MedDRA Coding/ AE Log Item 1 Refresher

ASPIRE Protocol Team Meeting
February 10, 2013

MedDRA Coding – Overview

- MedDRA: standardized dictionary of medical terminology
- Results from ICH initiative to standardize terms used world-wide to describe safety events in research studies
- MedDRA Structure – 5 levels
  - System Organ Class (SOC): 26
  - High Level Group Term (HLGT): 333
  - High Level Term (HLT): 1685
  - Preferred Term (PT): 15,149
  - **Lower Level Term (LLT): ~65,000**
    - **LLT "maps" the AE to categories in the 4 upper levels**

What is Coded?

- AE Log CRF Item 1 text is used for MedDRA coding

- Record as much detail as possible in order to accurately and completely describe the AE
  - Example: "red papular rash on upper arms" rather than just "rash"

- The MedDRA code is assigned based solely on text in item 1

MedDRA Coding at SCHARP

- AEs are coded once two data entry passes have occurred

- Automatic coding occurs when there is an exact match between AE text and a MedDRA LL term

- Manually-coded if no exact lower level term match

- SCHARP will send a Clinical Query to the sites if they need more or better information in AE Log item 1 in order to code
  - AE text ambiguous, inconsistent with comments, or not descriptive enough

AE Canned MedDRA Queries

- ☐ 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.

- ☐ AE CLARIFICATION REQUEST. Please clarify abbreviation _____ in item 1.

- ☐ 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.

AE Canned MedDRA Queries

- AE CLARIFICATION REQUEST. Please include relevant descriptors from the comments field to more fully describe reported term in item 1.

- 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).

- AE CLARIFICATION REQUEST. Please clarify unknown medical term _____ in item 1.

AE Text - Things to Consider in ASPIRE – *OLD GUIDANCE*

- ☐ Avoid mentioning the vaginal ring in AE text
    - ■ Ex. cervical edema at ring insertion site
    - ■ Ex. vaginal itching on day of ring insertion

- ☐ Why? Isn't t̶h̶ ... and descriptive?
    - ■ Text abo... Es to be coded to device ... an a term that describe...
    - ■ Info on ... y product) and AE timing ... ct use is already captured (iter... resolve dates)

AE Text - Things to Consider in ASPIRE – **NEW GUIDANCE**

Per Data Communique #5 and revised SSP section11.3:

☐ If the AE is determined to be <u>due to the act</u> of study ring **insertion** or **removal**, include this in the AE text description. For example, "vaginal laceration due to ring insertion".

Likewise -

☐ *If the AE is determined to be due to the **presence** of study ring, **DO NOT** include this in the AE text description or AE comments*

AE Log Comments Field

- Use to record additional notes as needed, making sure any comments are consistent with the AE text (item 1)

- Avoid adding comments about the AEs relationship to ring insertion or removal – just add to AE text per revised guidance
  - This will affect AE coding

Examples –

☐ **AE: "Vaginal Pain during ring insertion"**

- Comments: vaginal pain was noted <u>during ring insertion</u>…

☐ **AE: "vaginal discomfort with ring removal"**

- Comments: participant experienced vaginal discomfort with <u>the ring removal</u>, which resolved when the ring was removed.

AE Text & MedDRA Coding - Things to Consider in ASPIRE

- IPM 027 – also using MedDRA

- Since both studies are evaluating the same product in similar populations, the more we can do to ensure consistency of safety data across studies, the more informative the study results will be

AE Text – Lessons from VOICE

- If a ppt reports pain in the abdominal region, probe to determine if it is truly abdominal pain or if the source is some other area/organ

    Specify <u>exact anatomical </u>location of the pain
    - Examples: uterine pain, pelvic pain, urethral pain, ovarian pain, bladder pain, vulvovaginal pain, perineal pain

    - Do not use 'suprapubic pain' as it does not provide a precise enough anatomical location

- If an STI test result is positive
    - report the STI diagnosis (i.e., genitourinary gonorrhea) rather than as"X test positive"

AE Text – Lessons from VOICE

If a ppt reports ANY combination of vulvovaginal symptoms at a given visit:

- □ pain
- □ itching
- □ erythema
- □ edema

- □ rash
- □ tenderness
- □ discharge

before filing each as unique events, consider whether or not there is an overarching diagnosis OR if the term VULVUOVAGINITIS can be used

AE Text – Lessons from VOICE

☐ Pregnancy outcomes should not be reported as AEs (i.e. spontaneous abortions) – only the resulting maternal complications (if any).

☐ "Genital ulcer disease" is not a codeable event. Need to note a specific STI OR they should just report "Ulcer" with the anatomical location(s)

AE Text – Lessons from VOICE

- Pap test results
  - Use the actual results as AE text (for ex. LSIL)
  - <u>Do not</u> report as "abnormal pap result"

- Reporting of assault
  - Report each physical adverse event as an AE
  - In AE text, add "….due to assault"

A Bit More on Clinical Queries

- Distributed by SCHARP Clinical Affairs
- AE clinical coding clarification or a safety query

  AE clarification; product hold clarification

- Emailed to designated site staff
- Are resolved by making additions or corrections on applicable CRF to the data in question

Questions?