

- **Question:**
With regards to AE assessments, when protocols have a list of solicited events do you expect to see any additional documentation for those solicited events?

- At one attendee’s site, attendee indicated that: “We have special language for the provider to document in the EMR that they have reviewed the solicited AEs and assessed the patient during their research visit. It could be as simple as "the patient didn't experience any of the solicited AEs."

SWOG QA Answer:

- *However, would need to be careful that the line does not conflict with other areas of the note that indicate one of the solicited events were present.*

- **Question:**
Do all solicited AE's need to be reviewed and documented on the physician visit/assessment note?

SWOG QA Answer:

- *Their presence or absence should be documented somewhere in the record. Some, like lab values would not need to be documented in the note, if they were drawn. But would need to say, for example, Patient denies nausea, pain, vomiting . . . “ if they are not present.*

- **Question:**
General question - how to grade HTN when a patient is already taking one medication with stable blood pressure at baseline? Is this a grade 1 or 2?

SWOG QA Answer:

- *If blood pressure normal at baseline, and no increase in blood pressure. Note that Pt has hypertension but not necessarily put a grade on it because, the CTCAE grades based on the baseline value.*

CTCAE Term	Vascular disorders		
	Grade 1	Grade 2	Grade 3
Hypertension	<p>Adult: Systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg;</p> <p>Pediatric: Systolic/diastolic BP >90th percentile but < 95th percentile;</p> <p>Adolescent: BP ≥120/80 even</p>	<p>Adult: Systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (≥24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg;</p>	<p>Adult: Systolic BP ≥160 mm Hg or diastolic BP ≥100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated;</p> <p>Pediatric and adolescent:</p>

- *CTCAE criteria is defined as “over baseline”. If normal like, 120/80, on 1 pill. Would not consider it baseline event. Need to evaluate in reference to the baseline. If no increase in value or medication, then not a reportable AE.*
- *If taking medication for prophylaxis, then doesn’t mean you have AE. Can’t grade based on prophylactic medication.*

- **Question:**
If participant forgot to take medication and had a high value, then how do you record?

SWOG QA Answer:

- *Still have to report high value as an AE, but report attribution as not related to study treatment (related to forgetting to take medication).*

- **General Question/comment: Re: DARF.**
One attendee noted that the [DARF] that was shared [in the presentation] as "completed correctly" did not have the manufacturer noted in the manufacturer and lot column.
 - The attendee shared (as an Fyi for webinar participants) that in a recent site audit by ECOG/Alliance, this was one of the things that the site was dinged on (manufacturer was not indicated in the manufacturer and lot column). Thanks.

SWOG QA Answer:

 - *Pretend DARF was included in the presentation. Slide 22 has now been updated to correct this oversight in the "Post-Meeting" version of the slide set that is now posted with the course materials.*

- **Question:**
Are supportive IV medications during treatment required to be documented on con meds?

SWOG QA Answer:

 - *This depends on the instructions on the form.*
 - *If instructions are to report medications for an event, & medication is given as prophylaxis (cisplatin will cause nausea), and the patient is not nauseous, would not report.*
 - *If instructions are to report all concurrent medications, then it would be reported. You need to read the instructions on the concomitant medication form.*

- **Question:**
Do the reporting period end date and the next reporting period start date have to overlap?

SWOG QA Answer:

 - *They should overlap when the toxicity evaluation, and D1 occur on the same day. This is different for ECOG-ACRIN.*

- **Question:**
Is it ok if the patient signs before the consent discussion?

SWOG QA Answer:

 - *One of the principles of the regulation is the opportunity for questions and clarification. If this has not occurred, the document should not be signed yet. For this reason, consent must be signed after the discussion to be documentation of informed consent.*

- **Question:**
For baseline weight: Is that the weight taken on C1D1 before the first treatment to follow weight loss or gain? Or can a weight be used before C1D1? Ex. The patient was seen two weeks prior to C1D1 with wt 157lb. The weight on C1D1 is 155 lb. Would it be incorrect to use either weight to follow weight loss or gain for AE reporting?

SWOG QA Answer:

 - *Would use weight on the day of treatment; We are evaluating a weight change caused by the treatment. If get to lowest point, and start gaining weight again, then date would change. But, to start with, use the C1/D1 weight.*

- **Question:**
If a site receives their SWOG studies via the Alliance, are all studies audited by Alliance or SWOG?

SWOG QA Answer:

- *If accrual credited to LPO, then LPO that may not be 'leading' the trial, will also audit the accrued patients.*

- **Question:**
If a patient a baseline is taking antidepressants, would they be graded as grade 2 depression despite not having any symptoms of depression?

SWOG QA Answer:

- *The CTCAE does not use medication as a determinant of grade. Therefore, would look at the symptoms of the patient to determine grade. Not the medication.*

CTCAE Term	Grade 1	Grade 2	Grade 3
Depression	Mild depressive symptoms	Moderate depressive symptoms; limiting instrumental ADL	Severe depressive symptoms; limiting self care ADL; hospitalization not indicated
Definition: A disorder characterized by melancholic feelings of grief or unhappiness.			

- **Question:**
If our PI notes grade to be 1-2, should we addendum the note and request clarification as with AEs, for instance. This would likely trigger an audit if not clearly defined?

SWOG QA Answer:

- *If physician/investigator says either Gr. 1 or 2, then record the highest Grade, or clarify grade with MD.*

- **Question:**
If the patient is coming for visit as well as infusion on same day which vitals are applicable for data entry before visit or before infusion?

SWOG QA Answer:

- *Need to review protocol and see if there is a time requirement on the pre-treatment vital signs. If not, use the ones closest to the start of the treatment.*

- **Question:**
Concerning consent signatures...participants with limited English proficiency or decisionally impaired) if those signature lines do not apply to the patient, should N/A be entered to indicate they were reviewed?
SWOG QA Answer:
 - *Requirements for legally authorized representatives (who may serve as a LAR and how this is documented) may vary by institution (per compliance with institutional procedures, local and state regulations).*
 - *The CIRB model consent form for adult studies does not include an LAR signature line as a standard inclusion.*
 - *For most SWOG studies, an LAR signature line would not be included in the model consent form provided by SWOG.*
 - *If sites include an LAR signature line as part of the institution's standard practice, then this would be included as part of the institution's CIRB-approved boilerplate language (Study Specific Worksheet).*
 - *Herein, at audit SWOG QA would only verify that the LAR signature line addition was CIRB-approved.*
 - *If an LAR signature line is included on the (C)IRB-approved consent form, then as pertains to standard consent process (regardless of whether a translated consent or short form is involved):*
 - *In general: If the participant does not have a legally authorized representative, then it would be appropriate for the participant to indicate N/A on the document when signing the consent.*
 - *Conversely, if the LAR line is left blank, then (similar to the procedure for documenting intent of 'cross-out' change of signature date or Yes/No indication for optional components)³, the site may document that the participant did not have an LAR in the site regulatory file/ participant chart.*
 - *No answer was provided as pertains to the non-English speaking portion of the question.*
 - *SWOG QA will follow-up via email with the attendee who asked the question to request clarification. A translated consent or short form should be utilized for non-English speaking participants.*