Response,<br>MR =Marginal_Response,<br>SD =Stable_Disease,<br>PD =Progressive_Disease,<br>AJ =Adjuvant_Treatment,<br>PA =Palliative_Treatment,<br>NA =Not_Assessed,<br>NE =Not_Evaluable,<br>UK =Unknown |
| SS | | |
| | Biopsied | Y =Yes,<br>N =Not_Found,<br>I =Identified_Only |
| | CT_Scan | Y =Yes,<br>N =No,<br>E =Equivocal |
| | Gamma_Scan | Y =Yes,<br>N =No,<br>E =Equivocal |
| | Tiss_Class | N =Normal,<br>T =Tumor |

| TF | | |
|---|---|---|
| | Anti_RtVir | Y =Yes,<br>N =No,<br>U =Unknown |
| | Anti_Sense | Y =Yes,<br>N =No,<br>U =Unknown |
| | Bone_Marr | Y =Yes,<br>N =No,<br>U =Unknown |
| | Chemo_Unkn | Y =Yes,<br>N =No,<br>U =Unknown |
| | Chemo_Mult | Y =Yes,<br>N =No,<br>U =Unknown |
| | Chemo_Sing | Y =Yes,<br>N =No,<br>U =Unknown |
| | Extens_Rad | Y =Yes,<br>N =No,<br>U =Unknown |
| | Gene_Thrpy | Y =Yes,<br>N =No,<br>U =Unknown |
| | Hormonal | Y =Yes,<br>N =No,<br>U =Unknown |
| | Immunother | Y =Yes,<br>N =No,<br>U =Unknown |
| | Lim_Rad | Y =Yes,<br>N =No,<br>U =Unknown |
| | Non_Cyto | Y =Yes,<br>N =No,<br>U =Unknown |
| | Onco_Viro | Y =Yes,<br>N =No,<br>U =Unknown |
| | Oth_Thrpy | Y =Yes,<br>N =No,<br>U =Unknown |

| (TF) | Rad_Unkn | Y =Yes,<br>N =No,<br>U =Unknown |
|------|----------|------------|
|      | Vaccine  | Y =Yes,<br>N =No,<br>U =Unknown, |
|      | Surgery  | Y =Yes,<br>N =No,<br>U =Unknown |
| **TX** |        |            |
|      | Action   | '1' =None,<br>'2' =Dose_reduced,<br>'3' =Regimen_interrupted,<br>'4' =Therapy_discontinued,<br>'5' =Interrupted/reduced |
|      | AER_Filed | Y =Yes,<br>N =No,<br>U =Unknown |
|      | Attribut | '1' =Unrelated,<br>'2' =Unlikely,<br>'3' =Possible,<br>'4' =Probable,<br>'5' =Definite |
|      | Dose_Limit | Y =Yes,<br>N =No |
|      | Grade    | 1 =Mild,<br>2 =Moderate,<br>3 =Severe,<br>4 =Life_Threatening,<br>5 =Fatal<br><br>Note that the NCI Common Toxicity Criteria (and the CDUS) disallow some grade levels for adverse events falling into certain categories. |
|      | Outcome  | '1' =Recovered,<br>'2' =Still_Under_Treatment/observation,<br>'3' =Alive_With_Sequelae,<br>'4' =Died |
|      | Serious  | 1 =No,<br>2 =Life_Threatening,<br>3 =Death,<br>4 =Disability,<br>5 =Hospitalized,<br>6 =Congenital_Anomaly,<br>7 =Jeopardizes_Patient/Requires_Intervention |

| (TX) | Therapy | '1' =None,<br>'2' =Symptomatic,<br>'3' =Supportive,<br>'4' =Vigorous_Supportive |
|---|---|---|
|  | Tox_Code | restricted to codes from the<br>CTEP CDUS Toxic_Events.Tox_Type_Code list<br>(see Appendix B) |
| **UL** |  |  |
|  | Body_Site | There is no standard code list; use any reasonable terms.<br><br>When the Body Site is not known or not applicable, use "UNAVAIL" |
|  | Norm_Abnor | N =Normal,<br>A =Abnormal |
|  | Value_Type | N =Number,<br>L =Literal |
| **UX** |  |  |
|  | P_Amt_Unit | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
|  | P_Asy_Un_1 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
|  | P_Asy_Un_2 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
|  | P_Con_Unit | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |

| (UX) | M_Amt_Unit | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
|---|---|---|
| | M_Asy_Un_1 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | M_Asy_Un_2 | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| | M_Con_Unit | No code list,<br>but terms chosen from the<br>CTEP CDUS Course_Agents.Unit_Code list<br>by volume /ml are preferred. |
| **XT** | | |
| | Determined | no code list, but these terms are preferred:<br>PE =Physical_Exam,<br>X-ray,<br>CXR =Chest_X-ray,<br>CT-scan,<br>MRI,<br>Ultrasound,<br>Surgery,<br>Isotope-scan,<br>LumbarPunct =Lumbar_Puncture,<br>LabTest_(TM) =Lab_test_(tumor_markers),<br>RadNuc-scan =Radionuclide-scan |
| | Evaluation | N =New,<br>R =Resolved,<br>D =Decreasing,<br>I =Increasing,<br>S =Stable |
| | Eval_Num | 0 =Baseline,<br>sequential integer |
| All Lab Files | Significant | Y =Yes,<br>N =No or Normal,<br>H =High,<br>L =Low,<br>U =Unknown (when a Y/N/H/L would have been entered),<br>blank if the "Significant" attribute is not normally submitted |

**APPENDIX B**


**NCI/CTEP CTC/CDUS Toxicity Term Codelists**

The TX, LA, BS, and DT files all have Tox_Code fields for submission of a code that represents a standardized term for the adverse event. The specific terminology will be indicated in the protocol. Most active protocols approved before October 2003 will be using the NCI/DCTC/CTEP "Common Toxicity Criteria, version 2" (CTC2); protocols approved from October 2003 on will generally use the CTEP "Common Terminology Criteria for Adverse Events, version 3" (CTCAE3 or "CTC3").

Complete documentation for the CTC2 and CTC3 is available for download from the CTEP website "CTEP.cancer.gov". At the time of this writing, this could be accessed directly from the home page via a "CTCAE" link.

The code lists are available as computer-readable files from the CTEP website via the link to the "Codes and Values" and then to the "MedDRA Codes".

Note that some severity grades are not applicable for some adverse events. (For example, one cannot die of allergic rhinitis.) Inappropriate grades should not be submitted, as CTMS has implemented cross-checks against tables of allowable values.

# APPENDIX C


# Specifications for the Layout of the Data Files

```
      File 'BC-T310'    Labs: Blood Chemistries


      File_ID      (A3    @    1)    File ID Code: "BC "
      Version      (A4    @    4)    Layout Version "T310"
      Extracted    (D8    @    8)    Extraction Date
      Entered_By   (A8    @   16)    Data Entry Clerk
      Created      (D8    @   24)    Record Creation Date
      Changed      (D8    @   32)    Last Change Date
      Chg_Time     (T6    @   40)    Last Change Time
      Filler       (A1    @   46)    (reserved)
      Del_Flag     (A1    @   47)    Deletion Flag
      Del_Date     (D8    @   48)    Deletion Date (if deleted)
      Protocol     (A12   @   56)    *Protocol ID
      Inst_ID      (A8    @   68)    Institution Code
      Entry_Pass   (A1    @   76)    Multi-Entry Pass
      Touch_Date   (D8    @   77)    Touched Date
      Touch_Time   (I7    @   85)    Touched Timer
      Course_Num   (I3    @   92)    Course Number
      Patient      (A12   @   95)    *Patient
      Lab_Date     (D8    @  107)    *Lab Test Date
      Lab_Time     (T4    @  115)    *Lab Test Time
      Lab_Group    (A8    @  119)    Lab Code Group
      Lab_Code     (I4    @  127)    Lab Code
      BUN          (F9.3  @  131)    Blood Urea Nitrogen
      S_BUN        (A1    @  140)    Significant? Blood Urea Nitrogen
      Creatinine   (F9.3  @  141)    Creatinine
      S_Creat      (A1    @  150)    Significant? Creatinine
      Sodium       (F9.3  @  151)    Sodium
      S_Sodium     (A1    @  160)    Significant? Sodium
      Potassium    (F9.3  @  161)    Potassium
      S_Potass     (A1    @  170)    Significant? Potassium
      Chloride     (F9.3  @  171)    Chloride
      S_Chloride   (A1    @  180)    Significant? Chloride
      Magnesium    (F9.3  @  181)    Magnesium
      S_Magnes     (A1    @  190)    Significant? Magnesium
      Bicarb       (F9.3  @  191)    Bicarbonate
      S_Bicarb     (A1    @  200)    Significant? Bicarbonate
      Uric_Acid    (F9.3  @  201)    Uric Acid
      S_Uric       (A1    @  210)    Significant? Uric Acid
      Bilirubin    (F9.3  @  211)    Bilirubin
      S_Bilirub    (A1    @  220)    Significant? Bilirubin
      Alk_Phos     (F9.3  @  221)    Alk Phosphatase
      S_Alk_Phos   (A1    @  230)    Significant? Alk_Phosphatase
      SGOT_AST     (F9.3  @  231)    SGOT/AST
      S_SGOT_AST   (A1    @  240)    Significant? SGOT/AST
      SGPT_ALT     (F9.3  @  241)    SGPT/ALT
      S_SGPT_ALT   (A1    @  250)    Significant? SGPT/ALT
      SGGT         (F9.3  @  251)    SGGT
      S_SGGT       (A1    @  260)    Significant? SGGT
      LDH          (F9.3  @  261)    LDH
      S_LDH        (A1    @  270)    Significant? LDH
      Total_Prot   (F9.3  @  271)    Total Protein
      S_Tot_Prot   (A1    @  280)    Significant? Total Protein
      Albumin      (F9.3  @  281)    Albumin
      S_Albumin    (A1    @  290)    Significant? Albumin
      Globulin     (F9.3  @  291)    Globulin
```

```
S_Globulin   (A1    @ 300)   Significant? Globulin
Calcium      (F9.3  @ 301)   Calcium
S_Calcium    (A1    @ 310)   Significant? Calcium
Inorg_Phos   (F9.3  @ 311)   Inorg Phosphorus
S_Ing_Phos   (A1    @ 320)   Significant? Inorg_Phosphorus
Gluc_Fast    (F9.3  @ 321)   Glucose Fasting
S_Gluc_F     (A1    @ 330)   Significant? Glucose Fasting
Gluc_NFast   (F9.3  @ 331)   Glucose Non-Fasting
S_Gluc_NF    (A1    @ 340)   Significant? Glucose Non-Fasting
Cholest      (F9.3  @ 341)   Cholesterol
S_Cholest    (A1    @ 350)   Significant? Cholesterol
Amylase      (F9.3  @ 351)   Amylase
S_Amylase    (A1    @ 360)   Significant? Amylase
5-Nucleo     (F9.3  @ 361)   5-Nucleotidase
S_5-Nucleo   (A1    @ 370)   Significant? 5-Nucleotidase
Creat_Phos   (F9.3  @ 371)   Creatinine Phosphokinase
S_Creat_Ph   (A1    @ 380)   Significant? Creatinine Phosphok
                    - 380
```

```
File 'BM-T310'    Labs: Bone Marrow


File_ID      (A3    @    1)    File ID Code: "BM "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Myeloblast   (F9.3  @  119)    Myeloblasts
S_Myelobl    (A1    @  128)    Significant? Myeloblasts
Promyelo     (F9.3  @  129)    Promyelocytes
S_Promyelo   (A1    @  138)    Significant? Promyelocytes
Myel_Neut    (F9.3  @  139)    Myelocytes: Neutros
S_Myl_Neut   (A1    @  148)    Significant? Myelo: Neutros
Myel_Eos     (F9.3  @  149)    Myelocytes: Eosinos
S_Myl_Eos    (A1    @  158)    Significant? Myelo: Eosinos
Myel_Basos   (F9.3  @  159)    Myelocytes: Basos
S_Myl_Baso   (A1    @  168)    Significant? Myelo: Basos
Metamyelo    (F9.3  @  169)    Metamyelocytes
S_Metamyel   (A1    @  178)    Significant? Metamyelocytes
Poly_Neut    (F9.3  @  179)    Polymorphs: Neutros
S_Ply_Neut   (A1    @  188)    Significant? Poly: Neutros
Poly_Eos     (F9.3  @  189)    Polymorphs: Eosinos
S_Ply_Eos    (A1    @  198)    Significant? Poly: Eosinos
Poly_Basos   (F9.3  @  199)    Polymorphs: Basos
S_Ply_Baso   (A1    @  208)    Significant? Poly: Basos
Lymphocyte   (F9.3  @  209)    Lymphocytes
S_Lympho     (A1    @  218)    Significant? Lymphocytes
Plasma_Cel   (F9.3  @  219)    Plasma Cells
S_Plas_Cel   (A1    @  228)    Significant? Plasma Cells
Monocytes    (F9.3  @  229)    Monocytes
S_Monos      (A1    @  238)    Significant? Monocytes
Retic_Cell   (F9.3  @  239)    Reticulum Cells
S_Retic      (A1    @  248)    Significant? Reticulum Cells
Megakaryo    (F9.3  @  249)    Megakaryocytes
S_Megakar    (A1    @  258)    Significant? Megakaryocytes
Pronormo     (F9.3  @  259)    Pronormoblasts
S_Pronormo   (A1    @  268)    Significant? Pronormoblasts
Normoblast   (F9.3  @  269)    Normoblasts
S_Normobl    (A1    @  278)    Significant? Normoblasts
M_Rating     (F9.3  @  279)    M-Rating
S_M_Rating   (A1    @  288)    Significant? M-Rating (1-6)
                    -  288
```

```
File 'BS-T310'    Baseline Symptoms


File_ID      (A3    @    1)    File ID Code: "BS "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Pseudo_Crs   (I3    @   92)    Pseudo Course Number
Patient      (A12   @   95)    *Patient
Onset_Date   (D8    @  107)    *Onset Date
Toxicity     (A33   @  115)    *Toxicity
Tox_Code     (I10   @  148)    Toxicity Type Code
Grade        (I2    @  158)    Toxicity Grade
Relation     (A1    @  160)    Relation to Disease
                    -  160
```

```
File 'CA-T310'    Course Assessment


File_ID      (A3    @    1)    File ID Code: "CA "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Start_Date   (D8    @  107)    *Start Date
Response     (A2    @  115)    Response Assessment
Resp_Date    (D8    @  117)    Response Date
Prog_Date    (D8    @  125)    Progression Date
Crs_Disp     (A4    @  133)    Course Disposition
Toxicity     (A1    @  137)    Toxicity
Note         (A32   @  138)    Response Note
Dose_Diff    (I2    @  170)    Dose Different from TAC
                    -  171
```

```
File 'CI-T310'    Course Initiation


File_ID      (A3    @    1)    File ID Code: "CI "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Course       (D8    @  107)    *Course Start Date
Arm          (A4    @  115)    Treatment Arm
Treatment    (A10   @  119)    Treatment Assignment Code
Weight       (F6.2  @  129)    Weight
Wgt_Units    (A4    @  135)    Weight Units
Height       (F6.2  @  139)    Height
Ht_Units     (A4    @  145)    Height Units
BSA          (F5.2  @  149)    Body Surface Area
Treat_Inst   (A6    @  154)    Treating Institution Code
                    -  159
```

```
File 'CM-T310'    Concomitant Measures/Medications


File_ID      (A3    @    1)    File ID Code: "CM "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Start_Date   (D8    @  107)    *Start Date
Agent_Proc   (A24   @  115)    *Agent/Proc
Item         (I8    @  139)    *Additional Arbitrary Sequencer
Total_Dose   (A8    @  147)    Total Dose
Units        (A12   @  155)    Units
Schedule     (A24   @  167)    Schedule
Reason       (A24   @  191)    Reason For Use
End_Date     (D8    @  215)    End Date
                     -  222
```

```
File 'CS-T310'    Correlative Studies


File_ID       (A3    @    1)    File ID Code: "CS "
Version       (A4    @    4)    Layout Version "T310"
Extracted     (D8    @    8)    Extraction Date
Entered_By    (A8    @   16)    Data Entry Clerk
Created       (D8    @   24)    Record Creation Date
Changed       (D8    @   32)    Last Change Date
Chg_Time      (T6    @   40)    Last Change Time
Filler        (A1    @   46)    (reserved)
Del_Flag      (A1    @   47)    Deletion Flag
Del_Date      (D8    @   48)    Deletion Date (if deleted)
Protocol      (A12   @   56)    *Protocol ID
Inst_ID       (A8    @   68)    Institution Code
Entry_Pass    (A1    @   76)    Multi-Entry Pass
Touch_Date    (D8    @   77)    Touched Date
Touch_Time    (I7    @   85)    Touched Timer
Course_Num    (I3    @   92)    Course Number
Corr_Stdy     (A10   @   95)    *CTEP Study ID
Title         (A64   @  105)    Title of Study
Pats_Coll     (I6    @  169)    Num Patients, samples collected
Pats_Anal     (I6    @  175)    Num Patients, samples analyzed
Smpl_Coll     (I6    @  181)    Num Samples collected
Smpl_Anal     (I6    @  187)    Num Samples analyzed
Findings1     (A64   @  193)    Findings (1)
Findings2     (A64   @  257)    Findings (2)
Findings3     (A64   @  321)    Findings (3)
Findings4     (A64   @  385)    Findings (4)
Findings5     (A64   @  449)    Findings (5)
Findings6     (A64   @  513)    Findings (6)
Findings7     (A64   @  577)    Findings (7)
Findings8     (A64   @  641)    Findings (8)
                     -  704
```

```
File 'DA-T310'    Study Drug Administration


File_ID      (A3    @    1)    File ID Code: "DA "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Date         (D8    @  107)    *Date
Start_Time   (T4    @  115)    *Start Time
Drug         (A8    @  119)    *Drug
Lot_Number   (A24   @  127)    Lot Number
Dose_Level   (F9.3  @  151)    Dose Level
Lev_Units    (A12   @  160)    Level Units
Schedule     (A24   @  172)    Schedule
Total_Dose   (F9.3  @  196)    Actual Dose
Tot_Units    (A12   @  205)    Actual Units
Route        (A8    @  217)    Route
Duration     (F7.2  @  225)    Duration
Dur_Units    (A2    @  232)    Duration Units
                     -  233
```

```
File 'DS-T310'    Death Summary


File_ID       (A3   @    1)    File ID Code: "DS "
Version       (A4   @    4)    Layout Version "T310"
Extracted     (D8   @    8)    Extraction Date
Entered_By    (A8   @   16)    Data Entry Clerk
Created       (D8   @   24)    Record Creation Date
Changed       (D8   @   32)    Last Change Date
Chg_Time      (T6   @   40)    Last Change Time
Filler        (A1   @   46)    (reserved)
Del_Flag      (A1   @   47)    Deletion Flag
Del_Date      (D8   @   48)    Deletion Date (if deleted)
Protocol      (A12  @   56)    *Protocol ID
Inst_ID       (A8   @   68)    Institution Code
Entry_Pass    (A1   @   76)    Multi-Entry Pass
Touch_Date    (D8   @   77)    Touched Date
Touch_Time    (I7   @   85)    Touched Timer
Pseudo_Crs    (I3   @   92)    Pseudo Course Number
Patient       (A12  @   95)    *Patient
Death_Date    (D8   @  107)    Death Date
Cause         (A1   @  115)    Cause of Death
Oth_Cause     (A24  @  116)    Cause if Other
Autopsied     (A1   @  140)    Whether Autopsied
Result        (A1   @  141)    Autopsy Result
Oth_Result    (A24  @  142)    Result if Other
Site_1        (A18  @  166)    Site 1 of Disease
Site_2        (A18  @  184)    Site 2 of Disease
Site_3        (A18  @  202)    Site 3 of Disease
Site_4        (A18  @  220)    Site 4 of Disease
Site_5        (A18  @  238)    Site 5 of Disease
Site_6        (A18  @  256)    Site 6 of Disease
Site_7        (A18  @  274)    Site 7 of Disease
Site_8        (A18  @  292)    Site 8 of Disease
                    -  309
```

```
File 'DT-T310'   Dose Limiting Toxicities


File_ID      (A3    @    1)    File ID Code: "DT "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Pseudo_Crs   (I3    @   92)    Pseudo Course Number
Subgroup     (A10   @   95)    *Subgroup
Toxicity     (A33   @  105)    *Toxicity
Tox_Code     (I10   @  138)    Dose Limiting Toxicity
                    -  147
```

```
        File 'EC-T310'   Eligibility Checklist


        File_ID      (A3    @    1)   File ID Code: "EC "
        Version      (A4    @    4)   Layout Version "T310"
        Extracted    (D8    @    8)   Extraction Date
        Entered_By   (A8    @   16)   Data Entry Clerk
        Created      (D8    @   24)   Record Creation Date
        Changed      (D8    @   32)   Last Change Date
        Chg_Time     (T6    @   40)   Last Change Time
        Filler       (A1    @   46)   (reserved)
        Del_Flag     (A1    @   47)   Deletion Flag
        Del_Date     (D8    @   48)   Deletion Date (if deleted)
        Protocol     (A12   @   56)   *Protocol ID
        Inst_ID      (A8    @   68)   Institution Code
        Entry_Pass   (A1    @   76)   Multi-Entry Pass
        Touch_Date   (D8    @   77)   Touched Date
        Touch_Time   (I7    @   85)   Touched Timer
        Pseudo_Crs   (I3    @   92)   Pseudo Course Number
        Patient      (A12   @   95)   *Patient
        Checklist    (A2    @  107)   Checklist number
        Quest_1      (A1    @  109)   Question 1
        Quest_2      (A1    @  110)   Question 2
        Quest_3      (A1    @  111)   Question 3
        Quest_4      (A1    @  112)   Question 4
        Quest_5      (A1    @  113)   Question 5
        Quest_6      (A1    @  114)   Question 6
        Quest_7      (A1    @  115)   Question 7
        Quest_8      (A1    @  116)   Question 8
        Quest_9      (A1    @  117)   Question 9
        Quest_10     (A1    @  118)   Question 10
        Quest_11     (A1    @  119)   Question 11
        Quest_12     (A1    @  120)   Question 12
        Quest_13     (A1    @  121)   Question 13
        Quest_14     (A1    @  122)   Question 14
        Quest_15     (A1    @  123)   Question 15
        Quest_16     (A1    @  124)   Question 16
        Quest_17     (A1    @  125)   Question 17
        Quest_18     (A1    @  126)   Question 18
        Quest_19     (A1    @  127)   Question 19
        Quest_20     (A1    @  128)   Question 20
        Quest_21     (A1    @  129)   Question 21
        Quest_22     (A1    @  130)   Question 22
        Quest_23     (A1    @  131)   Question 23
        Quest_24     (A1    @  132)   Question 24
        Quest_25     (A1    @  133)   Question 25
        Quest_26     (A1    @  134)   Question 26
        Quest_27     (A1    @  135)   Question 27
        Quest_28     (A1    @  136)   Question 28
        Quest_29     (A1    @  137)   Question 29
        Quest_30     (A1    @  138)   Question 30
        Quest_31     (A1    @  139)   Question 31
        Quest_32     (A1    @  140)   Question 32
        Quest_33     (A1    @  141)   Question 33
        Quest_34     (A1    @  142)   Question 34
        Quest_35     (A1    @  143)   Question 35
        Quest_36     (A1    @  144)   Question 36
```

```
Quest_37    (A1   @ 145)   Question 37
Quest_38    (A1   @ 146)   Question 38
Quest_39    (A1   @ 147)   Question 39
Quest_40    (A1   @ 148)   Question 40
Eligible    (A1   @ 149)   Patient Eligible?
Why_not     (A64  @ 150)   Why not?
Waiver      (A12  @ 214)   Waiver identifier
                  - 225
```

```
     File 'EN-T310'    Enrollment


     File_ID     (A3    @    1)    File ID Code: "EN "
     Version     (A4    @    4)    Layout Version "T310"
     Extracted   (D8    @    8)    Extraction Date
     Entered_By  (A8    @   16)    Data Entry Clerk
     Created     (D8    @   24)    Record Creation Date
     Changed     (D8    @   32)    Last Change Date
     Chg_Time    (T6    @   40)    Last Change Time
     Filler      (A1    @   46)    (reserved)
     Del_Flag    (A1    @   47)    Deletion Flag
     Del_Date    (D8    @   48)    Deletion Date (if deleted)
     Protocol    (A12   @   56)    *Protocol ID
     Inst_ID     (A8    @   68)    Institution Code
     Entry_Pass  (A1    @   76)    Multi-Entry Pass
     Touch_Date  (D8    @   77)    Touched Date
     Touch_Time  (I7    @   85)    Touched Timer
     Pseudo_Crs  (I3    @   92)    Pseudo Course Number
     Patient     (A12   @   95)    *Patient
     Sex         (A1    @  107)    Sex
     Race        (A20   @  108)    Race Code(s)
     Ethnicity   (A2    @  128)    Ethnicity Code
     Birth_Date  (D8    @  130)    Date of Birth
     Reg_Date    (D8    @  138)    Registration Date
     Age         (F6.2  @  146)    Age
     Weight      (F6.2  @  152)    Weight
     Wgt_Units   (A4    @  158)    Weight Units
     Height      (F6.2  @  162)    Height
     Ht_Units    (A4    @  168)    Height Units
     Filter      (I1    @  172)    Filter Group
     BSA         (F5.2  @  173)    BSA
     Subgroup    (A10   @  178)    Subgroup
     Reg_Group   (A6    @  188)    Registering Group
     Reg_Inst    (A6    @  194)    Registering Inst Code
     Local_ID    (A12   @  200)    Local Patient ID Code
     Country     (A2    @  212)    Country Code
     Postal_Cod  (A10   @  214)    Postal Code
     Pay_Method  (A2    @  224)    Method of Payment
     Disease     (I10   @  226)    Disease Code
     Prim_Site   (A20   @  236)    Primary Site
     Dis_Stage   (A8    @  256)    Disease Stage
     Grade       (A4    @  264)    Disease Grade (obsolete)
     Perf_Stat   (I3    @  268)    Performance Status
     Histology   (A40   @  271)    Histology/Cytopath
     Confirmed   (D8    @  311)    Confirmation Date
     Diag_Date   (D8    @  319)    Diagnosis Date
     Consented   (D8    @  327)    Informed Consent Date
     Consent_Vr  (A12   @  335)    Version of Consent
     Treatment   (A10   @  347)    Assigned Treatment
                        -  356
```

```
      File 'EP-T310'    Protocol Endpoint


      File_ID      (A3    @    1)    File ID Code: "EP "
      Version      (A4    @    4)    Layout Version "T310"
      Extracted    (D8    @    8)    Extraction Date
      Entered_By   (A8    @   16)    Data Entry Clerk
      Created      (D8    @   24)    Record Creation Date
      Changed      (D8    @   32)    Last Change Date
      Chg_Time     (T6    @   40)    Last Change Time
      Filler       (A1    @   46)    (reserved)
      Del_Flag     (A1    @   47)    Deletion Flag
      Del_Date     (D8    @   48)    Deletion Date (if deleted)
      Protocol     (A12   @   56)    *Protocol ID
      Inst_ID      (A8    @   68)    Institution Code
      Entry_Pass   (A1    @   76)    Multi-Entry Pass
      Touch_Date   (D8    @   77)    Touched Date
      Touch_Time   (I7    @   85)    Touched Timer
      Pseudo_Crs   (I3    @   92)    Pseudo Course Number
      Subgroup     (A10   @   95)    *Subgroup
      Treatment    (A10   @  105)    Recommended Treatment
                          -  114
```

```
     File 'EX-T310'    Labs: Special Numeric Labs


     File_ID      (A3    @    1)    File ID Code: "EX "
     Version      (A4    @    4)    Layout Version "T310"
     Extracted    (D8    @    8)    Extraction Date
     Entered_By   (A8    @   16)    Data Entry Clerk
     Created      (D8    @   24)    Record Creation Date
     Changed      (D8    @   32)    Last Change Date
     Chg_Time     (T6    @   40)    Last Change Time
     Filler       (A1    @   46)    (reserved)
     Del_Flag     (A1    @   47)    Deletion Flag
     Del_Date     (D8    @   48)    Deletion Date (if deleted)
     Protocol     (A12   @   56)    *Protocol ID
     Inst_ID      (A8    @   68)    Institution Code
     Entry_Pass   (A1    @   76)    Multi-Entry Pass
     Touch_Date   (D8    @   77)    Touched Date
     Touch_Time   (I7    @   85)    Touched Timer
     Course_Num   (I3    @   92)    Course Number
     Patient      (A12   @   95)    *Patient
     Lab_Date     (D8    @  107)    *Lab Test Date
     Lab_Time     (T4    @  115)    *Lab Test Time
     Panel        (I2    @  119)    *Panel
     Lab_Group    (A8    @  121)    Lab Code Group
     Lab_Code     (I4    @  129)    Lab Code
     Test_1       (F9.3  @  133)    Test 1
     S_Test_1     (A1    @  142)    Significant? Test1
     Test_2       (F9.3  @  143)    Test 2
     S_Test_2     (A1    @  152)    Significant? Test2
     Test_3       (F9.3  @  153)    Test 3
     S_Test_3     (A1    @  162)    Significant? Test3
     Test_4       (F9.3  @  163)    Test 4
     S_Test_4     (A1    @  172)    Significant? Test4
     Test_5       (F9.3  @  173)    Test 5
     S_Test_5     (A1    @  182)    Significant? Test5
     Test_6       (F9.3  @  183)    Test 6
     S_Test_6     (A1    @  192)    Significant? Test6
     Test_7       (F9.3  @  193)    Test 7
     S_Test_7     (A1    @  202)    Significant? Test7
     Test_8       (F9.3  @  203)    Test 8
     S_Test_8     (A1    @  212)    Significant? Test8
     Test_9       (F9.3  @  213)    Test 9
     S_Test_9     (A1    @  222)    Significant? Test9
     Test_10      (F9.3  @  223)    Test 10
     S_Test_10    (A1    @  232)    Significant? Test10
     Test_11      (F9.3  @  233)    Test 11
     S_Test_11    (A1    @  242)    Significant? Test11
     Test_12      (F9.3  @  243)    Test 12
     S_Test_12    (A1    @  252)    Significant? Test12
     Test_13      (F9.3  @  253)    Test 13
     S_Test_13    (A1    @  262)    Significant? Test13
     Test_14      (F9.3  @  263)    Test 14
     S_Test_14    (A1    @  272)    Significant? Test14
     Test_15      (F9.3  @  273)    Test 15
     S_Test_15    (A1    @  282)    Significant? Test15
     Test_16      (F9.3  @  283)    Test 16
     S_Test_16    (A1    @  292)    Significant? Test16
```

```
Test_17      (F9.3  @ 293)    Test 17
S_Test_17    (A1    @ 302)    Significant? Test17
Test_18      (F9.3  @ 303)    Test 18
S_Test_18    (A1    @ 312)    Significant? Test18
Test_19      (F9.3  @ 313)    Test 19
S_Test_19    (A1    @ 322)    Significant? Test19
Test_20      (F9.3  @ 323)    Test 20
S_Test_20    (A1    @ 332)    Significant? Test20
Test_21      (F9.3  @ 333)    Test 21
S_Test_21    (A1    @ 342)    Significant? Test21
Test_22      (F9.3  @ 343)    Test 22
S_Test_22    (A1    @ 352)    Significant? Test22
Test_23      (F9.3  @ 353)    Test 23
S_Test_23    (A1    @ 362)    Significant? Test23
Test_24      (F9.3  @ 363)    Test 24
S_Test_24    (A1    @ 372)    Significant? Test24
Test_25      (F9.3  @ 373)    Test 25
S_Test_25    (A1    @ 382)    Significant? Test25
                    - 382
```

```
File_ID      (A3    @    1)    File ID Code: "FO "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Pseudo_Crs   (I3    @   92)    Pseudo Course Number
Patient      (A12   @   95)    *Patient
Off_Treat    (D8    @  107)    Date Off Treatment
Off_Follow   (D8    @  115)    Date Off Follow-up
Reason       (A1    @  123)    Reason Off Study
Oth_Reason   (A24   @  124)    Reason if Other
Best_Resp    (A2    @  148)    Best Response
Date_Best    (D8    @  150)    Best Response Date
Date_Prog    (D8    @  158)    Date of Progression
                    -  165
```

```
File 'FP-T310'    Follow-Up


File_ID     (A3   @    1)   File ID Code: "FP "
Version     (A4   @    4)   Layout Version "T310"
Extracted   (D8   @    8)   Extraction Date
Entered_By  (A8   @   16)   Data Entry Clerk
Created     (D8   @   24)   Record Creation Date
Changed     (D8   @   32)   Last Change Date
Chg_Time    (T6   @   40)   Last Change Time
Filler      (A1   @   46)   (reserved)
Del_Flag    (A1   @   47)   Deletion Flag
Del_Date    (D8   @   48)   Deletion Date (if deleted)
Protocol    (A12  @   56)   *Protocol ID
Inst_ID     (A8   @   68)   Institution Code
Entry_Pass  (A1   @   76)   Multi-Entry Pass
Touch_Date  (D8   @   77)   Touched Date
Touch_Time  (I7   @   85)   Touched Timer
Pseudo_Crs  (I3   @   92)   Pseudo Course Number
Patient     (A12  @   95)   *Patient
Last_Cont   (D8   @  107)   *Last Contact Date
Status      (A1   @  115)   Patient Status
Specify     (A24  @  116)   Status if Other
                  -  139
```

```
File 'HM-T310'    Labs: Hematology


File_ID      (A3    @    1)    File ID Code: "HM "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
Hemoglobin   (F9.3  @  131)    Hemoglobin
S_Hemoglob   (A1    @  140)    Significant? Hemoglobin
Hematocrit   (F9.3  @  141)    Hematocrit
S_Hematocr   (A1    @  150)    Significant? Hematocrit
WBC          (F9.3  @  151)    WBC
S_WBC        (A1    @  160)    Significant? WBC
Neutrophil   (F9.3  @  161)    Neutrophils
S_Neutros    (A1    @  170)    Significant? Neutrophils
Lymphocyte   (F9.3  @  171)    Lymphocytes
S_Lymphos    (A1    @  180)    Significant? Lymphocytes
Basophils    (F9.3  @  181)    Basophils
S_Basos      (A1    @  190)    Significant? Basophils
Monocytes    (F9.3  @  191)    Monocytes
S_Monos      (A1    @  200)    Significant? Monocytes
Eosinophil   (F9.3  @  201)    Eosinophils
S_Eos        (A1    @  210)    Significant? Eosinophils
Bands        (F9.3  @  211)    Bands
S_Bands      (A1    @  220)    Significant? Bands
Blasts       (F9.3  @  221)    Blasts
S_Blasts     (A1    @  230)    Significant? Blasts
Atyp_Lymph   (F9.3  @  231)    Atypical Lymphocytes
S_Atyp_Lym   (A1    @  240)    Significant? Atypical Lymphs
Other_Diff   (F9.3  @  241)    Other Diff
S_Oth_Diff   (A1    @  250)    Significant? Other-Diff
Platelets    (F9.3  @  251)    Platelets
S_Plates     (A1    @  260)    Significant? Platelets
ANC          (F9.3  @  261)    ANC
S_ANC        (A1    @  270)    Significant? ANC
RBC          (F9.3  @  271)    RBC
S_RBC        (A1    @  280)    Significant? RBC
Reticulo     (F9.3  @  281)    Reticulocytes
S_Reticulo   (A1    @  290)    Significant? Reticulocytes
ESR          (F9.3  @  291)    ESR
```

```
S_ESR        (A1   @ 300)   Significant? ESR
PT           (F9.3 @ 301)   Prothrombin Time
S_PT         (A1   @ 310)   Significant? Pro. Time
PTT          (F9.3 @ 311)   Partial Thromboplastin Time
S_PTT        (A1   @ 320)   Significant? Par Throm Time
                   - 320
```

```
      File 'IE-T310'    Infection Episode


      File_ID      (A3    @    1)    File ID Code: "IE "
      Version      (A4    @    4)    Layout Version "T310"
      Extracted    (D8    @    8)    Extraction Date
      Entered_By   (A8    @   16)    Data Entry Clerk
      Created      (D8    @   24)    Record Creation Date
      Changed      (D8    @   32)    Last Change Date
      Chg_Time     (T6    @   40)    Last Change Time
      Filler       (A1    @   46)    (reserved)
      Del_Flag     (A1    @   47)    Deletion Flag
      Del_Date     (D8    @   48)    Deletion Date (if deleted)
      Protocol     (A12   @   56)    *Protocol ID
      Inst_ID      (A8    @   68)    Institution Code
      Entry_Pass   (A1    @   76)    Multi-Entry Pass
      Touch_Date   (D8    @   77)    Touched Date
      Touch_Time   (I7    @   85)    Touched Timer
      Course_Num   (I3    @   92)    Course Number
      Patient      (A12   @   95)    *Patient
      Onset_Date   (D8    @  107)    *Onset Date
      Infection    (A20   @  115)    *Infection
      Prim_Site    (A20   @  135)    Primary Site
      Inf_Agent    (A24   @  155)    Infectious Agent
      Treatments   (A24   @  179)    Treatments
      Resolved     (D8    @  203)    Resolved Date
      Outcome      (A24   @  211)    Outcome
                          -  234
```

```
     File 'IP-T310'   Labs: Immune Parameters


     File_ID      (A3    @    1)    File ID Code: "IP "
     Version      (A4    @    4)    Layout Version "T310"
     Extracted    (D8    @    8)    Extraction Date
     Entered_By   (A8    @   16)    Data Entry Clerk
     Created      (D8    @   24)    Record Creation Date
     Changed      (D8    @   32)    Last Change Date
     Chg_Time     (T6    @   40)    Last Change Time
     Filler       (A1    @   46)    (reserved)
     Del_Flag     (A1    @   47)    Deletion Flag
     Del_Date     (D8    @   48)    Deletion Date (if deleted)
     Protocol     (A12   @   56)    *Protocol ID
     Inst_ID      (A8    @   68)    Institution Code
     Entry_Pass   (A1    @   76)    Multi-Entry Pass
     Touch_Date   (D8    @   77)    Touched Date
     Touch_Time   (I7    @   85)    Touched Timer
     Course_Num   (I3    @   92)    Course Number
     Patient      (A12   @   95)    *Patient
     Lab_Date     (D8    @  107)    *Lab Test Date
     Lab_Time     (T4    @  115)    *Lab Test Time
     Lab_Group    (A8    @  119)    Lab Code Group
     Lab_Code     (I4    @  127)    Lab Code
     Lymphocyte   (F9.3  @  131)    Lymphocyte Blasts
     S_Lymphs     (A1    @  140)    Significant? Lymphocyte Blasts
     B_Cell_Lev   (F9.3  @  141)    B-Cell Level
     S_B_Cell_L   (A1    @  150)    Significant? B-Cell Level
     T_Cell_Tot   (F9.3  @  151)    T-Cell Total
     S_T_Cell_T   (A1    @  160)    Significant? T-Cell Total
     T_Cell_Hlp   (F9.3  @  161)    T-Cell Helper
     S_T_Cell_H   (A1    @  170)    Significant? T-Cell Helper
     T_Cell_Sup   (F9.3  @  171)    T-Cell Suppressor
     S_T_Cell_S   (A1    @  180)    Significant? T-Cell Suppressor
     T_Cell_DTH   (F9.3  @  181)    T-Cell DTH
     S_T_Cell_D   (A1    @  190)    Significant? T-Cell DTH
     T_Cell_CTL   (F9.3  @  191)    T-Cell CTL
     S_T_Cell_C   (A1    @  200)    Significant? T-Cell CTL
     NK_Activ     (F9.3  @  201)    NK Activity
     S_NK_Activ   (A1    @  210)    Significant? NK Activity
     ADCC         (F9.3  @  211)    ADCC
     S_ADCC       (A1    @  220)    Significant? ADCC
     Cytotox      (F9.3  @  221)    Cytotoxicity
     S_Cytotox    (A1    @  230)    Significant? Cytotoxicity
     Cytostasis   (F9.3  @  231)    Cytostasis
     S_Cytostas   (A1    @  240)    Significant? Cytostasis
     Perox_Gen    (F9.3  @  241)    Peroxide Generation
     S_Perox_G    (A1    @  250)    Significant? Peroxide Generation
     Interferon   (F9.3  @  251)    Serum Interferon
     S_Interfer   (A1    @  260)    Significant? Serum Interferon
                         -  260
```

```
File 'LA-T310'    Late Adverse Events


File_ID      (A3    @    1)    File ID Code: "LA "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Follow_Up    (D8    @  107)    *Date Follow-up Began
Toxicity     (A33   @  115)    *Toxicity
Onset_Date   (D8    @  148)    *Onset Date
Tox_Code     (I10   @  156)    Tox Type Code
Resolved     (D8    @  166)    Resolved
AER_Filed    (A1    @  174)    AER Filed
Grade        (I2    @  175)    Grade
Attribut     (A1    @  177)    Attribution (Relation)
Dose_Limit   (A1    @  178)    Dose Limiting Toxicity
Serious      (I2    @  179)    Serious
Action       (A1    @  181)    Action
Therapy      (A1    @  182)    Therapy
Outcome      (A1    @  183)    Outcome
                     -  183
```

```
File 'LL-T310'    Labs: Specific Literal Labs


File_ID      (A3    @    1)    File ID Code: "LL "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Test     (A8    @  119)    *Lab Test
Body_Site    (A8    @  127)    *Body Site
Lab_Group    (A8    @  135)    Lab Code Group
Lab_Code     (I4    @  143)    Lab Code
Norm_Abnor   (A1    @  147)    Normal/Abnormal
Result       (A64   @  148)    Result
Result_2     (A64   @  212)    Result Continued
S_Result     (A1    @  276)    Significant? Result Continued
                    -  276
```

```
File 'LS-T310'    Lesion Description


File_ID      (A3    @    1)    File ID Code: "LS "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Pseudo_Crs   (I3    @   92)    Pseudo Course Number
Patient      (A12   @   95)    *Patient
Lesion       (I2    @  107)    *Lesion
Organ        (A8    @  109)    Organ
Descrip      (A32   @  117)    Description
Prev_Rad     (A1    @  149)    Previous Radiation
Category     (A1    @  150)    Category
Followed     (A1    @  151)    Followed for Response
                    -  151
```

```
File 'LX-T310'    Labs: Special Literal Results


File_ID      (A3    @    1)    File ID Code: "LX "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Panel        (I2    @  119)    *Panel
Field_1      (A64   @  121)    Field 1
Field_2      (A64   @  185)    Field 2
Field_3      (A64   @  249)    Field 3
Field_4      (A64   @  313)    Field 4
Field_5      (A64   @  377)    Field 5
Field_6      (A64   @  441)    Field 6
Field_7      (A64   @  505)    Field 7
Field_8      (A64   @  569)    Field 8
Field_9      (A64   @  633)    Field 9
Field_10     (A64   @  697)    Field 10
                    -  760
```

```
       File 'MH-T310'   Baseline Medical History


       File_ID      (A3    @    1)    File ID Code: "MH "
       Version      (A4    @    4)    Layout Version "T310"
       Extracted    (D8    @    8)    Extraction Date
       Entered_By   (A8    @   16)    Data Entry Clerk
       Created      (D8    @   24)    Record Creation Date
       Changed      (D8    @   32)    Last Change Date
       Chg_Time     (T6    @   40)    Last Change Time
       Filler       (A1    @   46)    (reserved)
       Del_Flag     (A1    @   47)    Deletion Flag
       Del_Date     (D8    @   48)    Deletion Date (if deleted)
       Protocol     (A12   @   56)    *Protocol ID
       Inst_ID      (A8    @   68)    Institution Code
       Entry_Pass   (A1    @   76)    Multi-Entry Pass
       Touch_Date   (D8    @   77)    Touched Date
       Touch_Time   (I7    @   85)    Touched Timer
       Pseudo_Crs   (I3    @   92)    Pseudo Course Number
       Patient      (A12   @   95)    *Patient
       Exam_Date    (D8    @  107)    *Exam Date
       HEENT        (A64   @  115)    H/E/E/N/T
       HEENT_2      (A64   @  179)    H/E/E/N/T continued
       Neck         (A64   @  243)    Neck
       Neck_2       (A64   @  307)    Neck continued
       Respirat     (A64   @  371)    Respiratory
       Respirat_2   (A64   @  435)    Respiratory continued
       Cardio       (A64   @  499)    Cardiovascular
       Cardio_2     (A64   @  563)    Cardiovascular continued
       Gastro       (A64   @  627)    Gastrointestinal
       Gastro_2     (A64   @  691)    Gastrointestinal continued
       MuscSkel     (A64   @  755)    Musculoskeletal
       MuscSkel_2   (A64   @  819)    Musculoskeletal continued
       Dermat       (A64   @  883)    Dermatologic
       Dermat_2     (A64   @  947)    Dermatologic continued
       Hem_Lym      (A64   @ 1011)    Hematopoietic/Lymph
       Hem_Lym_2    (A64   @ 1075)    Hematopoietic/Lymph continued
       Endo_Met     (A64   @ 1139)    Endocrine/Metabolic
       Endo_Met_2   (A64   @ 1203)    Endocrine/Metabolic continued
       Urinary      (A64   @ 1267)    Urinary
       Urinary_2    (A64   @ 1331)    Urinary continued
       Genital      (A64   @ 1395)    Genitalia
       Genital_2    (A64   @ 1459)    Genitalia continued
       Breasts      (A64   @ 1523)    Breasts
       Breasts_2    (A64   @ 1587)    Breasts continued
       Pelvis       (A64   @ 1651)    Pelvis
       Pelvis_2     (A64   @ 1715)    Pelvis continued
       Abdomen      (A64   @ 1779)    Abdomen
       Abdomen_2    (A64   @ 1843)    Abdomen continued
       Neurolog     (A64   @ 1907)    Neurologic
       Neurolog_2   (A64   @ 1971)    Neurologic continued
       Psychol      (A64   @ 2035)    Psychologic
       Psychol_2    (A64   @ 2099)    Psychologic continued
       Immune       (A64   @ 2163)    Immune
       Immune_2     (A64   @ 2227)    Immune continued
       Other        (A64   @ 2291)    Other
       Other_2      (A64   @ 2355)    Other continued
                           -2418
```

```
File 'OU-T310'    Labs: Other Urinalysis


File_ID      (A3    @    1)    File ID Code: "OU "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
Calcium      (F9.3  @  131)    Calcium
S_Calcium    (A1    @  140)    Significant? Calcium
Chloride     (F9.3  @  141)    Chloride
S_Chloride   (A1    @  150)    Significant? Chloride
Osmolality   (F9.3  @  151)    Osmolality
S_Osmolal    (A1    @  160)    Significant? Osmolality
Oxalate      (F9.3  @  161)    Oxalate
S_Oxalate    (A1    @  170)    Significant? Oxalate
Potassium    (F9.3  @  171)    Potassium
S_Potass     (A1    @  180)    Significant? Potassium
Prot_Album   (F9.3  @  181)    Protein Albumin
S_Prot_Alb   (A1    @  190)    Significant? Protein Albumin
Prot_Alph1   (F9.3  @  191)    Protein Alpha1
S_Prot_Al1   (A1    @  200)    Significant? Protein Alpha1
Prot_Alph2   (F9.3  @  201)    Protein Alpha2
S_Prot_Al2   (A1    @  210)    Significant? Protein Alpha2
Prot_Beta    (F9.3  @  211)    Protein Beta
S_Prot_Bet   (A1    @  220)    Significant? Protein Beta
Prot_Gamma   (F9.3  @  221)    Protein Gamma
S_Prot_Gam   (A1    @  230)    Significant? Protein Gamma
Sodium       (F9.3  @  231)    Sodium
S_Sodium     (A1    @  240)    Significant? Sodium
Urea_Nitro   (F9.3  @  241)    Urea Nitrogen
S_Urea_Nit   (A1    @  250)    Significant? Urea Nitrogen
Uric_Acid    (F9.3  @  251)    Uric Acid
S_Uric_Ac    (A1    @  260)    Significant? Uric Acid
                    -  260
```

```
File 'PE-T310'    Physical Exam


File_ID      (A3    @    1)    File ID Code: "PE "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Exam_Date    (D8    @  107)    *Exam Date
HEENT        (A1    @  115)    H/E/E/N/T Flag
HEENT_1      (A64   @  116)    H/E/E/N/T Note 1
HEENT_2      (A64   @  180)    H/E/E/N/T Note 2
Neck         (A1    @  244)    Neck Flag
Neck_1       (A64   @  245)    Neck Note 1
Neck_2       (A64   @  309)    Neck Note 2
Respirat     (A1    @  373)    Respiratory Flag
Respirat_1   (A64   @  374)    Respiratory Note 1
Respirat_2   (A64   @  438)    Respiratory Note 2
Cardio       (A1    @  502)    Cardiovascular Flag
Cardio_1     (A64   @  503)    Cardiovascular Note 1
Cardio_2     (A64   @  567)    Cardiovascular Note 2
Gastro       (A1    @  631)    Gastrointestinal Flag
Gastro_1     (A64   @  632)    Gastrointestinal Note 1
Gastro_2     (A64   @  696)    Gastrointestinal Note 2
MuscSkel     (A1    @  760)    Musculoskeletal Flag
MuscSkel_1   (A64   @  761)    Musculoskeletal Note 1
MuscSkel_2   (A64   @  825)    Musculoskeletal Note 2
Dermat       (A1    @  889)    Dermatologic Flag
Dermat_1     (A64   @  890)    Dermatologic Note 1
Dermat_2     (A64   @  954)    Dermatologic Note 2
Hem_Lym      (A1    @ 1018)    Hematopoietic/Lymph Flag
Hem_Lym_1    (A64   @ 1019)    Hematopoietic/Lymph Note 1
Hem_Lym_2    (A64   @ 1083)    Hematopoietic/Lymph Note 2
Endo_Met     (A1    @ 1147)    Endocrine/Metabolic Flag
Endo_Met_1   (A64   @ 1148)    Endocrine/Metabolic Note 1
Endo_Met_2   (A64   @ 1212)    Endocrine/Metabolic Note 2
Urinary      (A1    @ 1276)    Urinary Flag
Urinary_1    (A64   @ 1277)    Urinary Note 1
Urinary_2    (A64   @ 1341)    Urinary Note 2
Genital      (A1    @ 1405)    Genitalia Flag
Genital_1    (A64   @ 1406)    Genitalia Note 1
Genital_2    (A64   @ 1470)    Genitalia Note 2
Breasts      (A1    @ 1534)    Breasts Flag
Breasts_1    (A64   @ 1535)    Breasts Note 1
Breasts_2    (A64   @ 1599)    Breasts Note 2
```

```
Pelvis      (A1    @1663)   Pelvis Flag
Pelvis_1    (A64   @1664)   Pelvis Note 1
Pelvis_2    (A64   @1728)   Pelvis Note 2
Abdomen     (A1    @1792)   Abdomen Flag
Abdomen_1   (A64   @1793)   Abdomen Note 1
Abdomen_2   (A64   @1857)   Abdomen Note 2
Neurolog    (A1    @1921)   Neurologic Flag
Neurolog_1  (A64   @1922)   Neurologic Note 1
Neurolog_2  (A64   @1986)   Neurologic Note 2
Psychol     (A1    @2050)   Psychologic Flag
Psychol_1   (A64   @2051)   Psychologic Note 1
Psychol_2   (A64   @2115)   Psychologic Note 2
Other       (A1    @2179)   Other Flag
Other_1     (A64   @2180)   Other Note 1
Other_2     (A64   @2244)   Other Note 2
                   -2307
```

```
File 'PH-T310'    Comments


File_ID      (A3     @    1)    File ID Code: "PH "
Version      (A4     @    4)    Layout Version "T310"
Extracted    (D8     @    8)    Extraction Date
Entered_By   (A8     @   16)    Data Entry Clerk
Created      (D8     @   24)    Record Creation Date
Changed      (D8     @   32)    Last Change Date
Chg_Time     (T6     @   40)    Last Change Time
Filler       (A1     @   46)    (reserved)
Del_Flag     (A1     @   47)    Deletion Flag
Del_Date     (D8     @   48)    Deletion Date (if deleted)
Protocol     (A12    @   56)    *Protocol ID
Inst_ID      (A8     @   68)    Institution Code
Entry_Pass   (A1     @   76)    Multi-Entry Pass
Touch_Date   (D8     @   77)    Touched Date
Touch_Time   (I7     @   85)    Touched Timer
Course_Num   (I3     @   92)    Course Number
Patient      (A12    @   95)    *Patient
Note_Date    (D8     @  107)    *Note Date
Note_Type    (A3     @  115)    *Note Type
Note         (A1024  @  118)    Note
                     -1141
```

```
File 'PK-T310'    Pharmcokinetics


File_ID      (A3    @    1)    File ID Code: "PK "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Study_Drug   (A8    @  107)    *Study Drug
DosingDate   (D8    @  115)    *Dosing Date
Start_Time   (T4    @  123)    *Start Time
Specimen     (A8    @  127)    *Specimen
Duration     (I5    @  135)    *Duration
Par_Asy_1    (F8.3  @  140)    Parent Drug Assay 1
Par_Un_As1   (A10   @  148)    Units (Par Assay 1)
Par_Asy_2    (F8.3  @  158)    Parent Drug Assay 2
Par_Un_As2   (A10   @  166)    Units (Par Assay 2)
Par_Conc     (F8.3  @  176)    Par Drug Mean Concentration
Par_Units    (A10   @  184)    Units (Par Mean Conc)
Met_Asy_1    (F8.3  @  194)    Metabolite Assay 1
Met_Un_As1   (A10   @  202)    Units (Met Assay 1)
Met_Asy_2    (F8.3  @  212)    Metabolite Assay 2
Met_Un_As2   (A10   @  220)    Units (Met Assay 2)
Met_Conc     (F8.3  @  230)    Met Mean Concentration
Met_Units    (A10   @  238)    Units (Met Mean Conc)
                     -  247
```

```
       File 'PL-T310'    Labs: Physical Labs


       File_ID      (A3    @    1)    File ID Code: "PL "
       Version      (A4    @    4)    Layout Version "T310"
       Extracted    (D8    @    8)    Extraction Date
       Entered_By   (A8    @   16)    Data Entry Clerk
       Created      (D8    @   24)    Record Creation Date
       Changed      (D8    @   32)    Last Change Date
       Chg_Time     (T6    @   40)    Last Change Time
       Filler       (A1    @   46)    (reserved)
       Del_Flag     (A1    @   47)    Deletion Flag
       Del_Date     (D8    @   48)    Deletion Date (if deleted)
       Protocol     (A12   @   56)    *Protocol ID
       Inst_ID      (A8    @   68)    Institution Code
       Entry_Pass   (A1    @   76)    Multi-Entry Pass
       Touch_Date   (D8    @   77)    Touched Date
       Touch_Time   (I7    @   85)    Touched Timer
       Course_Num   (I3    @   92)    Course Number
       Patient      (A12   @   95)    *Patient
       Lab_Date     (D8    @  107)    *Lab Test Date
       Lab_Time     (T4    @  115)    *Lab Test Time
       Lab_Group    (A8    @  119)    Lab Code Group
       Lab_Code     (I4    @  127)    Lab Code
       Perf_Stat    (F9.3  @  131)    Performance Status
       S_Perf       (A1    @  140)    Significant? Performance Status
       Height       (F9.3  @  141)    Height
       S_Height     (A1    @  150)    Significant? Height
       Weight       (F9.3  @  151)    Weight
       S_Weight     (A1    @  160)    Significant? Weight
       Temperatur   (F9.3  @  161)    Temperature
       S_Temp       (A1    @  170)    Significant? Temperature
       Pulse        (F9.3  @  171)    Pulse
       S_Pulse      (A1    @  180)    Significant? Pulse
       Resp_Rate    (F9.3  @  181)    Respiration Rate
       S_Resp       (A1    @  190)    Significant? Respiration rate
       Sys_BP       (F9.3  @  191)    Systolic Blood Pressure
       S_Sys_Bp     (A1    @  200)    Significant? Systolic BP
       Dias_BP      (F9.3  @  201)    Diastolic Blood Pressure
       S_Dias_BP    (A1    @  210)    Significant? Diastolic BP
       Blood_Frsh   (F9.3  @  211)    Whole Blood (fresh)
       S_Bld_Frsh   (A1    @  220)    Significant? Whole blood-fresh
       Blood_Strd   (F9.3  @  221)    Whole Blood (stored)
       S_Bld_Strd   (A1    @  230)    Significant? Whole blood-stored
       P_RC_Fresh   (F9.3  @  231)    Fresh Red Cells (packed)
       S_P_RC_Fre   (A1    @  240)    Significant? Fresh red cells-pck
       P_RC_Strd    (F9.3  @  241)    Strd Red Cells (packed)
       S_P_RC_Str   (A1    @  250)    Significant? Strd red cells-pck
       P_WBC        (F9.3  @  251)    Packed White Cells
       S_P_WBC      (A1    @  260)    Significant? Packed white cells
       Platelets    (F9.3  @  261)    Platelets
       S_Plates     (A1    @  270)    Significant? Platelets
       PreEj_Per    (F9.3  @  271)    Pre-Ejection Period
       S_PreEj_Pe   (A1    @  280)    Significant? Pre-ejection period
       LV_Ej_Time   (F9.3  @  281)    LV Ejection Time
       S_LV_Ej_Tm   (A1    @  290)    Significant? LV ejection time
       LV_Ej_Frac   (F9.3  @  291)    LV Ejection Fraction
```

```
S_LV_Ej_Fr  (A1    @ 300)   Significant? LV ejection frac
                    - 300
```

```
File 'PR-T310'    Prior Radiation Supplement


File_ID       (A3    @    1)    File ID Code: "PR "
Version       (A4    @    4)    Layout Version "T310"
Extracted     (D8    @    8)    Extraction Date
Entered_By    (A8    @   16)    Data Entry Clerk
Created       (D8    @   24)    Record Creation Date
Changed       (D8    @   32)    Last Change Date
Chg_Time      (T6    @   40)    Last Change Time
Filler        (A1    @   46)    (reserved)
Del_Flag      (A1    @   47)    Deletion Flag
Del_Date      (D8    @   48)    Deletion Date (if deleted)
Protocol      (A12   @   56)    *Protocol ID
Inst_ID       (A8    @   68)    Institution Code
Entry_Pass    (A1    @   76)    Multi-Entry Pass
Touch_Date    (D8    @   77)    Touched Date
Touch_Time    (I7    @   85)    Touched Timer
Pseudo_Crs    (I3    @   92)    Pseudo Course Number
Patient       (A12   @   95)    *Patient
Start_Date    (D8    @  107)    *Start Date
Radiation     (A24   @  115)    *Radiation
Item          (I8    @  139)    *Additional Arbitrary Sequencer
Last_Date     (D8    @  147)    Last Dose Date
Site          (A24   @  155)    Site
Schedule      (A24   @  179)    Schedule
Dose          (A8    @  203)    Dose
Units         (A8    @  211)    Units
Response      (A2    @  219)    Response
Thrpy_Code    (A2    @  221)    Radiation Therapy Extent Code
                     -  222
```

```
File 'PS-T310'    Prior Surgery Supplement


File_ID       (A3    @    1)    File ID Code: "PS "
Version       (A4    @    4)    Layout Version "T310"
Extracted     (D8    @    8)    Extraction Date
Entered_By    (A8    @   16)    Data Entry Clerk
Created       (D8    @   24)    Record Creation Date
Changed       (D8    @   32)    Last Change Date
Chg_Time      (T6    @   40)    Last Change Time
Filler        (A1    @   46)    (reserved)
Del_Flag      (A1    @   47)    Deletion Flag
Del_Date      (D8    @   48)    Deletion Date (if deleted)
Protocol      (A12   @   56)    *Protocol ID
Inst_ID       (A8    @   68)    Institution Code
Entry_Pass    (A1    @   76)    Multi-Entry Pass
Touch_Date    (D8    @   77)    Touched Date
Touch_Time    (I7    @   85)    Touched Timer
Pseudo_Crs    (I3    @   92)    Pseudo Course Number
Patient       (A12   @   95)    *Patient
Date          (D8    @  107)    *Date
Proc_Site     (A24   @  115)    *Procedure/Site
Item          (I8    @  139)    *Additional Arbitrary Sequencer
Findings      (A24   @  147)    Findings
Resid_Dis     (A24   @  171)    Extent Residual Disease
Surg_Code     (A1    @  195)    Surgery Type Code (Therapeutic?)
                     -  195
```

```
File 'PT-T310'    Prior Therapy Supplement


File_ID      (A3    @    1)    File ID Code: "PT "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Pseudo_Crs   (I3    @   92)    Pseudo Course Number
Patient      (A12   @   95)    *Patient
Start_Date   (D8    @  107)    *First Dose Date
Agent        (A24   @  115)    *Agent
Item         (I8    @  139)    *Additional Arbitrary Sequencer
Stop_Date    (D8    @  147)    Last Dose Date
Schedule     (A24   @  155)    Schedule
Total_Dose   (A8    @  179)    Total Dose
Units        (A12   @  187)    Units
Response     (A2    @  199)    Response
Thrpy_Code   (A2    @  201)    Therapy Type Code
                    -  202
```

```
       File 'RC-T310'   Labs: Red Cell Indices


       File_ID      (A3    @    1)    File ID Code: "RC "
       Version      (A4    @    4)    Layout Version "T310"
       Extracted    (D8    @    8)    Extraction Date
       Entered_By   (A8    @   16)    Data Entry Clerk
       Created      (D8    @   24)    Record Creation Date
       Changed      (D8    @   32)    Last Change Date
       Chg_Time     (T6    @   40)    Last Change Time
       Filler       (A1    @   46)    (reserved)
       Del_Flag     (A1    @   47)    Deletion Flag
       Del_Date     (D8    @   48)    Deletion Date (if deleted)
       Protocol     (A12   @   56)    *Protocol ID
       Inst_ID      (A8    @   68)    Institution Code
       Entry_Pass   (A1    @   76)    Multi-Entry Pass
       Touch_Date   (D8    @   77)    Touched Date
       Touch_Time   (I7    @   85)    Touched Timer
       Course_Num   (I3    @   92)    Course Number
       Patient      (A12   @   95)    *Patient
       Lab_Date     (D8    @  107)    *Lab Test Date
       Lab_Time     (T4    @  115)    *Lab Test Time
       Lab_Group    (A8    @  119)    Lab Code Group
       Lab_Code     (I4    @  127)    Lab Code
       MCH          (F9.3  @  131)    MCH
       S_MCH        (A1    @  140)    Significant? MCH
       MCHC         (F9.3  @  141)    MCHC
       S_MCHC       (A1    @  150)    Significant? MCHC
       MCV          (F9.3  @  151)    MCV
       S_MCV        (A1    @  160)    Significant? MCV
       Bleed_Time   (F9.3  @  161)    Bleeding Time
       S_Bleed_Tm   (A1    @  170)    Significant? Bleeding Time
       Clot_Retr    (F9.3  @  171)    Clot Retraction Screen
       S_Clot_Ret   (A1    @  180)    Significant? Clot Retraction Scn
       Semi_Quant   (F9.3  @  181)    Semi Quantitative
       S_Semi_Qnt   (A1    @  190)    Significant? Semi Quantitative
       Quant        (F9.3  @  191)    Quantitative
       S_Quant      (A1    @  200)    Significant? Quantitative
       Clot_Time    (F9.3  @  201)    Clotting Time
       S_Clot_Tm    (A1    @  210)    Significant? Clotting Time
       FDP          (F9.3  @  211)    Fibrin Degradation Product
       S_Fibr_Dgr   (A1    @  220)    Significant? Fibrin Degrad Prod
       Fibrinogen   (F9.3  @  221)    Fibrinogen
       S_Fibrin     (A1    @  230)    Significant? Fibrinogen
       Thromb_Tim   (F9.3  @  231)    Thrombin Time
       S_Thromb_T   (A1    @  240)    Significant? Thrombin Time
       Nucl_RBCs    (F9.3  @  241)    Nucleated RBCs
       S_Nucl_RBC   (A1    @  250)    Significant? Nucleated RBCs
       Complement   (F9.3  @  251)    Complement
       S_Complem    (A1    @  260)    Significant? Complement
       Coombs_Tst   (F9.3  @  261)    Coombs Test
       S_Coombs     (A1    @  270)    Significant? Coombs Test
       ANF          (F9.3  @  271)    AntiNuclear Factor (ANF)
       S_ANF        (A1    @  280)    Significant? ANF
       Tot_Ser_Pr   (F9.3  @  281)    Total Serum Protein
       S_T_SerPro   (A1    @  290)    Significant? Total Serum Protein
       Albumin      (F9.3  @  291)    Albumin
```

```
S_Albumin   (A1    @ 300)    Significant? Albumin
Alpha1      (F9.3  @ 301)    Alpha1
S_Alpha1    (A1    @ 310)    Significant? Alpha1
Alpha2      (F9.3  @ 311)    Alpha2
S_Alpha2    (A1    @ 320)    Significant? Alpha2
Beta        (F9.3  @ 321)    Beta
S_Beta      (A1    @ 330)    Significant? Beta
Gamma       (F9.3  @ 331)    Gamma
S_Gamma     (A1    @ 340)    Significant? Gamma
                   - 340
```

```
        File 'RF-T310'   Labs: Respiratory Function


        File_ID     (A3    @    1)    File ID Code: "RF "
        Version     (A4    @    4)    Layout Version "T310"
        Extracted   (D8    @    8)    Extraction Date
        Entered_By  (A8    @   16)    Data Entry Clerk
        Created     (D8    @   24)    Record Creation Date
        Changed     (D8    @   32)    Last Change Date
        Chg_Time    (T6    @   40)    Last Change Time
        Filler      (A1    @   46)    (reserved)
        Del_Flag    (A1    @   47)    Deletion Flag
        Del_Date    (D8    @   48)    Deletion Date (if deleted)
        Protocol    (A12   @   56)    *Protocol ID
        Inst_ID     (A8    @   68)    Institution Code
        Entry_Pass  (A1    @   76)    Multi-Entry Pass
        Touch_Date  (D8    @   77)    Touched Date
        Touch_Time  (I7    @   85)    Touched Timer
        Course_Num  (I3    @   92)    Course Number
        Patient     (A12   @   95)    *Patient
        Lab_Date    (D8    @  107)    *Lab Test Date
        Lab_Time    (T4    @  115)    *Lab Test Time
        Lab_Group   (A8    @  119)    Lab Code Group
        Lab_Code    (I4    @  127)    Lab Code
        Acidity     (F9.3  @  131)    Acidity (pH)
        S_Acidity   (A1    @  140)    Significant? Acidity
        Part_CO2    (F9.3  @  141)    Partial CO2 Pressure
        S_Part_CO2  (A1    @  150)    Significant? Part CO2 Pressure
        Partial_O2  (F9.3  @  151)    Partial Oxygen Pressure
        S_Part_O2   (A1    @  160)    Significant? Part. Oxygen Pres
        Bicarb      (F9.3  @  161)    Bicarbonate
        S_Bicarb    (A1    @  170)    Significant? Bicarbonate
        Base_Exc    (F9.3  @  171)    Base Excess (only if positive)
        S_Base_Exc  (A1    @  180)    Significant? Base Excess
        Base_Def    (F9.3  @  181)    -Base Excess (only if negative)
        S_Base_Def  (A1    @  190)    Significant? Base Deficit
        Oxygen_Sat  (F9.3  @  191)    Oxygen Saturation
        S_Oxygen    (A1    @  200)    Significant? Oxygen Saturation
        Carb_Monox  (F9.3  @  201)    Carbon Monoxide
        S_CO        (A1    @  210)    Significant? Carbon Monoxide
        Methemoglo  (F9.3  @  211)    Methemoglobin
        S_Methemog  (A1    @  220)    Significant? Methemoglobin
        Vital_Cap   (F9.3  @  221)    Vital Capacity
        S_Vit_Cap   (A1    @  230)    Significant? Vital Capacity
        Exp_Vol_1   (F9.3  @  231)    Forced Expiratory Volume FEV1
        S_Exp_Vol1  (A1    @  240)    Significant? Forced Exp Vol 1
        Max_Cap     (F9.3  @  241)    Maximum Capacity
        S_Max_Cap   (A1    @  250)    Significant? Maximum Capacity
        Resid_Vol   (F9.3  @  251)    Residual Volume
        S_Res_Vol   (A1    @  260)    Significant? Residual Volume
        Tidal_Vol   (F9.3  @  261)    Tidal Volume
        S_Tid_Vol   (A1    @  270)    Significant? Tidal Volume
        Fun_Res_Cp  (F9.3  @  271)    Functional Residual Capacity
        S_F_Res_Cp  (A1    @  280)    Significant? Functional Res. Cap
        Pulm_Compl  (F9.3  @  281)    Pulmonary Compliance
        S_Pul_Comp  (A1    @  290)    Significant? Pulmonary Complianc
        Diff_Capac  (F9.3  @  291)    Diffusing Capacity (DLCO)
```

```
S_Diff_Cap  (A1    @ 300)    Significant? Diffusing Capacity
Max_Exp_Fl  (F9.3  @ 301)    Max Expiratory Flow Rate
S_Max_Exp   (A1    @ 310)    Significant? Max Exp Flow Rate
Mid_Exp_Fl  (F9.3  @ 311)    Max Mid-Expiratory Flow Rate
S_Mid_Exp   (A1    @ 320)    Significant? Max Mid-Exp Flow
                   - 320
```

```
      File 'SC-T310'    Labs: Other Serum Chemistries


      File_ID      (A3    @    1)     File ID Code: "SC "
      Version      (A4    @    4)     Layout Version "T310"
      Extracted    (D8    @    8)     Extraction Date
      Entered_By   (A8    @   16)     Data Entry Clerk
      Created      (D8    @   24)     Record Creation Date
      Changed      (D8    @   32)     Last Change Date
      Chg_Time     (T6    @   40)     Last Change Time
      Filler       (A1    @   46)     (reserved)
      Del_Flag     (A1    @   47)     Deletion Flag
      Del_Date     (D8    @   48)     Deletion Date (if deleted)
      Protocol     (A12   @   56)     *Protocol ID
      Inst_ID      (A8    @   68)     Institution Code
      Entry_Pass   (A1    @   76)     Multi-Entry Pass
      Touch_Date   (D8    @   77)     Touched Date
      Touch_Time   (I7    @   85)     Touched Timer
      Course_Num   (I3    @   92)     Course Number
      Patient      (A12   @   95)     *Patient
      Lab_Date     (D8    @  107)     *Lab Test Date
      Lab_Time     (T4    @  115)     *Lab Test Time
      Lab_Group    (A8    @  119)     Lab Code Group
      Lab_Code     (I4    @  127)     Lab Code
      Aldolase     (F9.3  @  131)     Aldolase
      S_Aldolase   (A1    @  140)     Significant? Aldolase
      Ammonia      (F9.3  @  141)     Ammonia
      S_Ammonia    (A1    @  150)     Significant? Ammonia
      Calcium      (F9.3  @  151)     Calcium-ionized
      S_Calcium    (A1    @  160)     Significant? Calcium-ionized
      Copper       (F9.3  @  161)     Copper
      S_Copper     (A1    @  170)     Significant? Copper
      Ferritin     (F9.3  @  171)     Ferritin
      S_Ferritin   (A1    @  180)     Significant? Ferritin
      HDL          (F9.3  @  181)     HDL
      S_HDL        (A1    @  190)     Significant? HDL
      Insulin      (F9.3  @  191)     Insulin
      S_Insulin    (A1    @  200)     Significant? Insulin
      Iron         (F9.3  @  201)     Iron
      S_Iron       (A1    @  210)     Significant? Iron
      Iron_Bind    (F9.3  @  211)     Iron Binding Capacity
      S_Iron_Bin   (A1    @  220)     Significant? Iron Binding Cap
      Iron_Sat     (F9.3  @  221)     Iron Saturation
      S_Iron_Sat   (A1    @  230)     Significant? Iron Saturation
      LDL          (F9.3  @  231)     LDL
      S_LDL        (A1    @  240)     Significant? LDL
      Lipase       (F9.3  @  241)     Lipase
      S_Lipase     (A1    @  250)     Significant? Lipase
      Osmolality   (F9.3  @  251)     Osmolality
      S_Osmol      (A1    @  260)     Significant? Osmolality
      Acid_Phos    (F9.3  @  261)     Acid Phosphatase
      S_Ac_Phos    (A1    @  270)     Significant? Acid Phosphatase
      Transferri   (F9.3  @  271)     Transferrin
      S_Transfer   (A1    @  280)     Significant? Transferrin
      Triglyc      (F9.3  @  281)     Triglycerides
      S_Triglyc    (A1    @  290)     Significant? Triglycerides
      T3           (F9.3  @  291)     T3
```

```
S_T3        (A1   @ 300)   Significant? T3
T4          (F9.3 @ 301)   T4
S_T4        (A1   @ 310)   Significant? T4
TSH         (F9.3 @ 311)   TSH
S_TSH       (A1   @ 320)   Significant? TSH
                  - 320
```

```
File 'SE-T310'    Labs: Serum Immune Electro


File_ID      (A3    @    1)    File ID Code: "SE "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
Ig_A         (F9.3  @  131)    Ig A
S_Ig_A       (A1    @  140)    Significant? Ig A
Ig_D         (F9.3  @  141)    Ig D
S_Ig_D       (A1    @  150)    Significant? Ig D
Ig_E         (F9.3  @  151)    Ig E
S_Ig_E       (A1    @  160)    Significant? Ig E
Ig_G         (F9.3  @  161)    Ig G
S_Ig_G       (A1    @  170)    Significant? Ig G
Ig_M         (F9.3  @  171)    Ig M
S_Ig_M       (A1    @  180)    Significant? Ig M
Monoclonal   (F9.3  @  181)    Monoclonal
S_Monoclon   (A1    @  190)    Significant? Monoclonal
Polyclonal   (F9.3  @  191)    Polyclonal
S_Polyclon   (A1    @  200)    Significant? Polyclonal
Kappa        (F9.3  @  201)    Kappa
S_Kappa      (A1    @  210)    Significant? Kappa
Lambda       (F9.3  @  211)    Lambda
S_Lambda     (A1    @  220)    Significant? Lambda
BenceJones   (F9.3  @  221)    Bence-Jones
S_BenceJon   (A1    @  230)    Significant? Bence-Jones
                    -  230
```

```
File 'SH-T310'    Scintigraphy Header


File_ID       (A3    @    1)    File ID Code: "SH "
Version       (A4    @    4)    Layout Version "T310"
Extracted     (D8    @    8)    Extraction Date
Entered_By    (A8    @   16)    Data Entry Clerk
Created       (D8    @   24)    Record Creation Date
Changed       (D8    @   32)    Last Change Date
Chg_Time      (T6    @   40)    Last Change Time
Filler        (A1    @   46)    (reserved)
Del_Flag      (A1    @   47)    Deletion Flag
Del_Date      (D8    @   48)    Deletion Date (if deleted)
Protocol      (A12   @   56)    *Protocol ID
Inst_ID       (A8    @   68)    Institution Code
Entry_Pass    (A1    @   76)    Multi-Entry Pass
Touch_Date    (D8    @   77)    Touched Date
Touch_Time    (I7    @   85)    Touched Timer
Course_Num    (I3    @   92)    Course Number
Patient       (A12   @   95)    *Patient
Trial         (I2    @  107)    *Trial
Date          (D8    @  109)    Date
Nuclide_1     (A8    @  117)    #1 Nuclide Name
Aliquot_1     (F8.3  @  125)    #1 Aliquot Count
Antibody_1    (A8    @  133)    #1 Antibody Name
Corr_CPM_1    (I9    @  141)    #1 Corrected CPM Aliquot
Tot_Adm_1     (F8.3  @  150)    #1 Total Administered
Nuclide_2     (A8    @  158)    #2 Nuclide Name
Aliquot_2     (F8.3  @  166)    #2 Aliquot Count
Antibody_2    (A8    @  174)    #2 Antibody Name
Corr_CPM_2    (I9    @  182)    #2 Corrected CPM Aliquot
Tot_Adm_2     (F8.3  @  191)    #2 Total Administered
                     -  198
```

```
File 'SR-T310'    Labs: Serology


File_ID      (A3    @    1)    File ID Code: "SR "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
PSA          (F9.3  @  131)    PSA
S_PSA        (A1    @  140)    Significant? PSA
CA125        (F9.3  @  141)    CA125
S_CA125      (A1    @  150)    Significant? CA125
CEA          (F9.3  @  151)    CEA
S_CEA        (A1    @  160)    Significant? CEA
CA19_9       (F9.3  @  161)    CA19-9
S_CA19_9     (A1    @  170)    Significant? CA19-9
CA15_3       (F9.3  @  171)    CA15-3
S_CA15_3     (A1    @  180)    Significant? CA15-3
CA27_29      (F9.3  @  181)    CA27.29
S_CA27_29    (A1    @  190)    Significant? CA27.29
AFP          (F9.3  @  191)    AFP
S_AFP        (A1    @  200)    Significant? AFP
HCG          (F9.3  @  201)    HCG
S_HCG        (A1    @  210)    Significant? HCG
HIV          (F9.3  @  211)    HIV
S_HIV        (A1    @  220)    Significant? HIV
HBs_Ag       (F9.3  @  221)    HBsAg
S_HBs_Ag     (A1    @  230)    Significant? HBsAg
Pregnant     (F9.3  @  231)    Pregnant
S_Pregnant   (A1    @  240)    Significant? Pregnant
Guiac        (F9.3  @  241)    Stool Guaiac
S_Guiac      (A1    @  250)    Significant? Stool Guaiac
                    -  250
```

```
        File 'SS-T310'    Scintigraphy Detail


        File_ID     (A3    @    1)    File ID Code: "SS "
        Version     (A4    @    4)    Layout Version "T310"
        Extracted   (D8    @    8)    Extraction Date
        Entered_By  (A8    @   16)    Data Entry Clerk
        Created     (D8    @   24)    Record Creation Date
        Changed     (D8    @   32)    Last Change Date
        Chg_Time    (T6    @   40)    Last Change Time
        Filler      (A1    @   46)    (reserved)
        Del_Flag    (A1    @   47)    Deletion Flag
        Del_Date    (D8    @   48)    Deletion Date (if deleted)
        Protocol    (A12   @   56)    *Protocol ID
        Inst_ID     (A8    @   68)    Institution Code
        Entry_Pass  (A1    @   76)    Multi-Entry Pass
        Touch_Date  (D8    @   77)    Touched Date
        Touch_Time  (I7    @   85)    Touched Timer
        Course_Num  (I3    @   92)    Course Number
        Patient     (A12   @   95)    *Patient
        Trial       (I2    @  107)    *Trial
        Sample_ID   (I3    @  109)    *Sample ID
        Source_Org  (A8    @  112)    Source Organ
        Sample_Dsc  (A18   @  120)    Sample Description
        Tiss_Class  (A1    @  138)    Tissue Class
        Gamma_Scan  (A1    @  139)    Gamma Scan Positive
        CT_Scan     (A1    @  140)    CT Scan Positive
        Biopsied    (A1    @  141)    Biopsied at Surgery
        Weight      (F8.3  @  142)    Weight of Sample
        Pct_Tumor   (F8.3  @  150)    Percent Tumor
        Corr_CPM_1  (I9    @  158)    Corrected CPM Nuclide 1
        Corr_CPM_2  (I9    @  167)    Corrected CPM Nuclide 2
                           -  175
```

```
File 'TF-T310'   Prior Treatment Summary


    File_ID      (A3   @    1)    File ID Code: "TF "
    Version      (A4   @    4)    Layout Version "T310"
    Extracted    (D8   @    8)    Extraction Date
    Entered_By   (A8   @   16)    Data Entry Clerk
    Created      (D8   @   24)    Record Creation Date
    Changed      (D8   @   32)    Last Change Date
    Chg_Time     (T6   @   40)    Last Change Time
    Filler       (A1   @   46)    (reserved)
    Del_Flag     (A1   @   47)    Deletion Flag
    Del_Date     (D8   @   48)    Deletion Date (if deleted)
    Protocol     (A12  @   56)    *Protocol ID
    Inst_ID      (A8   @   68)    Institution Code
    Entry_Pass   (A1   @   76)    Multi-Entry Pass
    Touch_Date   (D8   @   77)    Touched Date
    Touch_Time   (I7   @   85)    Touched Timer
    Pseudo_Crs   (I3   @   92)    Pseudo Course Number
    Patient      (A12  @   95)    *Patient
    Chemo_Sing   (A1   @  107)    Chemo Single Agent
    Lst_Chem_S   (D8   @  108)    Last Dose of Chemo Single
    Chemo_Mult   (A1   @  116)    Chemo Multi Agents
    Lst_Chem_M   (D8   @  117)    Last Dose of Chemo Multi
    Chemo_Unkn   (A1   @  125)    Chemo (NOS)
    Lst_Chem_U   (D8   @  126)    Last Dose of Chemo (NOS)
    Hormonal     (A1   @  134)    Hormonal
    Last_Horm    (D8   @  135)    Last Dose of Hormonal
    Surgery      (A1   @  143)    Surgery
    Last_Surg    (D8   @  144)    Last Date of Surgery
    Immunother   (A1   @  152)    Immunotherapy
    Last_Imm     (D8   @  153)    Last Dose of Immunotherapy
    Extens_Rad   (A1   @  161)    Extensive Radiation
    Lst_Ex_Rad   (D8   @  162)    Last Dose of Extensive Rad
    Lim_Rad      (A1   @  170)    Limited Radiation
    Lst_Lm_Rad   (D8   @  171)    Last Dose of Limited Rad
    Rad_Unkn     (A1   @  179)    Radiation (NOS)
    Lst_Un_Rad   (D8   @  180)    Last Dose of Radiation (NOS)
    Bone_Marr    (A1   @  188)    Bone Marrow Trans
    Last_BMT     (D8   @  189)    Last Date of Bone Marrow Trans
    Gene_Thrpy   (A1   @  197)    Gene Therapy
    Last_Gene    (D8   @  198)    Last Date of Gene Therapy
    Oth_Thrpy    (A1   @  206)    Prior Therapy (NOS)
    Last_Other   (D8   @  207)    Last Dose of Prior Therapy NOS
    Non-Cyto     (A1   @  215)    Non-Cytotoxic Chemotherapy
    Last_NoCyt   (D8   @  216)    Last Date of Non-Cyto Chemo
    Anti_RtVir   (A1   @  224)    Anti-Retro-viral
    Lst_AntRtV   (D8   @  225)    Last Date of Anti-Retro-Viral
    Antisense    (A1   @  233)    Antisense
    Lst_AntSns   (D8   @  234)    Last Date of Antisense
    Onco_Viro    (A1   @  242)    Oncolytic Virotherapy
    Lst_OncVir   (D8   @  243)    Last Date of Onco Virotherapy
    Vaccine      (A1   @  251)    Vaccine Therapy
    Last_Vac     (D8   @  252)    Last Date of Vaccine Therapy
                       -  259
```

```
File 'TX-T310'    Adverse Events


File_ID      (A3    @    1)    File ID Code: "TX "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Course       (D8    @  107)    *Course Date
Toxicity     (A33   @  115)    *Toxicity
Onset_Date   (D8    @  148)    *Onset Date
Tox_Code     (I10   @  156)    Tox Type Code
Resolved     (D8    @  166)    Resolved
AER_Filed    (A1    @  174)    AER Filed
Grade        (I2    @  175)    Grade
Attribut     (A1    @  177)    Attribution (Relation)
Dose_Limit   (A1    @  178)    Dose Limiting Toxicity
Serious      (I2    @  179)    Serious
Action       (A1    @  181)    Action
Therapy      (A1    @  182)    Therapy
Outcome      (A1    @  183)    Outcome
Apex_Nadir   (F8.3  @  184)    Apex/Nadir (obsolete)
                    -  191
```

```
File 'UE-T310'    Labs: Urine Immune Electro


File_ID      (A3    @    1)    File ID Code: "UE "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
Ig_A         (F9.3  @  131)    Ig A
S_Ig_A       (A1    @  140)    Significant? Ig A
Ig_D         (F9.3  @  141)    Ig D
S_Ig_D       (A1    @  150)    Significant? Ig D
Ig_E         (F9.3  @  151)    Ig E
S_Ig_E       (A1    @  160)    Significant? Ig E
Ig_G         (F9.3  @  161)    Ig G
S_Ig_G       (A1    @  170)    Significant? Ig G
Ig_M         (F9.3  @  171)    Ig M
S_Ig_M       (A1    @  180)    Significant? Ig M
Monoclonal   (F9.3  @  181)    Monoclonal
S_Monoclon   (A1    @  190)    Significant? Monoclonal
Polyclonal   (F9.3  @  191)    Polyclonal
S_Polyclon   (A1    @  200)    Significant? Polyclonal
Kappa        (F9.3  @  201)    Kappa
S_Kappa      (A1    @  210)    Significant? Kappa
Lambda       (F9.3  @  211)    Lambda
S_Lambda     (A1    @  220)    Significant? Lambda
BenceJones   (F9.3  @  221)    Bence-Jones
S_BenceJon   (A1    @  230)    Significant? Bence-Jones
                    -  230
```

```
File 'UL-T310'    Labs: Unanticipated Lab Data


File_ID     (A3    @    1)    File ID Code: "UL "
Version     (A4    @    4)    Layout Version "T310"
Extracted   (D8    @    8)    Extraction Date
Entered_By  (A8    @   16)    Data Entry Clerk
Created     (D8    @   24)    Record Creation Date
Changed     (D8    @   32)    Last Change Date
Chg_Time    (T6    @   40)    Last Change Time
Filler      (A1    @   46)    (reserved)
Del_Flag    (A1    @   47)    Deletion Flag
Del_Date    (D8    @   48)    Deletion Date (if deleted)
Protocol    (A12   @   56)    *Protocol ID
Inst_ID     (A8    @   68)    Institution Code
Entry_Pass  (A1    @   76)    Multi-Entry Pass
Touch_Date  (D8    @   77)    Touched Date
Touch_Time  (I7    @   85)    Touched Timer
Course_Num  (I3    @   92)    Course Number
Patient     (A12   @   95)    *Patient
Lab_Date    (D8    @  107)    *Lab Test Date
Lab_Time    (T4    @  115)    *Lab Test Time
Lab_Test    (A8    @  119)    *Lab Test
Body_Site   (A8    @  127)    *Body Site
Lab_Group   (A8    @  135)    Lab Code Group
Lab_Code    (I4    @  143)    Lab Code
Norm_Abnor  (A1    @  147)    Normal/Abnormal
Value_Type  (A1    @  148)    Type of Value (N or L)
Num_Value   (F9.3  @  149)    Numeric Value (if Type N)
Lit_Value   (A64   @  158)    Literal Value (if Type L)
Lit_Value2  (A64   @  222)    Literal Value Continued
S_Value     (A1    @  286)    Significant? Value
Units       (A12   @  287)    Units, if value is Numeric
                   -  298
```

```
File 'US-T310'    Labs: Urinalysis


File_ID      (A3    @    1)    File ID Code: "US "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Lab_Date     (D8    @  107)    *Lab Test Date
Lab_Time     (T4    @  115)    *Lab Test Time
Lab_Group    (A8    @  119)    Lab Code Group
Lab_Code     (I4    @  127)    Lab Code
Creat_Clr    (F9.3  @  131)    Creatinine Clearance
S_Creat_Cl   (A1    @  140)    Significant? Creat Clearance
Hydrogen     (F9.3  @  141)    Hydrogen Ion Concentration
S_Hydrogen   (A1    @  150)    Significant? Hydrogen Ion Conc
Sp_Gravity   (F9.3  @  151)    Specific Gravity
S_Sp_Grav    (A1    @  160)    Significant? Specific Gravity
WBCs         (F9.3  @  161)    White Blood Cells
S_WBCs       (A1    @  170)    Significant? White Blood Cells
RBCs         (F9.3  @  171)    Red Blood Cells
S_RBCs       (A1    @  180)    Significant? Red Blood Cells
Glucose      (F9.3  @  181)    Glucose
S_Glucose    (A1    @  190)    Significant? Glucose
Protein      (F9.3  @  191)    Protein
S_Protein    (A1    @  200)    Significant? Protein
Ketones      (F9.3  @  201)    Ketones
S_Ketones    (A1    @  210)    Significant? Ketones
Bile         (F9.3  @  211)    Bile
S_Bile       (A1    @  220)    Significant? Bile
Urin_Creat   (F9.3  @  221)    Urinary Creatinine
S_U_Creat    (A1    @  230)    Significant? Urinary Creatinine
Volume       (F9.3  @  231)    Volume
S_Volume     (A1    @  240)    Significant? Volume
Coll_Per     (F9.3  @  241)    Collection Period
S_Coll_Per   (A1    @  250)    Significant? Collection Period
                     -  250
```

```
File 'UX-T310'    Urinary Excretion


File_ID      (A3    @    1)    File ID Code: "UX "
Version      (A4    @    4)    Layout Version "T310"
Extracted    (D8    @    8)    Extraction Date
Entered_By   (A8    @   16)    Data Entry Clerk
Created      (D8    @   24)    Record Creation Date
Changed      (D8    @   32)    Last Change Date
Chg_Time     (T6    @   40)    Last Change Time
Filler       (A1    @   46)    (reserved)
Del_Flag     (A1    @   47)    Deletion Flag
Del_Date     (D8    @   48)    Deletion Date (if deleted)
Protocol     (A12   @   56)    *Protocol ID
Inst_ID      (A8    @   68)    Institution Code
Entry_Pass   (A1    @   76)    Multi-Entry Pass
Touch_Date   (D8    @   77)    Touched Date
Touch_Time   (I7    @   85)    Touched Timer
Course_Num   (I3    @   92)    Course Number
Patient      (A12   @   95)    *Patient
Dose_Date    (D8    @  107)    *Dose Date
Start_Time   (T4    @  115)    *Start Time
Drug         (A8    @  119)    *Drug
Coll_Date    (D8    @  127)    *Urine Collection Date
Coll_Time    (T4    @  135)    *Collection Start Time
End_Time     (T4    @  139)    End Time
Urine_Vol    (I4    @  143)    Urine Volume
Par_Asy_1    (F8.3  @  147)    Parent Drug Assay 1
P_Asy_Un_1   (A10   @  155)    Units (Par Assay 1)
Par_Asy_2    (F8.3  @  165)    Parent Drug Assay 2
P_Asy_Un_2   (A10   @  173)    Units (Par Assay 2)
P_Mean_Con   (F8.3  @  183)    Par Mean Concentration
P_Con_Unit   (A10   @  191)    Units (Par Mean Conc)
P_Amt_Void   (F8.3  @  201)    Par Amount in Void
P_Amt_Unit   (A10   @  209)    Units (Par Amt in Void)
Met_Asy_1    (F8.3  @  219)    Metabolite Assay 1
M_Asy_Un_1   (A10   @  227)    Units (Met Assay 1)
Met_Asy_2    (F8.3  @  237)    Metabolite Assay 2
M_Asy_Un_2   (A10   @  245)    Units (Met Assay 2)
M_Mean_Con   (F8.3  @  255)    Met Mean Concentration
M_Con_Unit   (A10   @  263)    Units (Met Mean Conc)
M_Amt_Void   (F8.3  @  273)    Met Amount in Void
M_Amt_Unit   (A10   @  281)    Units (Met Amt in Void)
                    -  290
```

```
File 'XT-T310'    Extent of Disease


File_ID       (A3    @    1)    File ID Code: "XT "
Version       (A4    @    4)    Layout Version "T310"
Extracted     (D8    @    8)    Extraction Date
Entered_By    (A8    @   16)    Data Entry Clerk
Created       (D8    @   24)    Record Creation Date
Changed       (D8    @   32)    Last Change Date
Chg_Time      (T6    @   40)    Last Change Time
Filler        (A1    @   46)    (reserved)
Del_Flag      (A1    @   47)    Deletion Flag
Del_Date      (D8    @   48)    Deletion Date (if deleted)
Protocol      (A12   @   56)    *Protocol ID
Inst_ID       (A8    @   68)    Institution Code
Entry_Pass    (A1    @   76)    Multi-Entry Pass
Touch_Date    (D8    @   77)    Touched Date
Touch_Time    (I7    @   85)    Touched Timer
Course_Num    (I3    @   92)    Course Number
Patient       (A12   @   95)    *Patient
Lesion        (I2    @  107)    *Lesion
Date          (D8    @  109)    *Date
Determined    (A12   @  117)    Determined by
X             (F7.2  @  129)    X Dimension (or Unidimension)
Y             (F7.2  @  136)    Y Dimension (if bidimensional)
Z             (F7.2  @  143)    Z Dimension (if 3D)
Eval_Num      (I2    @  150)    Evaluation Number
Evaluation    (A1    @  152)    Evaluation Code
                     -  152
```

# APPENDIX D

# Summary of Changes from Version 3.00 to 3.10

This appendix summarizes the changes from Version 3.00 of the CTMS Data Transfer Specifications that are being implemented in Version 3.10. Fortunately for all concerned there are not many changes. Below is a summary of the revisions to eleven of the current files and descriptions of two new files.

Submissions in the 3.00 formats will continue to be accepted during a reasonable transition period, but CTEP will appreciate an upgrade as soon as possible because some of the changes are needed to fulfill the requirements of the new CDUS-3 specifications. Test submissions in the new format are encouraged, with special arrangement for processing.

The CDUS-3 is introducing an additional change that will affect the submission of data but not the file formats. For some reason the sets of code numbers for diseases and adverse events have been changed. The new codelists are available on the CTEP web site. (Take the "List of Codes and Values" link on the right lower panel, then the "MedDRA Codes" link.) The actual lists of terms are not being changed, just the codes. Downloadable spreadsheets document the new codes and the correspondences to the old codes.

The Disease code is a field in the Enrollment (EN) file. The adverse event codes (specifying the CTC term) are fields in the Baseline Symptoms (BS), Dose Limiting Toxicities (DT), Late Adverse Events (LA), and Adverse Events (TX) files. CTMS will expect the new codes to be used in data submitted using these revised "3.10" file specifications, but will map data that has been submitted before the changeover.

For consistency, the "Version" field in all files, even those without changes, should be updated to "T310".

### CA – Course Assessment

A new field "Dose_Diff" has been added. The values for this field are the codes for the CDUS "Dose Modification" field, regarding whether the actual dose of the investigational agent(s) was different from that corresponding to the Treatment Assignment Code (TAC): 1=Yes, planned; 2=Yes, unplanned; 3=No; 9=Unknown.

The "Dose_Chgd" field is obsolete and has been dropped.

### CS – Correlative Studies (new)

This is a new file, for submitting summary data about Correlative Studies that is required by CDUS.

The key field is the Correlative Study ID code, as assigned by CTEP. If a suitable code was not appended to the protocol approval letter (along with the Treatment Assignment codes and the Subgroup codes), please apply to the CTEP Help Desk.

The four summary statistics are: the number of patients from whom samples have been collected; the number of patients for whom some samples have been analyzed; the number of samples collected; and the number of samples analyzed. Note that this record can be updated progressively as samples are collected and then analyzed.

When the study has been completed, the record can be updated with a short summary of the findings in eight short text lines.

## CM – Concomitant Medications

The width of the "Units" field has been increased to 12 characters, matching the CDUS spec.

## DA – Drug Administration

The widths of the "Level Units" and "Actual Units" fields have been increased to 12 characters.

## EN – Enrollment

The "Race" field has been redefined to meet the new Federal requirements for the indication of patient race. "Race" is now a character field of width 20. It should contain a string of two-digit CDUS race codes, space-delimited and left-justified. Thus a patient can be categorized into up to 7 race categories.

The "Other_Race" field is obsolete and has been dropped.

A new "Ethnicity" field has been added, again to meet Federal requirements. This field is 2-character string whose value should be one of the CDUS ethnicity codes.

(Note that CTEP has provided explicit instructions for mapping the race codes used in the CDUS-2 to the race and ethnicity codes used in the CDUS-3. These are available in the CDUS-3 "Instructions and Guidelines" document on the CTEP website.)

A new "Local ID" field has been added. This is an optional 12-character field which may be used to record the patient's local identifier if it is not the same as the ID used for reporting data to CTMS.

## FO – Offstudy

The "Date_Off" ("offstudy date") has been dropped because of greater specificity now required for CDUS reporting.

The "Off_Treat" date has been added. This is the "Date of Last Treatment" as used in the CDUS-3 specifications. It is the date the patient is off protocol treatment, which in most cases is the conventional "off study" date. Note the CDUS "Off Treatment Reasons".

The "Off_Follow" date has been added. This is the "Off Study Date" as used in the CDUS-3 specifications. It is the date the patient goes off protocol during (or when completing) a *protocol-specified* period of follow-up. This is not to be confused with the date of last contact during what is commonly termed "follow-up" of a patient who is already off-study. The "Off_Follow" date should only be submitted for a patient with specifically-relevant dispositions.

The set of codes for the "Reason (off-study)" field has been expanded to include both the CDUS-3 Off Treatment reasons and the Off Study reasons. Since these are mutually exclusive, only one field is needed to submit the information. The allowable code letters are listed on the Offstudy CRF.

The "Date_Rlps" has been dropped because of a confusing overlap with the "Date_Prog". The latter should be used to report either the date of relapse when there was no disease at enrollment or the earliest date of disease progression; whichever is relevant for any particular patient.

**LA – Late Adverse Events (new)**

This file corresponds to a new CRF introduced to collect information about late adverse events, i.e. ones that do not manifest while the patient is on-course.

The structure directly parallels that of the Adverse Events (TX) file. The only difference is the substitution of the "Follow_up" date field for the "Course_Date" field. The value of this key field should be the "Off Treatment" date – i.e. the date that the patient begins either a formal (protocol-specified) or informal follow-up period.

**MH – Medical History**

Two new fields, "Immune" and "Immune_2" have been added for the reporting of observations about the patient's immune system as part of the medical history.

**PR – Prior Radiation**

The "Thrpy_Code" field has been changed from I10 format using "IMT" code numbers to an A2 format using 1- or 2-letter codes as listed on the CRF. These codes – R, LR, ER – will allow easier data capture.

**PS – Prior Surgery**

The "Surg_Code" field has been changed from I10 format using "IMT" code numbers to a simple A1 format for a "Y" or "N" flag to indicate whether the surgery was intended to be therapeutic.

**PT – Prior Therapy**

The width of the "Units" field has been increased to 12 characters, matching the CDUS spec.

The "Thrpy_Code" field has been changed from I10 format using "IMT" code numbers to an A2 format using 1- or 2-letter codes as listed on the CRF. These are (semi-)mnemonic for more reliable data capture.

**TF – Prior Treatment Summary**

The flag fields "Reserved_2", "Reserved_3", "Reserved_4", and their associated dates have been dropped.

In their place are four new flag fields and dates corresponding to four new categories of prior therapies that are to be tracked in the CDUS-3: "Anti-RtVir" for anti-retroviral therapies; "Antisense" for antisense therapies; "Onco_Viro" for oncolytic virotherapy; and "Vaccine" for vaccine therapies.

**UL – Unanticipated Labs**

The width of the "Units" field has been increased to 12 characters, matching the CDUS spec.

# APPENDIX E


# Summary of Changes from Version 3.10 to 3.12

This appendix summarizes the changes from Version 3.10 of the CTMS Data Transfer Specifications that are being implemented in Version 3.12.

## CA – Course Assessment

Two new response codes are allowed:

TE "Too Early" may be used if it is too soon, per protocol, to assess a response.

DU "Disease Unchanged" may be used if the extent of disease is unchanged from the previous assessment and the CR/PR/MR or PD or SD codes are not appropriate, per protocol.

## FO – Offstudy

Two new response codes are allowed:

NP "Not Applicable Per Protocol" is used if the protocol does not include response assessment.

TE "Too Early" is used if all the Course Assessments were coded as Too Early.

A new Reason (and code) Offstudy is allowed, one is revised, and one eliminated:

Z = "No Treatment, per Protocol" is self-descriptive.

U = "Not Treated – Other Reasons" is a new code for this term, since "per protocol" has now been split out into a specific category.

N = The old code 'N' is being retired from future use in favor of U and Z. Existing records with code N will be treated as though they were code Z, that being effectively the use of N in the past.

## LL – Literal Labs

Two new lab test names are allowed:

PETSCAN may be used for PET scans.

CULTURE may be used for any culture, e.g. blood, urine.

**Revisions to the Manual**

In the "Data Elements" section, note that Course Number '0' should be used for "pre-study" data.

In the NOTES, clarify that the assignment of course number does not depend on the time.

In the NOTES, clarify that the FO.Off_Treat date is the date of the end of the last course.

In the NOTES, indicate that the restrictions on the fields in the LA file are the same as those for the comparable fields in the TX file.

In the NOTES, replace references to CTC2 with references to Appendix B.

Appendix B has been rewritten as a reference to the CTEP website rather than an explicit list of toxicity codes.

**Note that there are no changes to Appendix C, the Specifications for the Layout of the Data Files.**

In particular, the Version field ("Layout Version") in every record will continue to be "T310" since the layouts have not changed.