

- Question: Regarding CTCAE term *hyperglycemia* – what happens if is a non-fasting glucose level? How is that reported?

Answer: Clinical decision-making. If there is suspicion, with consideration of Sponsor requirements, you would need to repeat the lab in a fasting state. It would not be considered hyperglycemia if not fasting and if not repeated cannot be repeated in CTCAE V6.

- Question: To clarify, [CTCAE V6] will only affect new studies open to accrual after July 2026.

Answer: Yes, this is correct. The tentative roll out date for V6 in Rave is July 2026 for new studies only. There will be no conversion from CTCAE V5 to CTCAE V6 for existing studies.

- Question: How should we approach using the "Other" category. I have been told not to overuse it on some trials.

Answer: The reason why there have been many of the changes is because of some of the "other" terms added. If truly had an AE and it does not meet a CTCAE definition available, you must use "Other". Clarifications to terms have been added to help assign appropriate terms. "Other" should be used sparingly.

When auditing, the most common error seen is misuse of the CTCAE term assigned when there is a more appropriate term available. That is when a query will be issued.

- Question: I had an older study that used V4 for regular/late AEs, but V5 for SAE reporting. It sounds like that would not be something that would happen with this newer update.

Answer: That is correct. There will be no conversions for older studies utilizing a previous CTCAE version.

- Question: Are the apps approved by the NCI?

Answer: NCI is not going to approve a product as they are the government. However, NCI does have an online CTCAE dictionary tool available (Safety Profiler).

If you compare the apps available to the website, they are pretty much identical (CTCAE 6go, CTCAE6).

Quality Assurance: CTCAE V6 Polling Questions

1. *Participant has a lymphocyte count of 100/mm³ with a lower limit of normal reference of 1,800/mm³. What is the grade of lymphopenia?*
 - a. Grade 1
 - b. Grade 2
 - c. Grade 3
 - d. Grade 4

Answer: a. Grade 1

2. *What grade is an Alkaline Phosphatase of 750 U/L with a normal reference range of 44-147 U/L?*
 - a. Grade 1
 - b. Grade 2
 - c. Grade 3
 - d. Grade 4

Answer: a. Grade 1