NIH NATIONAL CANCER INSTITUTE

CTCAE v6.0 Implementation FAQs

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❖ General Questions:

When can CTCAE v6.0 be used?

- CTCAE v6.0 is ready for immediate use for any study except NCI CTEP or DCP NCORP studies.
    - If you have questions about whether you may or may not use CTCAE v6.0, please contact your study sponsor.

Are further changes anticipated to CTCAE v6.0?

- No further changes are planned. The release version is the final version of CTCAE v6.0.
- If you have comments regarding CTCAE v6.0, please send them to NCI CTEP CTCAE Comments at: **ncictcaehelp@mail.nih.gov**. Comments will be discussed during the CTCAE v7.0 update.
- CTCAE v7.0 is expected to be developed and released between 2027 and 2030.

How should multiple CTCAE versions be managed if data needs to be consolidated into a single version (e.g., for regulatory reporting or aggregate analysis)?

- The NCI has developed a comprehensive mapping resource that aligns all term and grade combinations from CTCAE v5.0 to their corresponding terms and grades in CTCAE v6.0.

❖ Specific Information for NCI CTEP/DCP-supported Studies:

Will NCI CTEP/DCP studies using CTCAE v5.0 be required to convert existing data to v6.0?

- **No**. Data conversion will **not** be required by NCI CTEP/DCP.
    - All NCI CTEP/DCP studies currently reporting in CTCAE v5.0 will continue to report in CTCAE v5.0 throughout the life of the study.
    - All NCI CTEP/DCP data reporting (CDUS, DMU, CTEP-AERS) will remain in CTCAE v5.0.

Which NCI CTEP/DCP studies will be required to use CTCAE v6.0?

- CTCAE v6.0 will be required for **ALL NEW** NCI CTEP/DCP studies whose Rave study build begins after the CTCAE v6.0 Rave ALS (ALS 7.2) is released.
    - This applies to **all** NCI CTEP and DCP studies regardless of IND status and includes non-IND and IND-Exempt studies.

When will Rave ALS 7.2 be released?

- The release of Rave ALS 7.2 is tentatively scheduled for July 2026.
- The timeline may be further pushed back based on resource needs in support of other Medidata-related priorities.