About CTCAE Mapping

The CTCAE Mapping documents provide additional information to support the implementation of CTCAE v3.0 and the transition from CTC v2.0 (MedDRA v5.0) to CTCAE v3.0 (MedDRA v6.0).

Note: All CTCAE mapping documents provided to the CTEP Web sites use MedDRA v6.0 codes, unless otherwise specified.

Several mapping files, in PDF and Excel format, are available to compare the two active versions of CTEP, NCI's CTCAE, they are:

1. CTC v2.0 to CTCAE v3.0 document

1. Provides information regarding how CTC v2.0 terms are represented (deleted, merged, split) in CTCAE v3.0.

2. This file may be used for updating systems with CTC v2.0 (MedDRA v5.0) data to CTCAE v3.0 (MedDRA v6.0) data.

2. CTCAE v3.0 to CTC v2.0 document

a. Provides guidance regarding how to use CDUS and AdEERS (for protocols assigned to CTCAE v3.0) prior to October 1, 2003.

b. Because CTEP data systems will not be updated with CTCAE v3.0 until October 1, 2003, protocols assigned to CTCAE v3.0 and activated prior to October 1, 2003 require this 'work-around' in CDUS and AdEERS:

- Use the CTCAE v3.0 to identify and grade adverse events on protocols assigned to CTCAE v3.0.

- Use the CTCAE v3.0 to CTC v2.0 Mapping document when reporting in CDUS and AdEERS.

- If the CTCAE v3.0 AE term is mapped directly to a CTC v2.0 AE term, report in CDUS and AdEERS using the CTC v2.0 term.

- If the CTCAE v3.0 AE term is *not* mapped directly to a CTC v2.0 term, use the CTC v2.0 'Other (Specify)' within the appropriate CATEGORY and enter the exact CTCAE v3.0 AE term (and MedDRA code as it appears on this mapping document).

- If the CTCAE v3.0 term resides in one of the four new CATEGORIES, use CTC v2.0 'CONSTITUTIONAL SYMPTOMS, Other (Specify)' and provide the exact CTCAE v3.0 AE term (and MedDRA code as it appears on this mapping document).

- When CTEP data systems are updated to accommodate CTCAE v3.0 on October 1, 2003, all AE data submitted on protocols assigned to CTCAE v3.0 using the CTC v2.0 'work-around' will be converted to corresponding CTCAE v3.0 data. A file representing the updates will be provided to Groups/Investigators for review.

Note: During the mapping task, eight (8) CTCAE v3.0 MedDRA codes were found to be inaccurate. Therefore, the CTCAE v3.0 comma delimited files Effective October 1, 2003 (at http://ctep.cancer.gov/guidelines/values.html) have been updated July 16, 2003. A 'Notice of Modifications' document accompanies this MedDRA code update.

3. CTC v2.0 (MedRA 5.0) to CTCAE 3.0 (MedRA 6.0) spreadsheet

Provides a comparison of the MedDRA 5.0 codes assigned to the CTC v2.0 with the MedDRA 6.0 codes used in the CTCAE v3.0.

4. CTC v2.0 to CTCAE v3.0 Grade Mapping spreadsheet

5. CTC v2.0 to CTCAE v3.0 Grade Mapping (Excel)
Some protocols originally assigned to CTC v2.0 will be converted to CTCAE v3.0. To ensure investigators are aware of how v2.0 AE grades will be represented in v3.0, CTEP developed this document. Each v2.0 grade is associated with a brief explanation of how v2.0 grades appear in v3.0. Refer to the Legend for complete information.

a. Provides information regarding how CTC v2.0 grades are represented (deleted, revised, etc.) in CTCAE v3.0. Two spreadsheets are included; the first lists *all* CTC v2.0 AEs and grades mapped to CTCAE v3.0. The second provides a subset of only the changed or deleted CTC v2.0 AEs and grades and their mapping.

b. The mapping included in this file is used extensively when migrating study data from v2.0 to v3.0.

c. It will also be used extensively in analysis tools in representing data in the latest CTCAE version as well provide query results across CTCAE versions.

Note: In some cases, for example a grade deletion or revision *will render a change of the original CTCAE data*. A review of this mapping file is highly recommended for those who are considering migrating their studies from CTC v2.0 to CTCAE v3.0.

Important for protocols migrating from CTC v2.0 to CTCAE v3.0:
- When a reported AE is migrated to CTCAE v3.0 and its grade is mapped to an 'Other (Specify),' the AdEERS and CDUS applications will preserve the originally reported v2.0 Adverse Event within the 'Other (Specify)' field.
- To ensure consistent data transfers and CDUS submissions, local databases must be updated with the grade mapping data and, when appropriate, the 'Other (Specify)' information contained in this spreadsheet.

Reminder: Once a study is migrated from CTC v2.0 to CTCAE v3.0, the study cannot be reverted back to CTC v2.0.

6. CTC v2.0 to CTCAE v3.0 Mapping with Short Name spreadsheet

Provides Adverse Event (AE) mapping information accompanied by each AE's Short Name.