Copy of Complete Trial Data Elements and Field Formats - Include v4.4 - ALT 2/15/2024 v2.0

Each row in a batch file is associated with a single record in the database. The first field in each line identifies the name of the table that a record belongs to. Subsequent fields contain different data element values for the same table. The number of fields required in each record, and the values they must cont ain, are provided in the Complete Trial Record Data Field Requirements table. Because many more elements are required in CDUS records than in CTRP records, many fields in your batch file will be null (contain no field values at all). In these cases, use a comma to indicate a field for which there is no datum.

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If a comma is part of the value, enclose the fields in double quotes. Otherwise the use of double quotes is optional.