

- **Question:**
Regarding Step 3..... 30 days after last dose, up to how long? Is there an 'up to' timeframe for reporting SAEs. For example, if the event occurs one year after the last dose, does it need to be reported?

SWOG QA Answer:

- *The requirement for expedited reporting (as an SAE) will depend on the attribution.*
 - *For example, if you look at events occurring more than 1 year (after off-treatment), then, in most cases, the investigator will (usually) make a determination that the event is not related to the study treatment. Herein (if the Investigator determines the event is not related to the study treatment), expedited reporting of the SAE is not necessary. AE reporting requirements still apply.*
 - *Conversely, IF the Investigator determines that the event IS possibly related or related to treatment, then the event must be reported as an SAE even if pt was off treatment for 1 year (or more).*

- **Question:**
Are the events included in SPEER because they happen commonly?

SWOG QA Answer:

- *Exactly. The SPEER contains adverse events that have commonly been reported in previous clinical trials. The pharmaceutical manufacturer / industry sponsor considers the events to be "known" (non-serious) events that do not require expedited monitoring (SAE reporting). During protocol development, known adverse event(s) are included in the SPEER so that sites do not have to report as SAEs due to already known frequency / expected occurrence of events.*

- **Question:**
So for SPEER reporting, are we still required to consider the seriousness for SAE reporting?

SWOG QA Answer:

- *Yes, an event would still need to meet SAE seriousness criteria if listed on the SPEERs list. It is important to note that the SPEER list is a list of exceptions from the requirements for SAE reporting.*
- *If a condition is not listed on the exception list, this does not necessarily mean that event/condition meets SAE reporting criteria. Sites will still need to review the criteria for SAE reporting as well to determine whether expedited reporting is required.*

- **Question:**
Does the SAE form require a PI/Co-I signature in order to submit form? If yes, what do we do if neither are available at the time we need to submit? Do we submit a follow-up when the PI becomes available to sign?

SWOG QA Answer:

- *On the last form of CTEP-AERS, there is a checkbox in the middle of the page certifying that the PI confirms that the information is complete and accurate.*
 - *If your site has delegated the responsibility for online submission to you to ensure timely reporting, then you may check the box on behalf of the PI and continue.*

- *If your site has a policy indicating that you are not able to submit an SAE report without continuing, then follow institutional policy.*
 - *If your site must submit an amendment when the PI is available to sign and there is no visible change in the follow-up report, then you might get a follow-up question. So, if it is possible to proactively include a clarification in the follow-up report, then this would be helpful to avoid questions.*
 - *If the PI is out, then site can include a comment in the narrative “Section 3” of the report. Or, if there is not enough information to submit, then it is OK to wait until you have the PI review and sufficient information. Document everything as to why the delayed submission – e.g., outside hospital and have requested records. It is best to submit available information (e.g., hospitalization) provided that you have enough information (CTCAE terms – enough information to determine both the grade and attribution of the event) to submit. It is always possible to submit a follow-up report.*
- **Question:**
So just to be clear, if a patient gets hospitalized for an event in the SPEER column but the grade is not higher than the grade in the column then no SAE is required?

SWOG QA Answer:

- *Yes, that is correct. The event must exceed the grade in the () listed on the SPEERs list. These are exceptions to SAE reporting, not routine AE reporting. This does not change the AE reporting.*
 - *Example: Grade 2 nausea with hospitalization. Up to and including Grade 2 nausea does NOT need to be reported as an SAE.*