



SCHARP

SCHARP Coding Queries

Clinical Affairs
Statistical Center for HIV/AIDS Research & Prevention
(SCHARP)





Presentation Goals

- **Quick review of Clinical Queries**
- **Review Coding Query process**
- **Review common AE Clarification Requests
(and why certain AEs have to be queried!)**





What are Clinical Queries?

- **Clinical queries are questions about data sent from the SCHARP Clinical Affairs Staff to the site via e-mail pdf attachments**
- **There are two types of queries that can be sent by Clinical Affairs in the same pdf attachment**
 - ▶ Clinical queries
 - ▶ Adverse Event Clarification Requests



Clinical Queries

- **Generated by SCHARP Clinical Affairs Safety Associates**
- **Request for additional information about an abnormal lab value, physical exam, and/or a clinical adverse event**
- **Often sent in response to Protocol Safety Review Team (PSRT) review**
 - ▶ May include PSRT suggestions or recommendations



Clinical Query

- **Lists the Participant ID and Visit #**
- **Lists the CRF/variable in question**
- **Includes site response line**
 - ▶ Must be filled in by a licensed healthcare provider
- **Includes signature/date line**
 - ▶ Must be signed by a licensed healthcare provider





Responding to Clinical Queries

- **As directed by the query, sites should write their response to the clinical query on the clinical query page, sign & date, then fax to SCHARP Clinical Affairs at (206)667-4812. Please do not use the DataFax #.**
- **If needed, update any related CRFs and fax to SCHARP DataFax.**





Coding Queries



HIV VACCINE
TRIALS NETWORK

SCHARP



AE Clarification Requests

- **Generated by SCHARP Adverse Event coding staff**
- **Prefaced with “AE CLARIFICATION REQUEST” to differentiate between queries about clinical events and queries specific to adverse event clarification**





AE Clarification Requests

- **“AE CLARIFICATION REQUEST” standard queries were developed by the DAIDS MedDRA Working Group**
 - ▶ Facilitates clear, consistent queries amongst all of the data centers conducting DAIDS sponsored trials.
- **Coders must code based solely on the reported verbatim term (Line #1 of the AE Log CRF) in adherence with the guidelines from the DAIDS Term Selection document.**
 - ▶ Drawing information from comments field or other sources is not permitted.





Participant ID

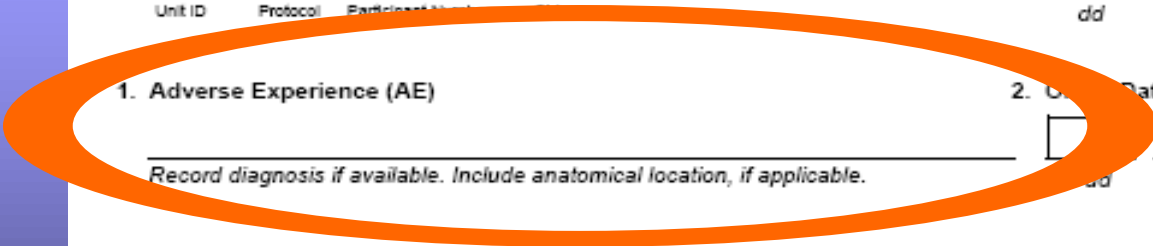
- 4 - -

Unit ID Protocol Participant ID

Adverse Experience Log

Date Reported to Site

dd MMM yy



1. Adverse Experience (AE)

Record diagnosis if available. Include anatomical location, if applicable.

2. Onset Date

dd MMM yy

3. Severity

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Life-threatening
- Grade 5 - Death

4. Relationship to Study Product

- Definitely related
- Probably related
- Possibly related
- Probably not related
- Not related

Record reason why AE is "not related" in Comments below.

5. Study Product Administration

- No change
- Held
- Permanently discontinued
- N/A

6. Status/Outcome

- Continuing
- Resolved
- Death
- Severity/frequency increased
Report as new AE.
- Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

dd MMM yy

7. Treatment Mark "None" or all that apply.

- None
- Medication(s)
Report on Concomitant Medications Log.
- New/Prolonged hospitalization
Comment below.
- Procedure/Surgery
Comment below.
- Other
Comment below.

8. Is this AE serious according to ICH guidelines? yes no

9. Has/will this AE be reported as an EAE? yes no

10. Was this AE reported on a Reactogenicity form? yes no

11. This AE was first reported at visit: Visit code required (regular or interim)

Item 12 is for HIV-infected participants only. For all other participants, go to Comments.

12. HIV/AIDS event code: Refer to code list on HVTN website.



Responding to AE Clarification Requests

- **As directed by the query, sites should clarify/amend the Adverse Experience Log.**
- **As directed Sites must refax edited AE Log page to SCHARP DataFax**
- **There is no need to fax the Clinical Query PDF back to Clinical Affairs unless the AE Clarification Request is on the same page as another clinical query.**



AE Clarification Requests

- **AE CLARIFICATION REQUEST.** Please indicate a single symptom or diagnosis in item 1, then initial/date/refax to SCHARP DataFax. Use separate AE CRF(s) to report additional symptoms or diagnoses.
- **AE CLARIFICATION REQUEST.** Please indicate the anatomical location in item 1. Initial/date/refax to SCHARP DataFax.
- **AE CLARIFICATION REQUEST.** Please clarify abbreviation _____ in item 1, then initial/date/refax to SCHARP DataFax.
- **AE CLARIFICATION REQUEST.** Please confirm spelling of _____ in item 1. If correct, please write "correct as written" next to word. If spelling is not correct, please correct, then initial/date/refax to SCHARP DataFax.
- **AE CLARIFICATION REQUEST.** Please include relevant descriptors from the comments field to more fully describe reported term in item 1. Initial/date/refax to SCHARP DataFax.
- **AE CLARIFICATION REQUEST.** Please include diagnosis in item 1 that is noted in the comments field if appropriate (i.e., if diagnosis directly related to reported symptoms). Then initial/date/refax to SCHARP DataFax.
- **AE CLARIFICATION REQUEST.** Please clarify unknown medical term _____ in item 1, then initial/date/refax to SCHARP DataFax.





AE Clarification Requests

AE CLARIFICATION REQUEST. Please indicate a single symptom or diagnosis in item 1, then initial/date/refax to SCHARP DataFax. Use separate AE CRF(s) to report additional symptoms or diagnoses.

- ▶ Each AE CRF can only received one MedDRA code
- ▶ Example: Diarrhea, nausea and vomiting reported on a single AE CRF. **Avoid combination terms** - these will have to be split into three separate AE CRFs : Diarrhea, Nausea, Vomiting, unless a unifying diagnosis can be provided.
- ▶ Example: Decreased hemoglobin (Anemia) reported on the AE CRF item 1. Either the diagnosis or the investigational finding must be chosen.





AE Clarification Requests

AE CLARIFICATION REQUEST. Please clarify abbreviation _____ in item 1, then initial/date/refax to SCHARP DataFax.

- **Please do not use abbreviations**
- **Examples:**
 - ▶ MI (myocardial infarction or mitral incompetence?)
 - ▶ GU pain (gastric ulcer pain or genito-urinary pain?)
 - ▶ Decreased BS (breath sounds, bowel sounds or blood sugar?)





AE Clarification Requests

AE CLARIFICATION REQUEST. Please include relevant descriptors from the comments field to more fully describe reported term in item 1. Initial/date/refax to SCHARP DataFax.

- Example: AE filed for “conjunctivitis”. In the comments field the site indicated that the conjunctivitis is a bacterial infection.
 - ▶ **The site will be queried to include that information in item 1 of the AE CRF because this information changes the MedDRA code associated with it.**





AE Clarification Requests

- **AE CLARIFICATION REQUEST.** Please include diagnosis in item 1 that is noted in the comments field if appropriate (i.e., if diagnosis directly related to reported symptoms). Then initial/date/refax to **SCHARP DataFax**.
 - ▶ Example: The AE CRF has a report of decreased hemoglobin on item 1. In the comments field the site has reported ‘malaria’. The site will be queried to report the diagnosis on item 1 if appropriate.





AE Clarification Requests

- **Avoid ambiguous terms.**
 - ▶ Example: sore. If an AE CRF has a report of genital sore in item 1 the coder must query the site. Is this a genital ulceration, genital pain, genital laceration or other?
 - ▶ Example: cold. Is the participant feeling cold, do they have a respiratory infection or Chronic Obstructive Lung Disease?





AE Clarification Requests

- **Death, hospitalization, and disability are outcomes and are not usually considered to be adverse events. The AE is what caused this type of outcome.**
- **Examples:**
 - ▶ “Death due to myocardial infarction” (Coded as *Myocardial infarction* with death captured as the severity grade and outcome)
 - ▶ “Hospitalization due to congestive heart failure” (Coded as *Congestive heart failure* with hospitalization captured as the “treatment”)



AE Clarification Requests

- **AE CRFs with ‘death’ or ‘hospitalization’ reported as the adverse event, without the underlying cause, will be queried.**
- **If the underlying cause of the outcome is not known, indicate on item 1 of the AE CRF.**
 - ▶ Example: Death, Cause Unknown.





Any Questions?

**Please feel free to e-mail
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