

SCHARP Clinical Affairs Tipsheet

1. Know the parameters for Grade 1 hypertension; file an AE for this event, according to the ranges noted in the newly clarified *DAIDS Toxicity Table*.
2. When documenting events of lymphadenopathy on an AE Log CRF, please mark “no” in Question #11 – “Was this AE reported on a Reactogenicity form?” Although the lymphadenopathy is noted to be “present” on the Reactogenicity Form, for safety reporting purposes, the severity grading information is taken from the AE Log CRF.
3. Report participant temperatures in Celsius units. A Fahrenheit temperature will appear as a Grade 4 event in SCHARP’s database and will trigger an e-mail alert to SCHARP Clinical Affairs.
4. If an adverse event is determined to be “Not Related,” you ***need to*** explain why it is not related in the “Comments” section of the AE Log (per the instructions on the form).
5. Document the resolution date of an AE when it is resolved; make it a habit to review all AEs with the participant at each clinic visit.
6. Review concomitant medications with the participant at each visit; record all updates, additions, or changes on the Concomitant Medications CRF.
7. Remember to mark the AE Severity Grade on the Laboratory CRF.
8. Review the WBC differential, noting whether the differential totals the WBC total.
9. Always calculate absolute neutrophils and absolute lymphocytes; when reported only as percentages, it is easy to overlook lymphopenia and neutropenia. These are gradable events, per the *DAIDS Toxicity Table*.
10. Always date and SIGN (at least first initial and entire last name) the Clinical Query responses that you FAX to SCHARP Clinical Affairs.