Expedited Reporting via DAERS

DAIDS Regulatory Support Center (RSC) Safety Office

ACTG Network Meeting
Washington DC
June 23, 2014

National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under contract No. HHSN272201000013C, entitled NIAID DAIDS Regulatory Support Center (RSC).

DAIDS Adverse Experience Reporting System (DAERS)

DAERS

DAERS: DAIDS Adverse Experience Reporting System

- **A secure, confidential, web-based system through which sites are required to submit expedited reports to DAIDS**
- **All EAEs and supporting information must be submitted using DAERS, unless the system is unavailable for technical reasons**
- **One module of many in the DAIDS Enterprise System**
- **DAERS Integration Group meets regularly to address current technical issues and system changes**
  - Updates to the system occur approximately every 6 months

Case Study and DAERS Demonstration

Case Study Description

- 6 Feb 2014: 36 year old, HIV infected Black female, enrolled in A5263
- At Wk 3 study visit, subject was in mild respiratory distress. Chest X-ray had no radiological abnormalities.
- 13 Mar 2014: subject complained of moderate epigastric pain and mild diarrhea without blood. Treated for moderate gastritis with omeprazole, Relcer gel, and Co-codamol.
- 20 Mar 2014: subject complained of acute chest pain at midnight and died at 0300 hours before being able to reach the hospital.
- No postmortem performed. Copy of death certificate not available.

Reporter and Site Information

- **Site Awareness Date: The date the site first became aware of the adverse event occurring at a reportable level**
  - Date adverse event (AE) occurred
    - **13 Mar 2014**
  - Date serious adverse event (SAE) occurred
    - **20 Mar 2014**
  - Date site aware event occurred at a reportable level
    - **20 Mar 2014**

Submission Timeline

Timeline for Submission: Must submit within 3 reporting days of site awareness

March 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20 Site Awareness (2:00 PM local time)	21	22
23	24 Report Due (11: 59 PM Local Time)	25	26	27	28	29
30	31					

Primary Adverse Event- 1

- **Seriousness Criteria**
  - Select appropriate ICH-SAE criteria
  - More than one criteria can be selected
    - **Results in Death**
- **Primary Adverse Event**
  - **Acute Chest Pain**
- **Severity Grade**
  - **Grade 5 (Death)**

Primary Adverse Event- 2

- **Onset Date: The date the primary adverse event first occurred at the level requiring expedited reporting**
  - **20 Mar 2014**
- **Did this AE result in Fetal Loss?**
  - **No**
- **Country of AE Origin: The country where the event occurred; may not necessarily be where the site is located**
  - **Uganda**

Primary Adverse Event- 3

- **Status Code at Most Recent Observation: The status code of the subject at the most recent observation**
  - **Death**
- **Status Date: Date of the most recent observation of the subject**
  - Date must be on or after the site awareness date
    - Date of most recent observation for subject status can be at or after the site is aware of the occurrence of the event
  - **20 Mar 2014**

Case Narrative

- **Provide information on reported Primary AE**
- **Describe:**
  - clinical course
  - therapeutic measures
  - outcome
  - relevant past medical history
  - concomitant medication(s)
  - alternative etiologies
  - any contributing factors
  - all other relevant information

Study Agents- 1

- **Not a free text field**
- **Choose study agent from drop down menu of smart text field**
  - Study Agent 1: **Paclitaxel Injection**
  - Study Agent 2: **Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate**
- **Relationship of Study Agent 1 to Primary AE**
  - **Not Related**
- **Dose and Unit of Measurement**
  - **200/300/600 mg**

Study Agents- 2

- Exposure to and duration of use of study agent is important information to assess the case
- Ensure accuracy of information
- If unsure, please notate that the date is estimated
- Date of First Dose
  - 7 Feb 2014
- Date of Last Dose: The date the subject took the last dose prior to the onset of the adverse event
  - 19 Mar 2014 (Estimated)

Study Agent- 3

- **Action Taken: Enter the study physician's action taken with the study agent after awareness of the SAE**
  - **Permanently Discontinued**
- **Action Date: Date has to be on or after the site awareness date, i.e., study physician can take action with the study agent only after the site is aware the AE has occurred at a reportable level**
  - **20 Mar 2014**
  - If action taken is "Course completed or Off Study Agent at AE Onset," action taken can be left blank

ConMeds and Other Events

- **Concomitant Medications:**
  - **Omeprazole**
  - **Relcer Gel**
  - **Co-codamol (paracetamol/codeine phosphate)**

- **Other Events: List other clinically significant signs and symptoms that more fully describe the nature, severity, and/or complications of the Primary AE**
  - **Epigastric Pain**
  - **Mild diarrhea**

Laboratory and Diagnostic Tests

- **Laboratory Tests:**
  - **None**
- **Diagnostic Tests:**
  - **None**

DAERS Submission

- Reporter: Completes and sends the report for final review
- Submitter: Reviews and submits the report to DAIDS
- E-mail notification of expedited report submission sent to CRS staff and other key stakeholders
- Site responsibility to ascertain that the report was submitted

Teaching Points- 1

- **Provide relevant information with adequate details to allow for assessment of the case by sponsor clinician and reviewing authority**
  - Distinguish symptom/sign/condition/diagnosis
  - Provide rationale for relationship assessment
  - Provide severity grade, units, normal ranges etc. where applicable
  - If information unavailable to site, express what information is pending or being sought and will be provided when available

Teaching Points- 2

- **Use best judgment as medically qualified person**
- **Continue to follow case until resolution or stable**
- **Additional information received at site should be reviewed for:**
  - Impact on initial assessment
  - Is it clinically associated with the primary AE in initial submission or is it another primary AE?
  - If another primary AE, does it meet reporting criteria?

How to Report to DAIDS

Reports must be submitted via DAERS:

- **DAERS via web:**

https://daidses.niaid.nih.gov/Phoenix

- **For emergency use only:**
  - FAX: +1-301-897-1710
    or 1-800-275-7619 (USA only)
  - E-mail: DAIDSRSCSafetyOffice@tech-res.com
    - If e-mailing, scan or FAX signature page

Where to Get Help

- **RSC Safety Office:**
  - E-mail: DAIDSRSCSafetyOffice@tech-res.com
  - Telephone: +1-301-897-1709
    or 1-800-537-9979 (USA only)
  - FAX: +1-301-897-1710
    or 1-800-275-7619 (USA only)

- **RSC Website:** **http://rsc.tech-res.com/**

- **DAIDS-ES Support:**
  - E-mail: DAIDS-ESSupport@niaid.nih.gov
  - Telephone: +1-240-499-2239
    or 1-866-337-1605 (USA only)
  - FAX: +1-301-948-2242