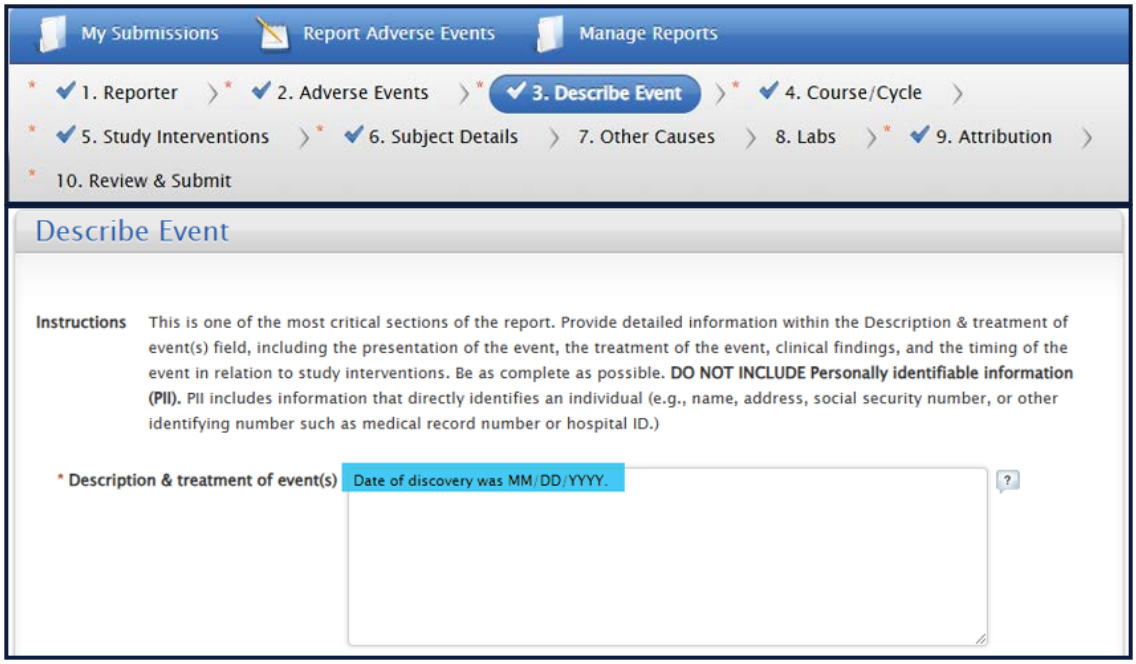
Serious Adverse Event Reporting Tips

- Please enter the date of discovery into *CTEP-AERS Section 3: Describe Event.* Late SAE reporting is a major deficiency at audits, and we don't want to penalize you for late reporting if it was not truly late.
    - SWOG defines date of discovery as the date you have the minimum information required to submit a CTEP-AERS report: CTCAE term(s), grade, and attributions to protocol treatment and underlying cancer.



- Each SAE must have *something* that is at least possibly related. If the SAE is unrelated or unlikely related to protocol treatment and to the underlying cancer, you must add an other cause in *CTEP-AERS Section 7: Other Causes.* If the cause is unknown, enter an other cause named 'unknown' and assign an attribution of possible, probable, or definite to this cause.
- If your patient is on a treatment arm that includes both investigational and commercial treatments, the entire treatment arm is considered investigational. You will use the investigational SAE reporting table for SAE reporting guidelines.
- As of 8/30/2024, all SAEs that occur in patients receiving investigational treatment must initially be reported within 24 hours of the date of discovery. You will submit an initial report within 24 hours, followed by a second report due within either 5 or 10 calendar days, depending on the phase of trial and grade of SAEs.
- CTEP-AERS reports that are not fully submitted to SWOG by the due date will be automatically deleted by the CTEP-AERS system. Once deleted, neither SWOG nor NCI can reinstate the report, and you will need to start over with a new report. To ensure you have fully submitted the report, look for a green checkmark with a date: