



Monday Morning Practice Pearls #1

What is the impact on C3D when your protocol has the following optional language (or something similar) which is taken from the NCI IRB protocol template?

An abnormal laboratory value will be considered an AE if the laboratory abnormality is characterized by any of the following:

- *Results in discontinuation from the study*
- *Is associated with clinical signs or symptoms*
- *Requires treatment or any other therapeutic intervention*
- *Is associated with death or another serious adverse event, including hospitalization.*
- *Is judged by the Investigator to be of significant clinical impact*
- *If any abnormal laboratory result is considered clinically significant, the investigator will provide details about the action taken with respect to the test drug and about the patient's outcome.*

1. During the C3D build process, the clinical analyst will recommend (via the C3D specification sheet) that you “turn off” the AE validation rule #AE10 which states “The CTC Term for the ongoing Adverse Event has a specified lab, but a lab record with lab date = AE onset date and lab grade = AE grade does not exist”. If they don’t, you should request this.
2. The impact on C3D is that once turned off, you will not receive a discrepancy that an AE is needed for the abnormal lab value.
3. The lab values will continue to be automatically graded as applicable, but no discrepancy appears in C3D.
4. You will need to ensure that there is CRIS documentation that the lab result is not clinically significant.
5. You will need to ensure that any lab value that meets the above criteria is captured as an AE.