

Complete Trial Data Record Formats

Each line of the data file contains one record, is prefixed by the table name, and is comma delimited.



Important!

Use blank fields for those fields that are included in the CDUS standard but not used by the CTRP.

Valid Record Formats and Field Sequence

```
COLLECTIONS,<Study_Identifier>,,,,,,,,,<Change_Code>
PATIENTS,<Study_Identifier>,<Study_Subject_Identifier>,<Zip_Code>,<Country_Code>,<Birth_Date>,<Gender>,<Ethnicity>,<Payment_Method>,<Subject_Registration_Date>,<Registering_Group_Identifier>,<Study_Site_Identifier>,,,,,,,,,<Subject_Disease_Code>,,
PATIENT_RACES,<Study_Identifier>,<Study_Subject_Identifier>,<Race>
```

Note: For additional information on the Data Elements required for Complete studies, go to [Accrual Data Elements with CTRP-Accepted Values for Complete Trials](#).

The following is an example of a Subject level accrual batch file for a study that has three study subjects, and one race per subject using CTRP accepted valid values. In the example below "Male", is used instead of a CDUS/OPEN accepted numeric value of "1".

Example Batch File

```
COLLECTIONS,"NCI-2011-03861",,,,,,,,,1
PATIENTS,"NCI-2011-03861",873222899999999,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,,,,,185.0,,
"PATIENT_RACES","NCI-2011-03861",8732228,White
"PATIENT_RACES","NCI-2011-03861",873222899999999,Asian
"PATIENT_RACES","NCI-2011-03861",1,White
```

The following is another example of a Subject level accrual batch file, accepted by CTRP, for the same study but using CDUS/OPEN accepted numeric codes instead of the text values used in the example above .

Example Batch File

```
COLLECTIONS,"NCI-2011-03861",,,,,,,,,1
PATIENTS,"NCI-2011-03861",873222899999999,84124,US,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,185.0,,
"PATIENT_RACES","NCI-2011-03861",8732228,01
"PATIENT_RACES","NCI-2011-03861",873222899999999,05
"PATIENT_RACES","NCI-2011-03861",1,01
```

The following is an example of a Partial level accrual batch file for a study that has two subjects, and only reporting the minimum data fields required for a Partial level accrual batch file (other accrual data fields are optional)

Example Batch File

```
"COLLECTIONS","NCI-2018-03045",,,,,,,,,
"PATIENTS","NCI-2018-03045","L1",,,,,,,,,,"20190101",,"WQ456",,,,,,,,,
"PATIENTS","NCI-2018-03045","L2",,,,,,,,,,"20110908",,"WQ456",,,,,,,,,
```

Special Characters

If you include any of the following characters in a value, enclose the field with double quotes:

! " # \$ % & ' () * + , - . / : ; < > = ? @ [] \ ^ _ { } | ~

If you enclose a field with double quotes (as in "NCI-2012-00225"), CTRP interprets the string inside the quote exactly as presented. If the field does not contain any special characters, the quote marks are optional.

ICD-O-3 Study Format for Topography Codes

For studies using ICD-O-3 codes, use the [Subject Disease Code position](#) for ICD-O-3 Topography and Morphology (which must include Histology and Behavior codes). When you use both Topography and Morphology codes, separate them by a semi-colon as per the example below.

Format: site code; histology code

Code: C64.9;8000/3

Examples:

SDC Topography

PATIENTS, "NCI-2011-03861", 8732228, 84124, US, 196311, 1, 9, 1, 20060809, CALGB, 149280, , , , , , , , , , , 238.7, ,

ICD-O-3 Topography and Morphology

PATIENTS, "NCI-2011-03861", 8732228, 84124, US, 196311, 1, 9, 1, 20060809, CALGB, 149280, , , , , , , , , , , C64.9;8000/3, ,