

SCHARP ADVERSE EVENT REPORTING GUIDELINES

1) REPORT ONLY ONE AE "TERM" PER CRF;

Example: Reported term in item #1 of the AE CRF reports, "cough, headache, ear pain and sinus congestion"

Standard query:

"Please amend item #1 of the AE CRF to include a single symptom or diagnosis, then initial, date and refax to SCHARP DataFax. Use separate AE CRF(s) to report additional symptoms or diagnoses. "

2) ALWAYS INCLUDE THE ANATOMICAL LOCATION OF REPORTED SYMPTOM OR DIAGNOSIS

Example: Reported term in item #1 of the AE CRF reports "Candidiasis." (Is this oral, vaginal, nasopharyngeal, etc?)

Standard query:

"Please amend item #1 of the AE CRF to include the anatomical location. Initial, date and refax to SCHARP DataFax."

3) DO NOT USE ABBREVIATIONS

Examples of mystery abbreviations: BOM (burning on micturition or bilateral otitis media?) LAP (lower abdominal pain or laparotomy?)

Standard query:

"Please amend item #1 of the AE CRF to clarify abbreviation _____, then initial date and refax to SCHARP DataFax"

4) CHECK & CONFIRM YOU ARE USING CORRECT SPELLING

Misspelled terms in Item #1 of AE CRF may impact the coding.

Standard query:

"Please amend item # 1 of AE CRF to confirm spelling of _____, then initial date and refax to SCHARP DataFax."

5) INCLUDE PERTINENT DESCRIPTORS OF EVENT IN ITEM #1

Example: Item #1 of the AE CRF reports 'RASH' but comments field adds, "red, itchy rash on both arms." Because there are different AE codes for rash, these descriptors are important.

Standard query to site:

"Please amend item #1 of AE CRF to include relevant descriptors from the comments field and refax to SCHARP DataFax"

6) REPORT THE DIAGNOSIS IN ITEM #1 WHENEVER POSSIBLE

Example; Item # 1 of AE CRF reports "myalgia, chills, headache." "Comments" section states symptoms are due to influenza. If there is a diagnosis such as influenza, be sure to include this on Item #1 and include the *symptoms* in either the 'comments' section or along with the diagnosis in Item #1.

Standard query to site:

"Please amend item #1, of AE CRF to include diagnosis that is noted in the comments field if appropriate (i.e. if diagnosis directly related to reported symptoms.) Then initial, date and refax to SCHARP DataFax"

7) USE MEDICAL TERMS WHEN DESCRIBING ADVERSE EVENT

Examples: "Sore on wrist" Is there a lesion, ulcer or abrasion on the wrist or is the wrist painful? "Open area on left leg" Is there an ulcer, a necrotic area or an abrasion?

Standard query to site:

Please amend item #1 of AE CRF to clarify unknown medical term_____ then initial, date and refax to SCHARP DataFax.

8) REPORTING AE'S RELATED TO A TIME OF LIFE or LIFE EVENT

When submitting an AE form with a symptom or diagnosis believed to be related to peri-menopause, menopause, adolescence, postpartum, it is important to include these descriptors in Item # 1 of AE CRF.

Example: If the term in item #1 of the AE CRF reports 'Hot Flashes' but site believes these are related to menopause or perimenopause, include this descriptor in item #1 .

Standard query to site:

No SQ at this time

9) INCLUDE THE RELATED DIAGNOSIS (when available) IN ITEM #1

When reporting an AE related to HIV or other underlying conditions, include the contributing diagnosis in the item #1 of the AE CRF.

Example: If the term in item #1 is "Edema" but the edema is related or secondary to congestive heart failure, include this diagnosis in item #1

Standard query to site

No SQ at this time